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Care Home Use of Medicines Study (CHUMS)

Medication errors in nursing & residential care homes
- prevalence, consequences, causes and solutions

Report to the Patient Safety Research Portfolio, Dept of Health

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Background: This work was funded by the Department of Health as part of the Patient Safety Research Portfolio with the aims of: establishing the prevalence, types and underlying causes of medication errors, estimating the ensuing harm and developing solutions to reduce the prevalence of error.

Methods: We chose residents at random in residential and nursing care homes in three areas of England. Medication errors were in prescribing, monitoring, dispensing and administering medicines, and were established by observation, interview and checking records (in homes, pharmacies and practices). Causes of errors were suggested from interviews and observation. Harm was estimated on a 0 (no harm) - 10 (death) scale.

Results: We studied 256 patients in 55 homes. Patients were on a mean of 7.2 medicines each and 69.5% of patients had at least one error.

The prevalence of errors was: prescribing 8.3%, monitoring 14.7% (for relevant medicines), dispensing 9.8% and administration 8.4%; these figures represent the likelihood that each act (prescribing a medicine, for example) will be an error. In terms of patients receiving errors: 39.1% received a prescribing error, 18.4% (of those who needed it) a monitoring error, 36.7% a dispensing error and 22.3% observed to receive an administration error.

Most errors had negligible consequences and we saw no cases of harm caused by errors, however harm can develop over time, so we estimated the harm from the observed errors, using a 0-10 scale. The mean harm (and range) for each type of error was: prescribing 2.6 (0.2-5.8), monitoring 3.7 (2.8-5.2), dispensing 2.0 (0.2-6.6) and administration 2.1 (0.1-5.8).

Discussion

The 58 interviews undertaken to understand what those involved thought were factors contributing to error led to a number of findings. Examples for prescribing error included not knowing the resident; prescribing without computerised notes or prescribing software and poor communication between primary and secondary care. Methods for identifying patients needing monitoring needed improvement and getting blood samples was problematic. Dispensing errors were partly related to Monitored Dosage Systems (MDS) that use cassettes (and were more likely to have labelling problems), and to the millions of tablets repackaged weekly into MDS. Administration errors could result from poor ordering of medicines and poorly trained staff. There is a trend that patients receiving residential care may be more likely to receive administration errors. Staff giving medicines had many distractions and the medicines trolleys were poorly designed.

General factors were the lack of any one person overseeing the whole system, the many, often conflicting, records on medication, and the ways medicines are dispensed and administered (care home staff spend 40-50% of their time on medicines related activities).

Conclusions: There is an unacceptable prevalence of medication errors in care homes, affecting some of the most vulnerable members of society. Action is required from all concerned.

Implications for practice: Our suggestions include a preferred GP per home with a link to their practice computer in the home. Monitoring errors require urgent attention. Pharmacists should regularly review residents' and their medication; they can also rationalise regimes to help home staff work more safely. Several of the primary care 'Connecting for Health' IT developments due early 2009 should help communication between GP, home and pharmacy (if pharmacy can see the medicines prescribed). Homes need to monitor and reduce the times when a medicine is not given, and ensure staff are competent to administer medicines. Pharmacists should identify and reduce their dispensing errors. Homes and pharmacies often use MDS, but this requires large amounts of resource. Research is needed on its effectiveness and alternatives. PCTs need to ensure there is sufficient support for the special needs of these patients. Someone should be

responsible for the safety of the whole medicines system in a care home; the under-pinning philosophy in the pharmacy White Paper (2008) suggests to us that this could be the responsibility of a pharmacist.

Executive Summary

Introduction

The Care Homes Use of Medicines Study was designed firstly to establish the prevalence, types and underlying causes of medication errors in residential and nursing homes, and assess the ensuing harm. Secondly, we looked at the findings to develop solutions to reduce the prevalence of error.

Method

In order to identify errors and understand why they occurred we adopted a broadly ethnographic approach. Researchers visited homes, talked to the staff, reviewed the medication of selected residents, observed medicines being given, and made observations in the home. We also visited the surgeries of the residents' GPs and reviewed records, as well as some pharmacies; we also interviewed GPs and pharmacists.

Medication errors were defined as prescribing, monitoring, dispensing or administration errors. Where errors of significance were noted they were pointed out or corrected. When this occurred we estimated the harm that would have otherwise occurred on a 0 (no effect) to 10 (death) scale. Our work was based on understanding how errors occur, and trying to identify causative factors at the level of the individual, the team and working conditions, and wider organisational factors. Once there was some information on errors the ergonomists could then study areas in more depth.

We chose to study homes in the geographically spread, and demographically diverse areas of West Yorkshire, Cambridgeshire and central London. Residents were included if they were on one or more medicines and their GP agreed to take part. Residential and nursing homes were chosen to represent a range of sizes and ownership. Within homes residents were chosen at random. Consent was obtained from residents, but if unable to give consent an assent process was used; the study received research ethics committee approval.

To understand the causes of errors interviews were conducted with the staff concerned. Further ergonomics research was conducted, particularly in the area of the medicines administration and records.

Results

The field work was carried out in 2006-7; of those we approached we had agreement to take part from 72% of homes, 67% of residents and 61% of general practices. We studied 256 elderly residents who lived in 55 residential and nursing care (usually mixed) homes. Residents had a mean age of 85 and were on a mean of 7.2 (range 1-22) medicines. Of the 55 homes 38 (69%) offered both residential and nursing care, a further 12 (22%) were residential only. There was a mean of 3.8 GP practices per home (range 1-14). The majority of care homes were serviced by one pharmacy (mean 1.5, range 1-4).

Seven out of ten residents were exposed to at least one medication error (178/256, 69.5%). The odds of a person in residential care receiving a medication error was 1.31 (95% CI 0.93-1.84) times greater than one receiving nursing care. This increase was not statistically significant after adjusting for age, sex and medication delivery system.

The prevalence of prescribing errors was 8.3% (95% CI 7.1-9.7); 39.1% of residents had at least one prescribing error (100/256). The commonest errors were 'incomplete information' (38%), 'unnecessary drug' (24%), 'dose/strength error' (14%) and 'omission' of a medicine that should have been prescribed (12%).

The prevalence of medication administration errors (MAE) was 8.4% (95% CI 7.0-10.0); 57/256 (22.3% 95% CI 17.3-27.9) residents had at least one administration error. Nearly half (49.1%) of all administration errors were 'omissions' and just over one fifth (21.4%) were 'wrong dose'. There was no statistically significant difference in MAE by residents' principal medicines delivery systems (MDS or not) ($p=0.36$). The odds of a MAE occurring were higher in residential care residents than nursing care residents, however this just failed to reach statistical significance at the 5% level (odds ratio 1.77 95% CI 0.96-3.25 $p=0.063$ adjusted for age, sex and medication delivery system).

The prevalence of dispensing errors was 9.8% (95% CI 8.5-11.2); 94 residents (36.7% 95% CI 30.8-42.9) had one or more errors each. Labelling errors were found in 7.3% of dispensed items, content errors in 2.3% and clinical errors in 0.21%. There was a borderline statistically significant difference in the odds of a dispensing error when analysing individual errors by delivery system ($p=0.056$). This was driven by the higher odds of a dispensing error with the cassette system (cassette vs. blister OR 2.53 95% CI 1.12-5.72 $p=0.022$). Non-MDS was similar to blister (OR 1.03 95% CI 0.57-1.87). The higher proportion of errors with the cassette system seemed to be predominantly a consequence of labelling errors. As several dosage forms cannot be given in an MDS comparisons between MDS and non-MDS errors need caution as they do not compare like with like.

Some medicines require regular monitoring of the resident to check for side effects or to ensure the medicine is working. The prevalence of monitoring errors for medicines that required monitoring was 14.7% (32/218). Of the 147 residents who were prescribed a medicine that required monitoring 27 (18.4%) had an error. The great majority of monitoring errors (91%) resulted from a failure to request monitoring. There was considerable variation between areas, with three-quarters of monitoring errors occurring in London.

We did not observe any residents harmed as a result of the above errors. Harm from medication errors can develop over time, so the absence of harm in the present does not mean harm will not develop in the future. We assessed the likely harm to result from the errors on a 0 (no harm) -10 (death) scale. The overall harm for each type of error was rated as low by the panel. Monitoring errors were associated with the greatest potential harm with a mean score of 3.7 (range 2.8-5.2); the corresponding figures were: prescribing errors, mean 2.6 (range 0.2-5.8); dispensing errors, mean 2.0 (range 0.2-6.6) and administration errors, mean 2.1 (range 0.1-5.8).

Fifty-nine interviews were conducted relating to 66 administration errors, 34 dispensing errors and 8 monitoring errors. For each type of error several factors were raised which represent that person's view and experience, but which may not apply to all cases, and may not be truly causal. Further ergonomics research was conducted, which identified 4 key areas of concern. The Medicines Administration Record (MAR Chart) was a

contributory factor to a cluster of errors associated with discontinued items. Interruptions of staff undertaking the drug round were common, and mostly came from other care home staff. Drug trolleys were not designed to facilitate the efficient storage and administration of both MDS and non-MDS medication. Communication between the pharmacy and care home (often by telephone or fax) contributed to a number of errors.

Discussion

For each prescribing, dispensing or administration event, there was a 8-10% chance of an error occurring, and for monitoring, a 15% chance. This is as high, or worse, than for people living in their own homes or hospital, and generally care home residents have reduced resilience to the harm that can result from medication errors.

Prescribing and monitoring errors were linked to the GP prescribing without having their computerised notes and prescribing software to hand; sometimes on returning to the practice they did not update notes. Some GPs were unfamiliar with the residents; sometimes advice from secondary care was not integrated into the notes accurately. In addition many residents (and some of their care staff) were unable to give an accurate history. The harm scores for monitoring errors was higher than for other forms of error, and failure to monitor residents was suggested as being linked to practice systems and software, and to difficulty in getting blood taken from residents.

Medicines are dispensed to homes either as a community pharmacy would for a normal ambulant patient, or they can be repackaged into monitored dosage systems (MDS). There are two forms of MDS, blister packaging and cassettes; each is designed for solid dosage forms (tablets etc) and involves the pharmacy opening the original packaging and repackaging each tablet etc individually. Blister packs encase each tablet in a single blister on a card which identifies when it should be given. Each dose of each tablet needs to be popped out individually. Cassettes group all the doses needed for a certain day/time (eg Monday breakfast) together in one compartment of a device. The repackaging of medicines into MDS is a substantial, unfunded activity by pharmacies, and we estimate that millions of tablets are 'popped out' of the manufacturers' packaging in pharmacies every day, and then repackaged in an MDS. Labelling was an issue, particularly of cassette MDS systems.

Administration errors were suggested to be linked to the medication administration system, poor design of the medicines trolley, distractions when administering medicines, lack of care home staff knowledge about how some medicines had to be taken with respect to food, lack of knowledge amongst some nurses/carers about how to administer medicines, as well as not recognising the need for anticipating and avoiding 'out of stock' situations.

Some system-wide issues were noticed which could contribute to error. First, generally no one had ownership of the system or was in a position to show leadership in reducing error across the interested parties in general practice, pharmacy and the homes themselves. Second, it was hard to find out what the correct prescription was, as there could be discrepancies between the several different sources of information. There needs to be much improved communication, and an authoritative source needs to be accessible (such as the Summary Care Record). Third, it can be very difficult for residents to leave the home to get assessed or treated, and hence the local provision of resources that can visit the home becomes important. Finally, the way in which MDS medicines are filled, and the way medicines are given in the home, are very labour intensive. Some home owners estimated 40-50% of staff time was spent on medicine related activities.

All research is subject to limitations. We could only work with those who chose to be part of the study. The presence of observers may have affected the prevalence of administration errors and observed behaviours. When interviewed about the causes of errors the accounts given by the subjects will be influenced by many factors, as will their interpretation by the research team. As there is little research into medication errors in care homes in the UK there is a limited evidence base to inform policy making.

Conclusions

There is an urgent research agenda around the use of MDS, and the ways in which medicines could be administered more safely and accurately in the home. Below we suggest some ways forward, however we do not guarantee their effectiveness, and there is need to study whether benefits are delivered, and how best to implement whole system change.

We make several suggestions to improve matters, based on our findings and current policy – there is no great evidence base to work from of tested solutions. In our view each home having a preferred GP provider, with the ability to electronically prescribe from the home, would be of benefit. GPs need to review how they identify residents to be monitored and ensure monitoring is carried out. Pharmacists should clinically review all residents and their medications for appropriateness at at least 6 monthly intervals. However, to achieve this, the historical human and financial under-resourcing of the care home sector will need to be addressed.

Homes need to seek ways to simplify the act of giving medicines, and ensure staff are appropriately knowledgeable about medicines. They need to monitor and reduce the extent of omission errors. Pharmacists need to be aware of the high rate of dispensing errors in some areas and reduce them. They need to advise homes about medicines that should be given at a special time in relation to meals. PCTs need to recognise the difficulties of getting treatments and tests to residents in homes (where ambulant patients would normally travel). All sides need to communicate with each other and set up relationships. In line with the White Paper on pharmacy we recommend a pharmacist has responsibility for the safe running of the whole system, involving all actors. Many of the communication issues have the potential to be eased if the English IT strategy is delivered as planned. Electronic transfer of prescriptions and other measures are planned to be available by early 2009 and could have considerable benefits, provided pharmacists can access the relevant part of the residents' notes.

We have been very impressed with the care homes; this was a challenging study and yet we had a high acceptance rate of 72%. We were impressed by the dedication of the staff and their wish to solve problems related to medication. We take this as a promising sign of the sector to engage in change to help one of society's most vulnerable groups.

List of Abbreviations

ACE inhibitors	Angiotensin converting enzyme inhibitors
ADE	Adverse drug event
BMA	British Medical Association
BNF	British National Formulary
CfH	Connecting for Health
CPRS	Computerised patient record system
CSCI	Commission for Social Care Inspection
FBC	Full blood count
GEMS	Generic error modelling system
GP	General practitioner
Hb	Haemoglobin
HTA	Hierarchical task analysis
ICC	Intra-cluster correlation coefficient
INR	International normalised ratio
IT	Information technology
LFT	Liver function tests
MAE	Medication administration error
MAR	Medication administration record
MDS	Monitored dosage system

NHS	National Health Service
PCT	Primary Care Trust
PMR	Patient medication record
RPSGB	Royal Pharmaceutical Society of Great Britain
S-K-R	Skill-Rule-Knowledge
TFT	Thyroid function tests
UCL	University College London
U&E	Urea and electrolytes
VistA	Veterans Health Information Systems and Technology architecture

Contents

CHAPTER 1

INTRODUCTION	1
1.1 Background.....	1
1.2 The challenges of measuring medication errors in care homes	3
1.3 Types of medication error.....	4
1.4 Aims and Objectives	6
1.4.1 Aims	6
1.4.2 Objectives	6

CHAPTER 2

THE MEDICINES MANAGEMENT SYSTEM IN CARE HOMES.....	8
2.1 Introduction	8
2.2 Key components of the medicines management system.....	9
2.2.1 Prescribing	9
2.2.2 Ordering.....	11
2.2.3 Dispensing & supply.....	11
2.2.4 Documentation.....	16
2.2.5 Administration & storage	19
2.2.6 Monitoring and Review	19
2.3 Visits by GPs and pharmacists to the homes	20

CHAPTER 3

METHODS FOR QUANTITATIVE ARM	21
3.1 Overview	21
3.2 Ethics and Research Governance	21
3.3 Sample Size	21
3.3.1 Locations and type of Care Homes	22
3.4 Entry criteria	22
3.4.1 Recruitment of Care Homes	24
3.4.2 Recruitment of GP Practices.....	24
3.4.3 Entry criteria for Residents.....	24
3.4.4 Recruitment of Residents	24
3.5 Discovering the prevalence of medication errors.....	26
3.5.1 Study database and data collection materials.....	26
3.5.2 Background and training of research pharmacists	27
3.5.3 Ensuring consistency in data collection.....	28
3.6 Prescribing errors	28
3.7 Monitoring errors.....	32
3.7.1 Development of monitoring criteria	32
3.8 Dispensing errors	35
3.9 Medication administration errors.....	39
3.10 Assessing the potential for harm	41
3.11 Data analysis.....	42
3.11.1 Statistical analysis.....	42
3.11.2 Potential harm analysis.....	42

CHAPTER 4

QUANTITATIVE RESULTS	43
4.1 Demographics.....	43
4.2 Prevalence and typology of medication errors	51
4.2.1 Prescribing errors.....	52
4.2.2 Monitoring errors	52
4.2.3 Medication administration errors (MAE).....	53
4.2.4 Dispensing Errors	54
4.2.5 Linked Errors.....	55
4.3 Harm	65
4.3.1 Prescribing errors.....	65
4.3.2 Monitoring errors	66
4.3.3 Medication Administration errors	67
4.3.4 Dispensing errors.....	68

CHAPTER 5

THE CAUSES OF ERRORS I: ANALYSIS OF IDENTIFIED ERRORS.....	71
5.1 Introduction	71
5.2 Methods.....	74
5.3 Results.....	75
5.3.1 Administration errors	76
5.3.2 Prescribing and monitoring errors.....	87
5.3.3 Dispensing errors.....	95
5.4 Summary	102
5.4.1 Administration errors	102
5.4.2 Prescribing and monitoring errors.....	103
5.4.3 Dispensing errors.....	104

CHAPTER 6

CAUSES OF ERRORS - THE DISPENSING PROCESS	105
6.1 Introduction	105
6.2 System.....	106
6.2.1 Structure	106
6.2.2 Process.....	107
6.2.3 Outcome	108
6.3 Human participants.....	109
6.3.1 Structure	109
6.3.3 Outcome	117
6.4 Organisation	118
6.4.1 Structure	118
6.4.2 Process.....	118
6.4.3 Outcome	119
6.5 Discussion	119

CHAPTER 7

ERGONOMICS.....	122
7.1 Aims	122
7.2 User-centred design.....	122
7.3 Familiarisation with the existing system	125

7.3.1 Shadowing data collectors	125
7.3.2 Pilot studies.....	125
7.3.3 Results from the familiarisation process.....	126
7.4 Identifying key priority areas.....	131
7.4.1 Data analysis.....	131
7.4.2 The priority areas	138
7.5 Investigating the key priority areas.....	139
7.5.1 Research questions	139
7.5.2 Background	139
7.5.3 Method	142
7.5.4 Results.....	147
7.5.5 Consequences and areas for action	158
7.6 Further Potential Systems Improvements	164
7.7 Discussion	168
7.7.1 Existing system	168
7.7.2 Future systems and information technology (IT).....	170
 CHAPTER 8	
DISCUSSION	176
8.1. Introduction	176
8.2 Prevalence of errors and comparison with other sectors	179
8.2.1 Prescribing and monitoring errors.....	179
8.2.2 Dispensing errors.....	180
8.2.3 Administration errors	180
8.2.4 Harm	181
8.2.5 Limitations	181
8.3 Drawing together findings from quantitative & qualitative research.....	185
8.3.1 Contributory factors to prescribing and monitoring errors	185
8.3.2 Contributory factors to dispensing errors	187
8.3.3 Contributory factors to administration errors	190
8.4 Whole system assessment.....	191
8.4.1 Leadership and ownership	192
8.4.2 Calming the sea of information	193
8.4.3 The home-bound resident	196
8.4.4 Medicine dispensing systems	197
8.4.5 Drug round issues.....	199
8.5 Appetite for change	199
8.5.1 Diagnostic questions	200
8.5.2 Implications for practice.....	202
 CHAPTER 9	
CONCLUSION.....	205
ACKNOWLEDGEMENTS.....	207
CONTRIBUTIONS OF AUTHORS.....	208
REFERENCES	210

Figures

Figure 2.1: Flowchart for regular prescriptions	10
Figure 2.2: Nomad MDS	13
Figure 2.3: Boots MDS blister packs.....	14
Figure 3.1: Route from identification of care home to data collection	23
Figure 3.2: Flow diagram of data collection.	25
Figure 4.1: The number of medicines per resident based on prescribing denominator.....	45
Figure 4.2: Type of care.....	45
Figure 4.3: Size of home.....	46
Figure 4.4: Owner type	46
Figure 4.5: Number of GP practices per home	47
Figure 4.6: Number of GP practices per home - Bradford	47
Figure 4.7: Number of GP Practices per home - Cambridgeshire	48
Figure 4.8: Number of GP Practices per home - London	48
Figure 4.9: Medicine system.....	49
Figure 4.10: Medicine system - Bradford	49
Figure 4.11: Medicine system - Cambridgeshire.....	49
Figure 4.12: Medicine system - London	50
Figure 4.13: Number of pharmacies per home	50
Figure 4.14: Number of pharmacies per home - Bradford.....	50
Figure 4.15: Number of pharmacies per home - Cambridgeshire	51
Figure 4.16: Number of pharmacies per home - London.....	51
Figure 5.1: Adapted Organisational Accident Causation Model incorporating both Reason's and Vincent et al.'s framework for the analysis of critical incidents and adverse events.	73
Figure 6.1: Evaluation Framework. (Based on Cornford <i>et al.</i> 1994, fig. 3, page 499).....	106
Figure 7.1: User-Centred design.....	123
Figure 7.2: User-Centred design in a system framework	123
Figure 7.3: Systems-based user-centred approach to healthcare design (DofH 2003).....	124
Figure 7.4: A drug round in progress	126
Figure 7.5: Figure Simplified systems diagram.....	127
Figure 7.6: Drug round procedure	129
Figure 7.7: Dispensing procedure	130
Figure 7.8: Within component statistics (error location).....	133
Figure 7.9: Errors including communication issues (crossing system boundaries).....	134
Figure 7.10: Object/Task factors (see appendix J for list of factors).....	135
Figure 7.11: MAR and drug round issues within the care home.....	135
Figure 7.12: Significance of discontinued drugs on the MAR chart.....	136
Figure 7.13: Significance of interruptions during the drug round	137
Figure 7.14: Computer software issues in the pharmacy	137
Figure 7.15: A typical MAR chart.....	140
Figure 7.16: A completed MAR chart	140
Figure 7.17: Typical drug trolley used in care homes	141
Figure 7.18: A typical data sheet recording events and observations during a drug round	148
Figure 7.19: Variations in dispensing practices.....	150

Figure 7.20: Variations in drug round practice	151
Figure 7.21: Drug round practices, interruption issues	155
Figure 7.22: Dispensing practices, communication issues.....	157

Tables

Table 3.1: Typology of prescribing errors	31
Table 3.2: Medication monitoring for maintenance therapy	34
Table 3.3: Medication monitoring for initiation of therapy	35
Table 3.4: Types of monitoring error	35
Table 3.5: Types of dispensing error	36
Table 3.6: Types of medication administration error	40
Table 4.1: Demographics	44
Table 4.2: Error prevalence.....	56
Table 4.3: Typology of prescribing errors	57
Table 4.4: Typology of monitoring errors	58
Table 4.5: Monitoring errors by drug type.....	58
Table 4.6: Typology of administration errors	59
Table 4.7: All administration errors classified by type of care and medicine delivery system	60
Table 4.8: Typology of dispensing errors	61
Table 4.9: All dispensing errors classified by medicine delivery system	63
Table 4.10: Potential harm	70
Table 7.1: Ergonomics systems problems, consequences and actions	161
Table 7.2: SHERPA Analysis.....	166
Table 8.1: Care Homes Use of Medicines Study – compliance chart	178

Chapter 1

Introduction

1.1 Background

This study pulls together two policy streams – those of patient safety and of older people – and links them with standards in care homes. A report documenting the extent of medical error in the UK highlighted medication errors as a particular concern, and the government committed to reducing such errors.^{1,2} A report by the Chief Pharmaceutical Officer in 2004³ included in detail the particular types of errors which can occur in the care home setting, and noted that current GP repeat prescribing systems may make it difficult to ensure that therapy is adequately monitored or reviewed. The specific needs of the elderly were recognised in a National Service Framework for Older People;⁴ and an accompanying report recognised the particular medication needs of older people, and the need for regular review of therapy.⁵

In the field of patient safety it is likely that medication errors are the greatest cause of harm. A systematic review found that 3.7% of hospital admissions (an admission rate similar to that for cancer related illness), were as a result of preventable medicine-related harm.⁶ Although work is emerging on the types of problems in primary care, there is little work on error prevalence; what work there is often suffers from a poor definition of an error, and use of methods such as spontaneous reporting, which miss the vast majority of errors.

The elderly are particularly at risk from medication errors. They have a high level of morbidity, often with multiple health problems and hence are often prescribed several medicines. In addition the presence of frailty, altered pharmacodynamics, changes in drug distribution and susceptibility to renal and hepatic impairment all mean that these patients are more susceptible to adverse drug events (ADEs). Evidence from the UK suggests that 19% of admissions of elderly people to hospital are as a result of therapeutic misadventure.^{7,8}

Nearly half a million older people in England live in care homes.⁹ These facilities house some of the most frail, vulnerable and least visible members of our society. A survey of

these homes in Gloucestershire found a third of the residents were incontinent of urine or faeces; one in five showed bouts of unconventional behaviour; 15% were chair-fast or bed-fast.¹⁰ Residents in homes take significantly more medicines than those in the community.^{11,12} Many residents have some degree of cognitive impairment which may prevent them from being an actor in the detection of errors.¹³

The quality of care provided by homes is assessed by the Commission for Social Care Inspection (CSCI) (previously the National Care Standards Commission [NCSC]) who regulate and inspect care homes. Inspection is made against national minimum standards, one of which (Standard 9) relates directly to medicines.¹⁴ In 2002/3 less than half (44%) of the care homes currently met or exceeded its national standard for the safe handling and administering of medicines.¹⁵ The NCSC's report 'The Management of Medication in Care Services',¹⁶ acknowledged concerns over prescribing and medicines use, and made recommendations to improve practice. The main areas of concern were:

- wrong medication being given to residents;
- poor recording of medicines;
- inappropriate handling of medicines by unqualified staff;
- inappropriate storage of medicines.

A follow-up report published in February 2006 found some slight improvement in overall performance in care homes; however, this was with the exception of nursing homes.¹⁷ Nearly half of care homes for older people still did not meet the minimum medication standard and the CSCI concluded that the failings were down to the homes themselves.

There is a wealth of research that illustrates inappropriate prescribing in nursing homes in the UK and USA. While the largest and best studies have been conducted in the USA,^{18,19,20} given the different regulations, systems of care, databases, and medicines used, the results cannot be directly compared. Few have been prospective studies of prescribing or drug administration error. A US study of medication administration errors using direct observation found an error rate of 22% (12% excluding "wrong time" errors) in nursing homes.¹⁹ In the UK there is a body of literature expressing concern about prescribing in care homes, however it is framed as 'inappropriate' prescribing, rather than prescribing

error.²¹ Although errors are a sub-set of inappropriateness, we do not know the extent to which the two literatures overlap. In addition, used alone, medication appropriateness scales can produce many false judgements that prescribing is inappropriate, while missing prescribing errors.^{22,23} Nevertheless, studies of prescribing in UK homes suggest inappropriate prescribing occurs in between 50 and 90% of patients.^{11,24,25}

In addition to the evidence of inappropriate prescribing in this vulnerable population, the potential for error is increased due to the complex nature of the medicines management systems in care homes, for example, many residents receive clinical intervention from multiple sources; medicines may be dispensed from multiple sites; and medicines may be dispensed in several formats with the use of monitored dosage systems (MDS) being common. The processes for prescribing, ordering, dispensing, administering and recording medicines vary between different homes, GP practices and pharmacies. Understanding the medicines management systems and their variations is crucial when investigating errors and, therefore, a detailed description of the systems in use in the care home setting is presented in Chapter 2.

1.2 The challenges of measuring medication errors in care homes

In the previous section we established that medication errors are a significant problem for the elderly, and that studies of residents in care homes supported this. However the picture of medication errors in care homes is very incomplete, particularly in the UK. In this section we illustrate some of the challenges to be overcome in measuring the extent of errors, and understanding why they happen. We explain the problems and give some indication of the ways we tried to overcome them.

Conducting research in the care home setting is extremely complex with significant barriers to recruitment and data collection to be overcome.²⁶ For this study we needed the co-operation of the care home and the consent of *all* of the following

- individual care home staff
- GPs
- community pharmacists and

-
- residents (or assent).

The recruitment of care homes themselves can be difficult. There is great variation between homes in their management style and their autonomy, quite often reflecting their ownership. Some are independent and owner-run, others are owned by local authorities, others by voluntary organisations or charities, and many by large national public or private companies. Furthermore, this study could have been seen to be particularly threatening to the care homes.

Obtaining consent from vulnerable older adults is a complex and time-consuming process. Due to the high levels of cognitive impairment in this population, many residents are unable to give informed consent and, therefore, assent is sought from next of kin.

As stated above, there is wide variation in medicine management systems in care homes and this can make data collection problematic. There is a lack of uniformity of recording health and medicine-related information in care homes, both in terms of what is recorded and where the data are held. Consequently, multiple data sources need to be accessed and the mode of collection needs to be flexible in order to account for this variation.

1.3 Types of medication error

Four main types of medication error can occur:

- prescribing
- monitoring (e.g. biochemical monitoring of therapy)
- dispensing
- administration (i.e. the administration or taking of the medicine incorrectly).

Multiple methodologies and a multidisciplinary approach have been taken in this study to investigate such errors in the care home setting. The methodology and methods used in previous studies of medication error in secondary care were adapted for the care home context. Where no current methods exist, these were developed and validated as appropriate.

Five main features of medication error were studied:

- prevalence;
- nature (typology);
- potential harm;
- causes; and
- potential solutions.

Data on these features were collected simultaneously; however, because of the different methodologies and methods employed, they are presented in separate chapters to aid the reader.

The prevalence, nature and potential harm of error were determined using quantitative methods adapted from previous studies in secondary care and are presented in Chapters 3 and 4. The causes of error were investigated using qualitative methods and by applying human error theory^{27,28} in Chapters 5 and 6. The question of *how* an error occurred is addressed using Reason's Generic Error Modelling System²⁸ and Reason's Organisational Accident Model.²⁸ The question of *why* an error occurred uses Vincent et al's framework for analysing risk and safety in clinical practice.²⁹ In addition, the technology of monitored dosage systems was investigated using an approach informed by a socio-technical perspective using Cornford's framework.³⁰ We will use these findings to gain understanding of the underlying causes of errors and hence possible solutions.

Potential solutions were also developed by applying ergonomic methods to understand the medicines management system and design factors that contribute to errors (Chapter 7). A systems-based user-centred approach to healthcare design was used, as documented in the 'Design for Patient Safety' report published in 2003 by the Department of Health.³¹ Methods such as focus groups, semi-structured interviews and observation were used to ensure users of medicines were involved when generating solutions.

In the final chapters, the findings from the component studies are brought together and discussed with regards to the implications for policy, practice and future research.

In summary, the prevalence, nature, causes and potential harm of medication error in the UK care home setting is unknown. Identifying and understanding these aspects of medication error will lead to the generation of potential solutions.

1.4 Aims and Objectives

The aims and objectives of the project were proposed as:

1.4.1 Aims

- To establish the prevalence, types and underlying causes of medication errors, and the ensuing harm
- To develop solutions to reduce the prevalence of error

1.4.2 Objectives

1. To investigate the prevalence of different types of medication error (prescribing, monitoring, administration, dispensing) with sufficient precision to:
 - a) indicate their relative frequency
 - b) identify the areas of greatest concern
 - c) allow sample size calculations for further intervention studies.
2. To provide a typology of the errors.
3. To
 - a) identify the proportion of patients who:
 - i. have suffered an error of any kind,
 - ii. have been harmed by the errors,
 - iii. could have been harmed by the errors, had intervention not taken place
 - b) compare different methodologies for assessing harm as a result of the error.
4. To understand the underlying causes of errors.
5. To apply the principles of ergonomics to:
 - a) Analyse existing systems
 - b) Understand and map the medication pathway.

-
- c) Understand and map the information pathways.
 - d) Generate, evaluate and prioritise solutions.

Chapter 2

The medicines management system in care homes

2.1 Introduction

Care homes vary widely in their nature. They range from small homes providing residential (personal) care only, to large establishments with residential and nursing care provided on different floors or in separate units. They may be privately owned, part of a chain, or belong to a voluntary organisation or local authority. The job titles, training, qualifications (if any), skills and responsibilities of staff working in the homes vary. All of these factors influence the way medicines are managed and there is no single prevalent model. Regulations and guidelines relating to medicines management in care homes have been produced by the Commission for Social Care Inspection (CSCI) and the Royal Pharmaceutical Society of Great Britain (RPSGB).

Although these are generally based on accepted best practice, the extent of the evidence base for their guidance is variable. They are listed below:

- CSCI:
 - Handled with care: managing medication for residents of care homes³²
 - Professional advice: Medicines administration records (MAR) in care homes and domiciliary care³³
 - Professional advice: Administration of medicines in care homes³⁴
 - Professional advice: Training care workers to safely administer medicines in care homes³⁵
- RPSGB:
 - Practice Guidance: Advisory services to care homes³⁶
 - Practice Guidance for the provision of printed medication administration record charts (MAR) by community pharmacists³⁷
 - The handling of medicines in social care³⁸

-
- Fitness to Practice & Legal Affairs Directorate Fact Sheet 6. Monitored dosage systems and compliance aids³⁹

2.2 Key components of the medicines management system

The key components of the process are:

- Ordering
- Prescribing
- Dispensing and supply
- Storage
- Administration of medicine to resident
- Monitoring of effect of medicines

A component running through each of these 6 aspects is the relevant documentation.

All aspects can vary. For example, homes do not all keep the same type of records, they may use different terms for 'records', and keep them in different places in the home.

This chapter will help with an understanding of these various processes. A flow chart depicting the processes relating to 'Regular' prescriptions, is shown in Figure 2.1

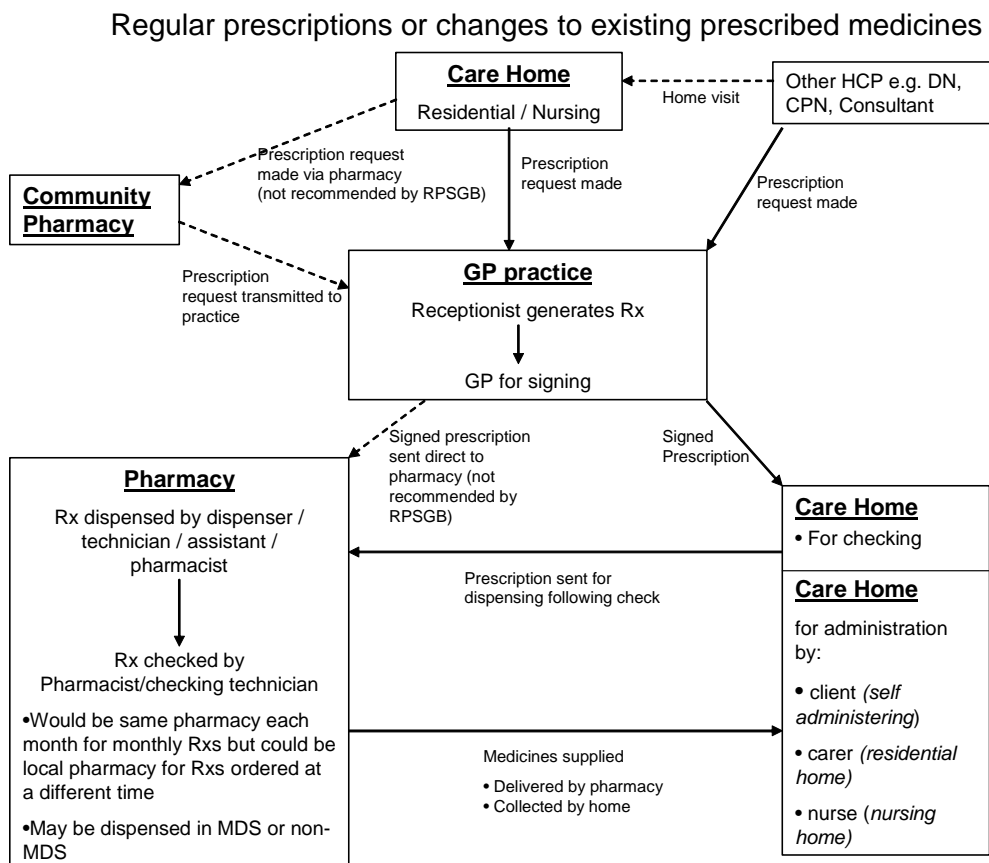
2.2.1 Prescribing

To allow for patient choice, and because many doctors may be reluctant to register large numbers of care home residents (because of the workload they represent - see Section 2.3), many care homes have more than one general practice responsible for its residents. Most (but not all) care homes have a relationship with a single pharmacy for dispensing repeat (long-term) prescriptions (called 'repeats' in this report). Because most residents take several long-term medicines (Zermansky et al¹² found the mean number was 7), there is generally an arrangement with the GPs to provide repeat prescriptions every 28 days.

GP computer records have a repeat medication file which lists all current authorised repeats, and the prescriptions are prepared by receptionists at the practice for the doctor to sign.⁴⁰ The process involves the receptionist identifying each drug requested by the home,

and then printing off the prescription forms. The only constraints on the receptionists are that the drug needs to have been “authorised” on the computer system by a doctor as a repeat, and that the patient’s review interval (set on the computer system) has not been passed. It is therefore predicated on the prescriber(s) having authorised each item accurately, since there is generally no detailed check by the doctor who actually signs the prescription. It also requires that the GP computer system reflects accurately any change in medication that has been authorised or started by other prescribers outside the practice, who might include hospital departments, visiting psychiatrists, out-of-hours doctors. It should be noted that the system described above applies equally for people living in their own homes as for those in care homes.

Figure 2.1: Flowchart for regular prescriptions



2.2.2 Ordering

Requests for repeats are generally made by the care homes, though in some instances the pharmacist makes the requests (this is not recommended in the RPSGB guidance). Unfortunately pharmacists do not have access to GP computer records, and so their records of patients' current medication may not match those of the general practice. This is especially true of medicines discontinued or in which there has been a change in frequency of administration. Whilst medicines that are started are inevitably prescribed on a prescription form that reaches the pharmacy, there is no such document as an "unprescription", so the pharmacy may not be aware of medicines that are stopped, even those that have been stopped because of an adverse drug event. They must rely on the care home informing them of such changes.

Repeat prescriptions are ordered in a number of ways:

- The Home orders the medicines direct from GP practice using the repeat slip (the 'Right Hand Side' of the prescription form – see 2.2.4 for explanation)
- The Home orders the medicines direct from GP practice using the MAR (Medication Administration Record) sheets (See also 2.2.4)
- Pharmacy orders from the GP practice after visiting/consulting with the home
- Pharmacy orders from GP practice without contacting the home

2.2.3 Dispensing & supply

Homes usually use one pharmacy, although some will use one pharmacy for their monthly repeat prescriptions and another more local one for acute/interim prescriptions.

The medicines are dispensed in one of two ways. Some pharmacists dispense in the traditional way in individual packs, labelled with the recipient's name and the dosage details. Others dispense into monitored dosage systems (MDS)(see below for description). It depends on the wishes of the care home manager or owner, and whether their local community pharmacy offers an MDS service. Even if a home is using an MDS, it may still receive any interim medication as non-MDS in individual medicine bottles or packs - this will depend on the pharmacy it uses. MDS are discussed in detail below.

Dispensed medicines usually reach the home as follows:

- Pharmacist delivers personally
- Someone else from the pharmacy delivers
- Home staff collect from pharmacy

If there is an addition to a resident's medication (between the monthly supply of existing medicines):

- Home faxes script to usual pharmacy
- GP contacts usual pharmacy with script
- Request telephoned to usual pharmacy
- Prescription taken to nearest pharmacy

Monitored Dosage Systems (MDS)

The monitored dosage system or MDS is an approach to medicines dispensing and administration designed to eliminate the need for the carer to determine which tablets to administer at each dosage time during the day. They take the form of an oblong tray with a grid of suitably sized depressions in its surface, each to contain one or more doses of treatment for a particular time, and each sealable in the pharmacy. The grid is marked with the days of the week and times of day, and each patient has one or more trays labelled with their identification, which may also include a photograph. The original Monitored Dosage System (MDS) was developed in 1975 in the US to reduce the time taken to give medications in nursing homes by packaging them into blister cards.⁴¹ In 1981 the Scottish Health Service Planning Council published a wide ranging report on pharmaceutical services for the elderly and recommended the use of MDS in residential homes.⁴² In the United Kingdom MDS first appeared in 1989, when Boots launched its Canadian-developed Manrex system, which was later renamed "Boots MDS". In 1995 over 60 percent of care homes in the UK used some form of MDS.⁴¹

MDS were intended to simplify the drug round for the home and to simplify the administration process for untrained staff. Instead of selecting the tablets to be given from a

resident's individual medicine bottle or box, after checking the drug chart, the carer only needs to check the identity of the resident and give the tablets in the dispensing tray that relates to the date and time of the dosage. The systems are designed to be filled in a pharmacy by trained staff, then checked by the pharmacist, and labelled with patient and medication details. Once sealed in the pharmacy, the doses should remain in the MDS until they are administered to the patient.

Monitored dosage systems can vary:

- Number of days supply can be 28 days, 7 days or one calendar month
- *Cassette MDS*: multi-dose i.e. several different medications can be in one compartment e.g. Nomad[®], Dosett[®], some Venalink[®]
- *Blister MDS*: single-dose i.e. only one dose of medication per compartment e.g. Manrex[®], Pilpack[®], some Venalink[®]

Cassette MDS

In the cassette MDS, **all** the medicines for a particular dosage time are placed in one compartment of the weekly box. The Nomad system consists of a reusable cassette type box made up of individual compartments. Each cassette holds seven days' supply of drugs with compartments for up to six doses a day (figure 2.2).

Figure 2.2: Nomad MDS



Sliding lids give access to single compartments of the cassette. A medication card detailing the patient's drug and dosage requirement slots into the back of the cassette. A "side card" with the patient's details fits into a side compartment. Coloured dots may be used as

reminders for additional medications, such as liquids and “as needed” medications, which are not contained in the cassette.

Blister MDS

There are blister type monitored-dosage systems (i.e. medicines required at a certain time are packed in individual blisters) as well as cassette type systems.

The Boots MDS system is based on a 28-day cycle. Only one type of medication is placed in each blister pack and then sealed. For a once daily dose, one blister pack is dispensed, for a twice a day dosage, two blister packs, etc. Blister packs have a dispensing label that identifies the patient, the medicine and directions. The blister packs are placed in reusable plastic pill packs that hold the sealed medication. They are available in four colours, which are used for different times of the day (figure 2.3).

Figure 2.3: Boots MDS blister packs



When filled, the packs are placed on metal loop files in a suitable resident order, separated by using identity cards placed on the loop between each resident's packs. Reminder cards may be used to identify all doses which are not in blister packs, for example liquids or short term medications. They are labelled in the same way as the dispensed medication, with one card for each dosing time, and placed in sequence with the other blisters on the loop files. A medicines trolley is available which is designed to accommodate the loop files.^{43,44,45,46}

The Venalink system is similar to the Boots system but comprises a completely disposable pack. The blister is supported by card as an integral part of the pack.^{41,47}

Different systems are laid out differently e.g.-

28 day system

Week	1	2	3	4
Mon				
Tues				
Wed				
Thurs				
Fri				
Sat				
Sun				

There will be a different blister

for each time of day.

Can be multi or single dose

7 day systems

	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Morning							
Lunch							
Teatime							
Bedtime							

	Morning	Lunch	Teatime	Bedtime
Mon				
Tues				
Wed				
Thurs				
Fri				
Sat				
Sun				

These can be single or multidose.

MDS have many claimed advantages and disadvantages and these are discussed along with the findings of this study in subsequent chapters

2.2.4 Documentation

Medication Administration Records (MARs):

The principal record used in care homes which documents residents' medicines information is the Medication Administration Record or MAR. They are usually referred to as a 'MAR chart' and they contain a list of the medicines administered to residents, which identifies the appropriate medicines for the person giving them and allow them to record that administration. A chart usually relates to a 28 day cycle for one resident. Once one chart is completed, a new chart is produced for the next cycle. MAR charts are usually produced in the pharmacy, when dispensing takes place into both cassette and blister MDS. However, some homes prefer to use pre-printed charts and hand-writing each one individually.

The MAR chart is produced in triplicate in the Boots and Manrex systems (others may be in duplicate or only on a single sheet). The top copy serves as the medication record in the home, while the other copies are used for medication review and re-ordering. They are a fundamental part of the MDS and serve several important functions.⁴¹ As well as recording the identity of each medication the resident is taking, they also enable the carer to record each tablet given (or not given) in a readily visible way. They reduce the time spent by home staff manually writing drug administration charts each month, reduce the potential for transcription errors normally associated with handwritten documents and are an important source of information when conducting medication reviews. The MAR sheet provides an audit trail of all medicines administered to residents as well as what medications are received by, or returned to, the pharmacy.^{41,48}

There is RPSGB guidance relating to the provision of printed MAR charts for use by community pharmacists.³⁷ These acknowledge that MAR charts are official records. It also says that care workers are highly dependent on the content and accuracy of printed MAR charts. However, the MAR chart is not "the prescription". MAR charts are purely records of administration and do not act as a medication order as would occur in a hospital drug chart. However, they play a pivotal role in the way medicines are managed in care homes.

-
- MARs may be computer generated by the community pharmacy, or can be handwritten at the home by staff (copied from the dispensing label not the previous MAR) or in some cases by the GP.
 - MARs come in different formats but essentially the contents are the same.
 - MARs most commonly last for 28 days, but can cover one calendar month or can be on-going for up to 3 months or occasionally even longer.

The MAR often doubles as a medication profile i.e. somewhere where all the medication that the resident is on is recorded. For example, it should include medication that is self-administered or is administered by District Nurse, Community Psychiatric Nurses or GP, but it sometimes doesn't. However, there is sometimes a separate medication profile, as well as other records of medication being administered or taken elsewhere.

When changes occur mid-cycle these would be recorded on the MAR chart, and if medicines are changed close to the end of the cycle, after the request has been put in for the repeats, it is possible that the change may not be carried forward. The home must keep MARs for at least 3 years, but sometimes they are not easily located. They could be rolled up and put in a box to await sorting with many other previous MARs, or kept in with the resident's clinical or care history.

Repeat prescriptions for residents are usually produced by the GP practice computer. The Right Hand Side (RHS) of the FP10 prescription may be kept as a record. It consists of a tear-off slip on which is printed a complete list of the patient's repeat medication, with a tick box next to each item for re-ordering.

GP clinical record

The GP clinical record is now always computer based, though some practices may still use paper-based notes for some information. Because residents are inevitably seen away from the practice, practices often print out summaries for doctors to take on visits. The doctors should then subsequently write up their notes on computer when they return to base. A few homes have a computer link to residents' clinical records at the practice so prescriptions may be generated in the home and signed by the GP during a visit.

Occasionally the pharmacy may have a computer terminal from which all the prescriptions are generated.

The records in the home may be kept in different places e.g. communication book, repeat prescription request slips/book, care plans, clinical records, admission information. The clinical records may be locked away in the home and sometimes only the GP has a key.

- In the GP surgery records may be entirely on computer or partly in paper. Some GPs may only record repeat prescriptions on the computer, using hard copy prescriptions on a pad (called 'FP10s') for all acute medication and associated medical notes; this may be in Lloyd George envelopes at the surgery or at the care home or both.

Other documentation

There is a variety of other types of documentation relevant to the use of medicines in a care home. There may be:

- Admissions information
- Hospital discharge letters
- Treatment Advice Notes from out-patients
- Patient/client profiles
- Care records/nursing notes
- Shared care records (eg anticoagulant book)

Different homes use different terminology for these records and they vary in how much information is stored in them

All homes have to keep a daily log of care. This may just refer to personal care but can also include relevant medical information. It should include reference to sleep and bowel activity where relevant, and this may be pertinent to the medication review. Different floors/units in the same care home may have different ways of storing information and can also use different systems for ordering, administering etc.

2.2.5 Administration & storage

Drugs are administered by trained care staff in residential homes and by registered nurses in nursing homes. The method varies from home to home, though most have a drug trolley and conduct a drug round at the appropriate intervals through the day. There are usually 3-4 drug rounds per day, although residents are most likely to have medicines given at the morning and teatime drug rounds.

Each dose of each drug administered is generally recorded by the carer on the MAR chart. If a dose is not given for any reason (eg not required, patient asleep, patient refused etc) a code for the reason is recorded on the chart.

The drug round will generally be conducted by one member of the care staff, and can take from 30 minutes to 2 hours or more. It often coincides with residents' meal times, so that some residents can have their medicines together in the dining room. However, some will remain in their rooms where staff will visit them. Some homes have a 'drug room' instead of a trolley.

2.2.6 Monitoring and Review

It is always important to review patients and their medicines at intervals, because the medication regimen that is entirely appropriate now may be less appropriate as a result of change in the patient's physical and mental condition. Indeed the National Service Framework for Care of the Elderly recommends that patients over 75 (and most care home residents will fall into this age group) should have their medicines reviewed every six months.⁴ It is important to review the medicines in the context of the patient's medical condition. In addition, some medicines need to have specific monitoring to check on efficacy and identify adverse effects. Examples are the monitoring of blood pressure in patients with hypertension, measuring thyroid function in patients on levothyroxine, checking renal function in patients taking ACE inhibitors, checking INR in patients on warfarin. Evaluating medication review generally was outside the scope of this study, and has been reported elsewhere,²⁶ but ensuring the monitoring of drugs with a risk profile cannot and should not be separated from the process of drug prescribing. The institution of

a failsafe mechanism to ensure it takes place should be a vital part of the system, and is properly the responsibility of the prescriber (i.e. the general practitioner)

2.3 Visits by GPs and pharmacists to the homes

Care home patients present a major workload issue for general practitioners. They are frail, sick, vulnerable and often unable to be advocates for their own health needs because of mental infirmity and institutional dependency. Their care needs may be greater than those of many older patients in their own homes, and virtually all their care needs to take place on-site. Furthermore, each attendance can be prolonged because the resident is slow moving and may present communication difficulties because of speech, hearing and/or mental impairment.

In addition, record keeping is problematic because of the need to ensure that changes in treatment are recorded on the patient's computer file "back at base". Many (but not all) practices allocate one doctor as the responsible doctor for each home, and some make regular scheduled visits to ensure continuity and availability. On the other hand no-one works every day, and residents are seen by out-of-hours doctors and visiting specialists, so maintaining concordance of drug records can be difficult.

Communication with community pharmacists is generally only by prescription, and pharmacists are therefore limited in what they know about indications for and risks of treatment. There is probably scope for devising protocols of medicines management that ensure consistency of drug records between home, pharmacy and general practitioner records.

Chapter 3

Methods for Quantitative Arm

3.1 Overview

This chapter presents a description of the recruitment of care homes and GP practices, and the consent or assent of residents. It describes how the research nurse and research pharmacists who, following training:

- Collected 'demographic' data for each home and their systems for ordering, prescribing and administering medicines
- Reviewed any relevant records at the care home, the pharmacy and at the GP surgery
- Selected and undertook a clinical medication review of three or more consented or assented residents in each home
- Observed at least one set of drug administrations (preferably two) to those residents
- Made a visual check of whether the medicines were dispensed correctly

This is then followed by a detailed description of data collection and synthesis.

The methods for the Qualitative arm of the study are given in Chapter 5 (Section 5.2) and the Ergonomics arm in Chapter 7 (Sections 7.3 and 7.3.3)

3.2 Ethics and Research Governance

Research Ethics approval was obtained from the Central Office for Research Ethics Committees. Research Governance approval was obtained from participating Primary Care Trusts (PCTs). Criminal Records Bureau clearance was also obtained for the researchers working in the homes.

3.3 Sample Size

The sample size was calculated to provide sufficient precision to allow a meaningful estimate of the prevalence of medication errors, and to provide future researchers with

sufficient information (including intra-cluster correlation co-efficients (ICC)) to calculate sample sizes for intervention studies.

To get within +/-2% of a prescribing error rate of 10%, when between home variability was up to a maximum of 6%, 100 homes with 3 residents per home were required. Alternatively, fewer homes could be used if the proportion included per home was increased.

A detailed description of the sample size calculation is available in Appendix A.

3.3.1 Locations and type of Care Homes

Care homes were recruited from PCTs in Bradford, Cambridgeshire and London. 120 residents were to be recruited from 40 homes in each of Bradford and London, and 60 residents from 20 homes in Cambridgeshire. Cambridgeshire was chosen due to its rural location and the presence of significant numbers of dispensing doctors.

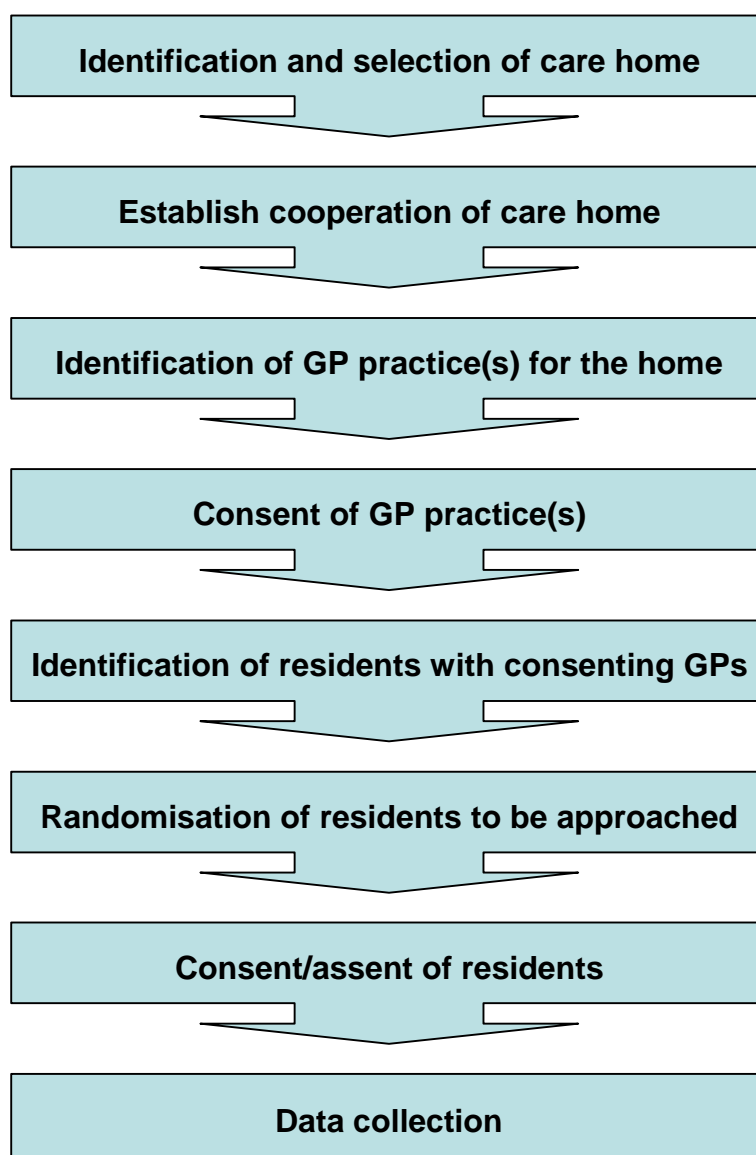
Care homes were purposively sampled to obtain a varied sample with respect to:

- ownership (single home, small chain, local authority, larger chain, not for profit),
- size
- type of care provided (nursing only, residential only, mixed).

3.4 Entry criteria

All registered nursing and residential homes which primarily catered for older people, in the chosen PCTs, were eligible for inclusion.

Figure 3.1: Route from identification of care home to data collection



3.4.1 Recruitment of Care Homes

A database of care homes in the relevant locations was constructed using data from the CSCI website (www.csci.org.uk). Homes which did not cater primarily for older people, for example, homes for children, or homes for those with alcohol problems were excluded. Care home managers were contacted by telephone to arrange a meeting to discuss the project. Written information was provided to the care home in the form of a staff information letter (Appendix B). Follow-up telephone calls were then made and if the care home manager wished to participate, a further visit from a member of the research team was made to collect demographic data and data regarding their medicines management system on the care home profile (Appendix B).

3.4.2 Recruitment of GP Practices

GP practices serving the homes were identified using the data collected on the care home profile. The practice manager for each surgery was contacted by telephone and/or email and a brief synopsis of the project was provided. An information leaflet was also sent. If a GP practice wished to participate, a consent form was sent by post.

3.4.3 Entry criteria for Residents

Residents receiving one or more repeat medications were eligible for inclusion. It was expected that the vast majority of these residents would be 65 or older, however younger patients were not excluded. Residents were excluded if they were already in another trial, terminally ill (life expectancy <3 months), or if their GP wished them not to be included.

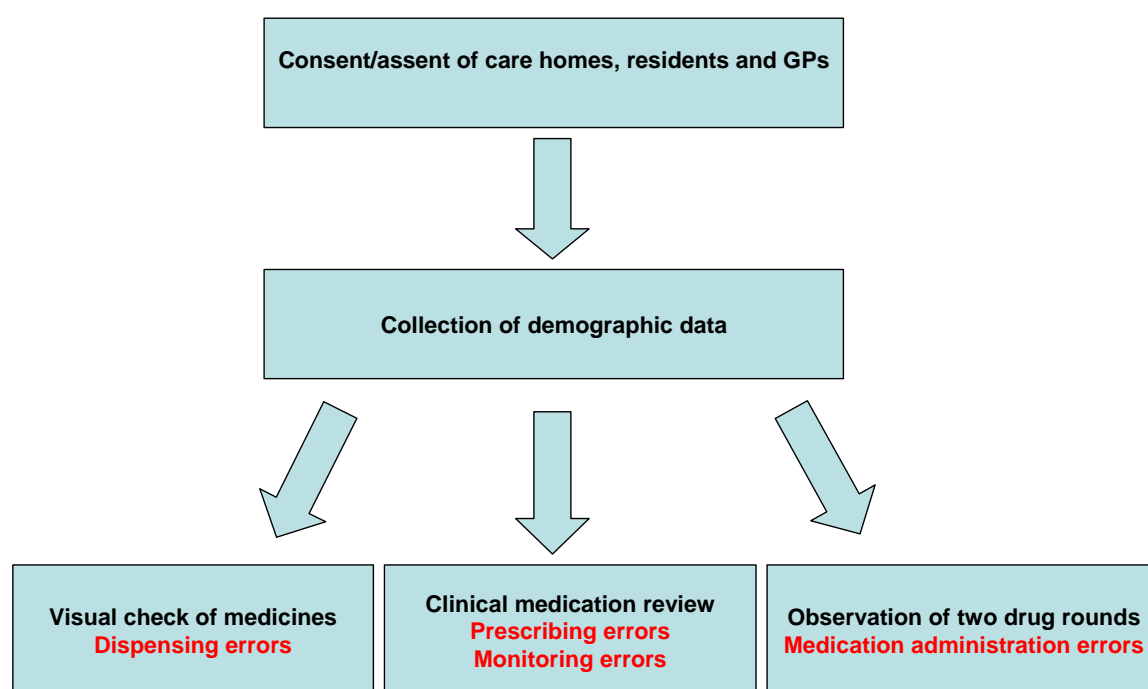
3.4.4 Recruitment of Residents

An anonymised list of residents whose GPs had consented was obtained from the care home. From this list, ten residents were randomised (using a random number generator) to approach for consent or assent. The care home staff then identified the ten residents and gave an indication whether or not they had capacity to provide informed consent. For residents with capacity, a resident information leaflet was provided and a researcher explained the project. Residents were then given at least twenty-four hours to decide whether or not to participate. If they decided to participate, written consent was obtained. For those residents lacking capacity, assent was sought from the next of kin. Where

residents had no next of kin, assent was obtained from the care home manager. Consent was obtained in accordance with the Reference Guide to Consent for Examination or Treatment¹ and Seeking Consent: Working with Older People.⁴

This study may have been seen as threatening by some care homes, GPs, pharmacies, and with the potential to create anxiety in residents and their relatives. It was stressed to all healthcare practitioners and carers that anonymity would be maintained, that our approach would be blame free, and that errors were viewed as part of a system, which we were trying to understand and improve.

Figure 3.2: Flow diagram of data collection.



Case summaries were constructed for each resident who had an error associated with one or more of their medicines. These were used by a second assessor to confirm whether an error had occurred, and to act as a basis for an assessment of harm.

In addition, a broadly ethnographic approach including a mixture of observation, interviews (based round a formal structure) and field notes was taken to investigate the causes of each error. Where possible, when an error was identified (defined below), the research pharmacists interviewed care home staff, the GP and community pharmacists to understand why an error had occurred. In addition to interviews relating to specific errors, in-depth interviews and the observation of the dispensing process was conducted in a small selection of pharmacies. These data, along with more detailed methods, are presented in Chapters 5 and 6.

3.5 Discovering the prevalence of medication errors

The prevalence of four types of medication error was to be established:

- prescribing
- monitoring
- dispensing
- medication administration

Error definitions, data collection methods and denominators can all have a marked effect on the reported prevalence of error.⁴⁹ Consequently, in this next section, particular attention is paid to these issues.

Spontaneous reporting was rejected because it can identify only a thousandth of the errors.⁵⁰ Retrospective reviews of documents and patient records alone were rejected as they are often incomplete and, in this setting, they are sometimes completely missing.

3.5.1 Study database and data collection materials

An Access® database from a previous study of medication error in secondary care was adapted for this study.⁵¹ Due to the differences between the hospital and care home settings, significant amendments to the database were required to ensure it was appropriate for this study. Some data were entered directly into the database when collected, however, paper forms were also required for certain data (such as observations of the drug rounds) and these data were then subsequently entered into the database (see individual sections on types of errors below for more detail). Data collection forms were based on those used in

previous studies of medication error in secondary care.^{52,53,54,55} These forms were adapted to the care home setting and revised following piloting.

3.5.2 Background and training of research pharmacists

The research pharmacists for London and Bradford had several years clinical experience, including experience of conducting clinical medication reviews for care home residents. The research pharmacist for Cambridgeshire had less experience in this area and, therefore, received training and practical experience of medication review from members of the study steering group and from the other two research pharmacists.

A two-day training event was held for the 3 research pharmacists to encompass the following:

- Aims and objectives of the study, researchers' roles
- Context of care homes; establishing relationships; introduction to key stakeholders
- Ethical and research governance issues; recruitment and informed consent
- Nature of research; separating research and practice; qualitative and quantitative methods
- Recording overview of home details and systems
- Error definitions, differences between error and an intervention, difference between error and optimum practice, Human Error Theory
- Data collection forms, database and data management
- Observation of drug rounds and action on discovery of an error
- Medication review
- Qualitative interviewing
- Studying causes of error, being supportive to those being interviewed, being constructive and positive
- Health and safety

3.5.3 Ensuring consistency in data collection

As this was a multisite study with three research pharmacists gathering and recording data, it was essential to ensure consistency between areas. This was done by:

1. providing training on the method of data collection
2. using robust and objective definitions of error
3. providing a data collection manual, which was constantly updated in the light of experience
4. using standardised data collection materials and database
5. frequent contact between the research pharmacists and other pharmacists and the GP on the research team (who had experience of medication errors and care homes) to resolve any problems.

In addition to this, a three monthly subgroup meeting was held with the three research pharmacists and members of the study steering group to resolve any ambiguities; this process was continuous and iterative.

3.6 Prescribing errors

Definition: Prescribing errors were identified using the definition developed and validated using the Delphi technique by Dean et al.⁵⁶ This definition has been used in the Department of Health report “Building a safer NHS for patients – improving medication safety”,³ and has been successfully operationalised in several empirical studies.^{57,58,59,55}

A clinically meaningful prescribing error was therefore defined as:

“A prescribing decision or prescription-writing process that results in an unintentional, significant:

1. *Reduction in the probability of treatment being timely and effective, or*
2. *Increase in the risk of harm, when compared to generally accepted practice”.*

This definition includes omissions, as these are considered to be a decision not to prescribe a drug which other doctors would normally prescribe in the circumstances. Prescribing without taking into account the patient's clinical status, failure to communicate essential information and transcription errors were also considered prescribing errors. However, failures to adhere to standards such as prescribing guidelines or the drug's product license, were not considered to be errors if this reflected accepted practice – a judgement that came out clearly from a previous Delphi process with prescribers (Dean et al 2000).

Data collection: The approach was a tiered application of clinical judgement. The technique of clinical medication review was used, in which the clinical pharmacists reviewed the resident, the illness and the drug treatment during a consultation. This is a process previously developed by research team members and studied in patients living in their own home⁶⁰ and in care homes.⁶¹

Clinical medication review involved evaluating the therapeutic efficacy of each drug and the progress of the conditions being treated. The pharmacists identified inappropriate doses, dose frequencies, formulations or routes. Actual and potential adverse drug events, drug-drug interactions and contra-indicated medication were identified. Other issues, such as compliance/adherence (if applicable), and the resident's understanding of the condition and its treatment were also considered when appropriate. The outcome of the review is normally a decision about the continuation (or otherwise) of the treatment. Residents were seen by appropriately trained clinical pharmacists, who reviewed their notes at both the GP surgery and at the care home, as well as seeing the resident when possible.

Due to the complex medicines management systems, multiple data sources were accessed when identifying prescribing errors (Appendix C). Prescribing error data were entered directly into the study database.

For each resident, the clinical pharmacists provided a case history and summary of the medicines prescribed, and described what they considered to be prescribing errors. The cases were discussed with a second clinical pharmacist, to determine whether they considered it a prescribing error; any disagreements between the pharmacists were resolved during dedicated meetings of the study steering group. Prescribing errors were

classified as in Table 3.1 and were not mutually exclusive ie there could be more than one prescribing error per item. If a prescribing error was linked to a dispensing or medication administration error, this was recorded (“linked error”).

Denominator: The number of opportunities for error was the number of prescription items written, plus any omissions.

Table 3.1: Typology of prescribing errors

Omission	Failure to prescribe a drug that has been previously prescribed or had been initiated by another health care professional and which was not intentionally stopped by prescriber, or failure to prescribe a drug that was clinically indicated
Patient incorrect	Prescribing for the wrong patient
Unnecessary drug	Prescribing a drug for which there is no indication. Note that not all diagnoses are always written in the notes. Excludes when residents and/or relatives put pressure on the GP to prescribe an unnecessary drug
Duplication	Two drugs which have the same action are prescribed together in error e.g. generic and branded, two different statins, two different forms of the same drug. Excludes intentional prescribing e.g. anti-Parkinsonism drugs
Drug incorrect	Choosing the wrong drug e.g. when two drugs have similar names
Allergy error Contraindication	Prescribing a drug for which the patient has a known drug allergy Prescribing a drug which is contraindicated because of a co-existing clinical condition
Interaction	Prescribing a drug which may cause a serious drug interaction, unless this was a recognised risk and appropriate action taken to reduce risk e.g. if two interacting drugs were both considered essential for patient and dose adjustments had been made or a further drug added to address this
Dose/strength error	Prescribing a drug in a dose above or below that appropriate for that patient and/or for their clinical condition
Formulation error	Prescribing a drug in a formulation that is unsuitable for the route of administration including modified release preparations for administration via a PEG tube
Frequency error	Prescribing a drug for which the frequency is inappropriate and would result in a sub-therapeutic effect or risk of toxicity
Timing error	Prescribing a drug for a time which is unsuitable for that preparation e.g. prescribing simvastatin in the morning
Information incomplete	Omission of strength for drugs available in more than one strength. Omission of route for drugs that can be given by more than one route e.g. eye, ear and nose drops. Patient name omitted. Omission of maximum daily dosing frequency for an "as required" medicine when overdose could result in harm. Omission of directions for correct administration (eg prescribing GTN tablets "as directed")
MAR transcription error	Poor transcription on to the MAR by the prescriber which results in an error e.g. use of Latin abbreviations on MAR in a residential home
Other	Record anything else that is not covered in the above
Linked error	To be used if a prescribing error is linked to another error e.g. prescription and dispensing of penicillin to a penicillin allergic patient

3.7 Monitoring errors

There is a paucity of evidence and often disagreement amongst health care professionals regarding how often, if at all, a particular medicine should be monitored. Several national and local guidelines exist for the monitoring of medication, however, they often differ in their recommendations

- BNF;⁶²
- North West Drug Information Letter;⁶³
- London and South East Medicines Information Service and Croydon PCT;⁶⁴
- Hinchingsbrooke Hospital;⁶⁵

Quality indicators for medication monitoring in vulnerable older people have been published.⁶⁶ However, specific monitoring criteria were limited to antidepressants, diuretics, angiotensin converting enzyme inhibitors (ACE inhibitors) and warfarin; other potentially harmful medicines were not included. Gurwitz et al⁶⁷ conducted a study of preventable adverse drug events in two US long-term care facilities and identified monitoring errors including inadequate laboratory monitoring, a delayed response or failure to respond to signs or symptoms or laboratory evidence of drug toxicity. However, criteria to identify monitoring errors for specific medicines were not reported. Consequently, it was necessary to develop and validate a definition and criteria for a monitoring error for this setting.

3.7.1 Development of monitoring criteria

The intention was to develop a definition and criteria that were pragmatic, easily operationalised, and owned by practising GPs and clinical pharmacists. The intention was to focus on the drugs most likely to be prescribed that had the potential for harm in the care home setting. It was not intended to produce an exhaustive list of drugs that required monitoring.

A literature search was conducted using MEDLINE (May 2006) and EMBASE (May 2006) using the search terms “medication error”, “drug monitoring” and “monitoring error” to identify whether criteria for determining medication monitoring errors had previously been

published, or whether a monitoring error had previously been defined. No generic definition of a monitoring error was identified.

A definition of a monitoring error was therefore developed and agreed by the study steering group. Criteria were initially developed by two clinical pharmacists on the study steering group, using local and national guidelines for the monitoring of pharmacotherapy.^{63,64,65,66} This took into account the drugs included in the above guidelines. Sixteen drugs or groups of drugs were deemed to have properties which made monitoring necessary in the primary care setting. The criteria were split into two sections:

- a) monitoring following the initiation of therapy
- b) monitoring of maintenance therapy

The criteria for each drug were then agreed by experienced practitioners and academics from the study steering group. These comprised four clinical pharmacists, a pharmacist lecturer in patient safety, two professors of pharmacy practice and one practising GP/research fellow. To ensure external validity, the criteria were reviewed by a sample of GPs (21) and clinical pharmacists with primary care experience (11) who were selected from the Primary Care Pharmacy Network (5 pharmacists), from GP trainers (9 GPs) and from a convenience sample (6 pharmacists, 12 GPs). The pharmacists and general practitioners were e-mailed the criteria in August 2006 and asked to indicate whether they agreed or disagreed with each specific medication monitoring criterion and to give comments where they disagreed. An overall consensus rate of 70% was deemed pragmatically sufficient to accept each criterion.

The core definition of a monitoring error was agreed by the study steering group as:

“A monitoring error occurs when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. It includes the absence of tests being carried out at the frequency listed in the criteria, with tolerance of +50%. This means, for example, that if a drug requires liver function tests at 3 monthly intervals, we would class as an error if a test has not been conducted within 18 weeks. If a patient refused to give consent for a test, then this would not constitute an error.”

We chose to allow at 50% tolerance in the timing of tests , this was a pragmatic judgment based on our knowledge of the field; if anything it was a generous limit.

The final agreed criteria, validated by the GPs and clinical pharmacists, are presented in Tables 3.2 and 3.3. For more detail on the validation process see Appendix D “Development and validation of criteria to identify medication monitoring errors in care home residents” accepted for publication pending revision (International Journal of Pharmacy Practice).

Table 3.2: Medication monitoring for maintenance therapy

Drug/drug group	Maintenance monitoring
ACE inhibitor	12 monthly U&E
Amiodarone	6 monthly TFT 6 monthly LFT
Azathioprine	3 monthly FBC
Carbimazole	3 monthly TFT (6 monthly if patient been stabilised for over 1 year)
Digoxin	Digoxin level if toxicity or lack of efficacy suspected.
Diuretics	12 monthly U&E
Glitazones	12 monthly LFT
Levothyroxine	12 monthly TFT
Lithium	3 monthly lithium levels 12 monthly TFT
Methotrexate	3 monthly FBC 3 monthly LFT 6 monthly U&E
Sulfasalazine	FBC 3 monthly in 1 st year LFT 3 monthly in 1 st year FBC 6 monthly in 2 nd year LFT 6 monthly in 2 nd year No further monitoring if stable
Theophylline	Theophylline level if toxicity suspected
Valproate	3 monthly LFT for first 6 months
Warfarin	12 Weekly INR

Table 3.3: Medication monitoring for initiation of therapy

Drug/drug group	Monitoring on initiation
ACE inhibitor	On initiation: Pre U&E and 2 week after
Digoxin	Pre U&E
Diuretics	Pre U&E and 1 month after starting
Glitazones	Pre LFT

Data collection: Monitoring errors were identified by the clinical pharmacists from the residents' medical records and where appropriate care home records. Monitoring errors were entered directly into the study database. Monitoring errors were classified according to Table 3.4 and were not linked to the other types of error. The types of monitoring error were considered to be mutually exclusive and that each drug could be associated with a maximum of one monitoring error.

Denominator: The number of opportunities for error was the number of prescribed items that required monitoring according to the validated criteria.

Table 3.4: Types of monitoring error

Monitoring not requested	The prescriber has not requested the monitoring which would normally be considered necessary. Note that if patient has refused to be monitored this should be recorded as this would not to be considered an error
Requested but not done	e.g. blood sample has not been taken although it has been requested by the prescriber
Results not available	The tests have been done but the results either have not been sent or have been lost
Results not acted upon	The results have been received and clinically significant results recorded, but these have not been acted upon

3.8 Dispensing errors

Definition: The definition of a dispensing error developed by Beso et al 2005 was adopted. Due to the nature of MDS, extra categories of error were developed by the study steering group (see section 4.2.4 of results). A dispensing error was defined as:

“One or more deviations from an interpretable written prescription or medication order, including written modifications to the prescription made by a pharmacist following contact with the prescriber”.

Data collection: The clinical pharmacists studied the residents’ medicines and checked these against the medication prescribed. Medicines were identified which had been:

- added or omitted erroneously
- packaged to be given at the wrong time (deviation of more than 2 hours)
- dispensed in the wrong dose or formulation, or to be given by the wrong route.

Dispensing errors were recorded on a data collection form (Appendix E) and then entered into the study database. Dispensing errors were classified according to Table 3.5 and were not mutually exclusive ie there could be more than one dispensing error per item. If a dispensing error was linked to a prescribing or medication administration error, this was recorded.

Denominator: The number of opportunities for error was the number of prescription items dispensed or omitted.

Table 3.5: Types of dispensing error

Contents errors	
Omission	Failure to dispense a prescribed item
Unprescribed drug	Dispensing a medication that was not prescribed e.g. supplying a drug that had been discontinued
Drug incorrect	Dispensing a drug that is different to that prescribed. Excludes changes made following the pharmacist contacting the prescriber to correct an error
Dose/strength error	Dispensing a dose unit containing the wrong amount of the correct drug, without an appropriate adjustment to the dosing instructions
Formulation error	Dispensing the correct drug in a dosage form different to that prescribed. Includes supplying a modified release formulation when a standard formulation was prescribed
Extra dose(s)	Dispensing a larger quantity of medication to that prescribed. If a MDS is used it will include where an extra tablet has been put in a compartment by mistake

Missing dose(s)	Dispensing a smaller quantity of medication to that prescribed. If a MDS is used it will include where a tablet has been left out of a compartment
Timing error	Dispensing a medication into a MDS at a different time of day to that prescribed or usually recommended for that drug. Dispensing medicine in the wrong colour tray or sheet eg donepezil prescribed at night but dispensed in pink "morning" tray; warfarin dispensed in white "short course " or "as required" tray
Frequency error	Dispensing a medication into a MDS at a different frequency to that prescribed. This includes dispensing a drug prescribed to be taken "when required" into the regular dosing sections of the MDS
Patient incorrect	Dispensing the correct medications but for the wrong patient
Deteriorated drug	Dispensing a medication that has exceeded its expiry date or has been stored at a temperature different to that required, or for which the primary packaging is damaged. N.B: Drugs in a heat sealed MDS system have a shelf life of 8 weeks
Labelling errors	
Patient name incorrect	Omission of the patient's name or use of a different name to that on the prescription
Drug name incorrect	The drug name on the label deviated from that specified by the prescriber, except where amendments are necessary to conform to good pharmaceutical practice. Incorrect would include a modified release product which was not labelled as such
Drug strength incorrect	Where more than one strength available, the strength on the label is different to the strength of the drug supplied
Quantity incorrect	The drug quantity on the label deviated from that specified by the prescriber, except where amendments are necessary to conform to good pharmaceutical practice, or where there is a record of medication owing.
Dosage incorrect	The dosage on the label deviated from that specified by the prescriber except where amendments are necessary to conform to good pharmaceutical practice. (eg: substituting a specific dose or maximum daily dose when prescriber has indicated "as directed")
Date incorrect	Omission of the date of dispensing or use of a date different to that on which the product was dispensed. Note that MDS are sometimes pre-packed and if so should have an additional label which has batch number, original expiry date and date of dispensing
Route error/omission	The route has not been stated for medicines which can be administered via more than one route e.g. eye, ear and nose drops

Instructions incorrect	The instructions deviated from those prescribed, except where amendments are necessary to conform to written local policy or good pharmaceutical practice
Additional warning(s)	Omission or use of incorrect additional warnings, according to professional references (for example the British National Formulary)
Pharmacy address	Failure to include the correct name and address of the supplying pharmacy on the label
No label	Failure to add a dispensing label (eg tube of cream or inhaler; multiple packs dispensed with only one label on transparent outer wrap)
Other labelling errors	Any other labelling error not included in the above categories
Clinical errors	
Allergy error	Dispensing a drug for which the patient has an allergy and the pharmacy is aware of the allergy
Contraindication	Dispensing a drug which is contraindicated in that patient and where the pharmacy could be reasonably expected to have had knowledge of this e.g. from the other drugs that the patient is taking
Interaction	Dispensing a drug which could result in a serious drug interaction
Other	Any other error not included in the above categories
Linked error	Use to record that the dispensing error is linked to another error e.g. administration error

3.9 Medication administration errors

Definition: A medication administration error was defined using previous work by Allan and Barker⁶⁸ (1990) and Dean and Barber⁶⁹:

“Any deviation between the medication prescribed and that administered”.

Originally, timing of medication administration was not felt to be considered as a source of error. However, on reflection it was agreed by the study steering group that some timing errors were of clinical significance and therefore a list of medicines of which timing was deemed important was established by the study steering group (see appendix F). Any deviation in the correct timing of administration of these particular medicines was classified as an error.

Data collection: Following informed, written consent from care home staff, the clinical pharmacists observed two drug rounds per resident to identify and classify medication administration errors (see appendix G for more details of this process). Medication administration errors were recorded on a data collection form (Appendix H), classified according to Table 3.6, and subsequently entered into the study database. Medication administration errors were not mutually exclusive, i.e. there could be more than one medication administration error per item. If a medication administration error was linked to a prescribing or dispensing error, this was recorded.

Denominator: The number of opportunities for error was the number of doses given, plus any doses that should have been given but were omitted.

Table 3.6: Types of medication administration error

Omission	A dose of medication that has not been administered by the time of the next scheduled dose. Does not include doses omitted according to doctor's instructions, nurse's clinical judgement (N.B. only be relevant in care homes with nursing), if resident refuses or if resident not at the home)
Allergy error	Administration of a drug for which the patient has a known drug allergy
Extra dose(s)	The administration of an additional dose of a prescribed medication. Includes administration of a drug more times in the day than prescribed and administration of a dose of drug after it has been crossed off the MAR
Wrong dose	The administration of the correct drug by the correct route but in a quantity that was not that prescribed. Includes administering inhaled steroid without spacer when one is available; administration of incorrect number of dose units; failure to shake a bottle of suspension prior to admission; measurement of an incorrect volume of an oral liquid. Where liquid preparations are not measured correctly or poured into non-graduated medicines cups, a wrong dose error has occurred only when the observer is certain that the wrong volume has been administered. If wrong strength is given because of a dispensing error this is still an MAE, but it will be linked to the dispensing error
Unprescribed drug	The administration of a drug that was not prescribed for the patient concerned (classified as a "drug incorrect" error if drug X prescribed but drug Y given instead). This may occur if medication had been stopped by the prescriber but was not removed from drug trolley
Drug incorrect	A dose of a drug administered that is not the drug prescribed. This could occur if administration followed an undetected dispensing error and would be a linked error
Formulation error	The administration of the correct dose of the drug by the correct route but in a formulation that was not prescribed. Includes administration of a modified release when non-modified prescribed, and vice versa. This may be linked to a dispensing error if the wrong form was dispensed
Route error	The administration of the correct drug by a route or site which was not that prescribed
Deteriorated Drug	Administration of a drug that has exceeded its expiry date or a drug with its physical or chemical integrity compromised, where none of above error types occurred. N.B. Note that MDS have a shelf life of 8 weeks from date of dispensing and are sometimes prepacked and if so should have an additional label which has batch number, original expiry date and date of dispensing
Timing error	Timing errors will only be recorded if the timing of the administration could have clinical significance
Other	Use to record anything that is not covered above
Linked error	Use to record that the MAE is linked to another error

3.10 Assessing the potential for harm

There is little consensus about how to define harm in prospective studies, such as this one, in which the researchers intervened when they observed error. Hence we intended to compare different methods. Two types of harm were of interest:

- whether the patient had suffered harm as a result of a medication error (often called a preventable adverse drug event (ADE))
- whether the patient would be likely to suffer harm (a preventable ADE) in the future, had we not observed the error and intervened to correct it.

The group of DW Bates in the USA use an ordinal scale of harm when assessing patients' records which includes

- 'no harm'
- 'significant'
- 'serious'
- 'life threatening'
- 'fatal'¹⁸

'Significant', for example, includes non-urticarial rashes and drug induced falls without fracture. For assessing the harm likely to have occurred if the researcher had not intervened, Dean and Barber⁷⁰ developed a valid, reliable measure of the harm likely to result from an error, using a 0-10 scale ("no effect" to "death").

The case summaries were assessed for potential error by a panel of five experts using the scale developed by Dean and Barber.⁷⁰ The expert panel consisted of a clinical pharmacologist, a consultant psychiatrist, a GP and two clinical pharmacists.

3.11 Data analysis

3.11.1 Statistical analysis

Statistical analysis was performed using the software R 2.3 (R project for statistical computing, www.r-project.org). Statistical 'significance' was pre-defined at the 5% level. Exact binomial confidence intervals were calculated for proportions. Chi-square tests were used to assess differences in error rates between areas. Generalised Estimating Equations (library geepack, version 1.0-10) were used to model patient level odds of errors, allowing for clustering in homes and using an independence correlation structure. Multilevel models were also used to model patient level odds of errors, using the MLwiN 2.03 software (Multilevel models project, University of Bristol, <http://www.cmm.bristol.ac.uk>), fitting variance components at the various levels.

3.11.2 Potential harm analysis

The scores from each assessor were transferred to an Excel® spreadsheet and mean scores for each error were calculated. Overall means were calculated for each category of error (prescribing, monitoring, dispensing and medication administration) along with standard deviations and ranges.

Chapter 4

Quantitative Results

4.1 Demographics

For each home we measured the prevalence on the day of inspection – a point prevalence for that home. Taking all these point preferences together, we are estimating prevalence.

In this section we describe the residents and care homes involved in the study. 256 residents were recruited from 55 care homes. Table 4.1 shows demographic data for these residents. The majority of the residents were female (69.1%) and very elderly (mean age 85.2 years). There were slightly more residential home residents (54.3%) than nursing home residents. Figure 4.1 shows a frequency distribution of the number of medicines per resident based on the prescribing denominator (the number of medicines prescribed plus any omissions). 220 (85.9%) of residents were dispensed their medicines in MDS. Nearly all (96.7%) of residents in Bradford received their medicines in MDS, however, this figure was significantly lower for London (76.9%) and Cambridgeshire (74.2%).

One hundred and eight care homes were approached and 79 (72.1%) agreed to participate. Fifty five homes were included in the final sample. Figure 4.2 shows the type of care provided by these homes. The majority (38, 69.1%) of the 55 care homes provided both residential and nursing care with the corresponding figures for residential care only and nursing care only being 12 (21.8%) and 5 (9.1%), respectively. The sample contained a good spread of home size (Figure 4.3); the most common size of home had 20-29 residents representing 25.5% of the sample. Different owner-types were well represented (Figure 4.4). Small chains (34.5%), single homes (21.8%) and not for profit homes (27.3%) accounted for 83.6% of the sample.

Table 4.1: Demographics

No. of residents approached	399
No. of residents consented/assented (%)	269 (67.4)
No. of residents excluded	13
Consent given post cut-off	6
Died	4
In hospital	3
No. of residents entered into study	256
Cambridgeshire	31
Bradford	121
London	104
Female, no. (%)	177 (69.1)
Age (y), mean, SD (range)	85.2, 8.6 (60-102)
Nursing residents, no. (%)	117 (45.7)
Residential residents, no. (%)	139 (54.3)
Mean no. of medicines per resident* (SD, range)	7.2 (3.6, 1-22)
No. of residents using MDS overall (%)	220 (85.9)
Cambridgeshire (%)	23 (74.2)
Bradford (%)	117 (96.7)
London (%)	80 (76.9)

GPs = general practitioners; *based on prescribing denominator; MDS = monitored dosage systems

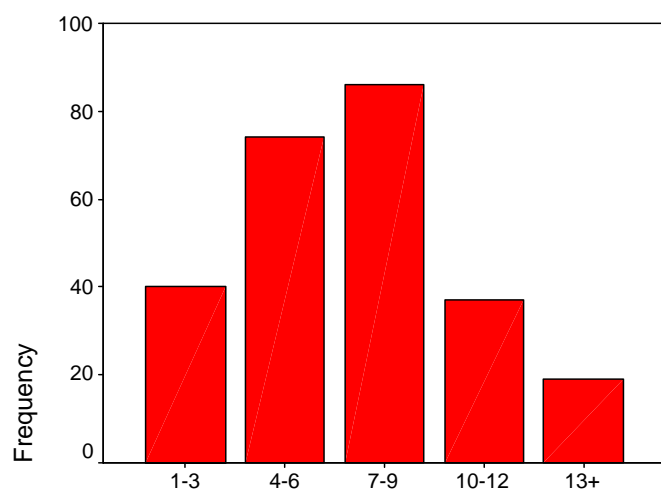


Figure 4.1: The number of medicines per resident based on prescribing denominator

(Residents needed to be prescribed at least one medicine to be entered into the study.)

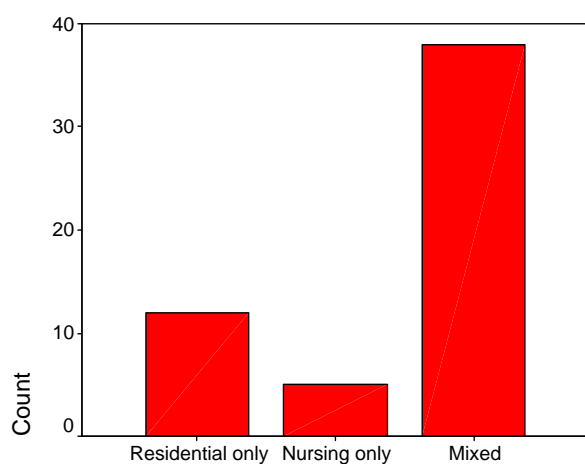


Figure 4.2: Type of care

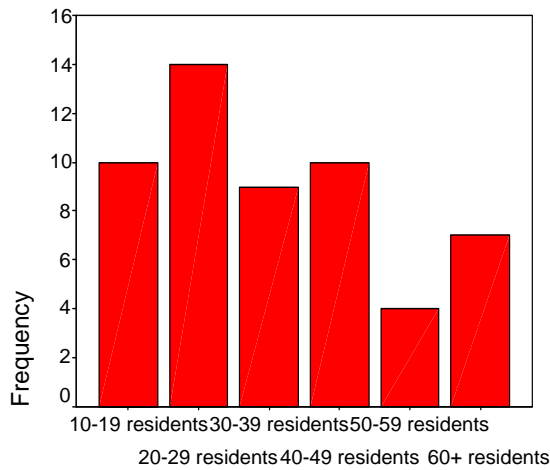


Figure 4.3: Size of home

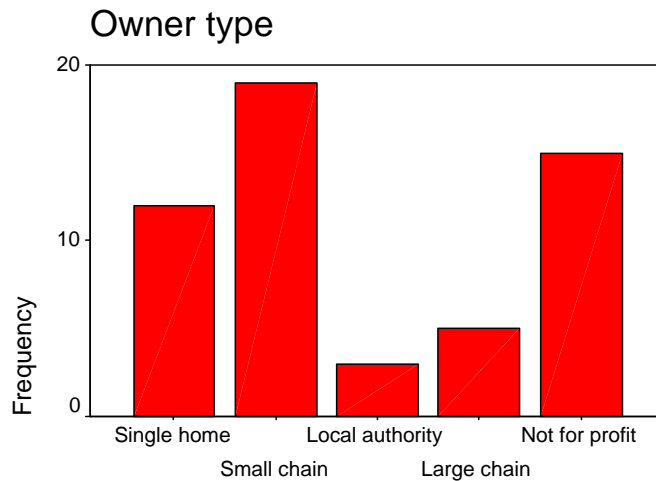


Figure 4.4: Owner type

Eighty nine GP practices were approached and 54 (60.7%) agreed to participate. Figure 4.5 shows the number of GP practices that served each care home. The mean number of GP practices per care home was 3.8 with a range of 1-14. There was considerable variation between areas (Figures 4.6, 4.7, 4.8). In the London area, it was the norm for the care homes to be serviced by one GP practice (mean 1.35, range 1-3). Conversely, in Bradford it was usual to have multiple GP practices servicing care homes (mean 5.3, range 1-14).

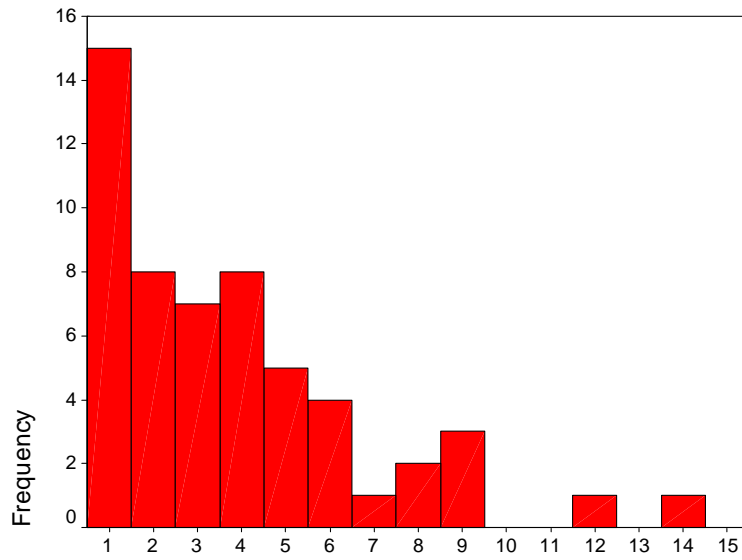


Figure 4.5: Number of GP practices per home

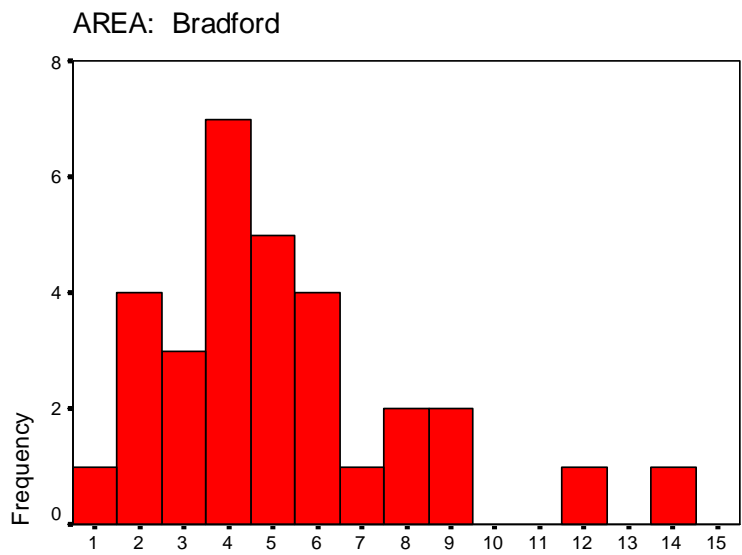


Figure 4.6: Number of GP practices per home - Bradford

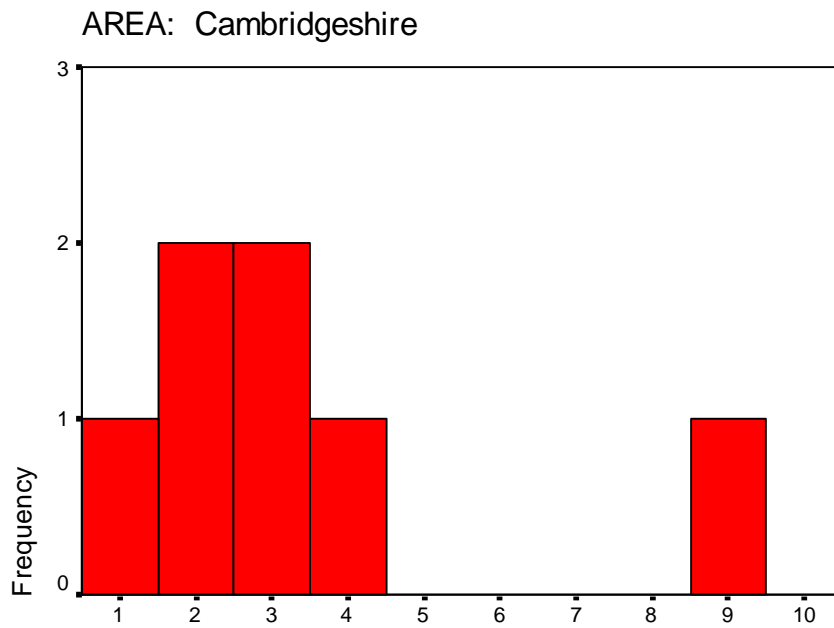


Figure 4.7: Number of GP Practices per home - Cambridgeshire



Figure 4.8: Number of GP Practices per home - London

There was also dissimilarity between areas in the use of MDS. Figure 4.9 shows the medication delivery systems used by care homes. The majority of care homes used MDS (88.9%), with blister systems (70.4%) being more popular than cassette systems (18.5%). Non-MDS was more likely to be used in Cambridgeshire (2/7, 28.6%) and London (3/17, 17.6%) than in Bradford (1/30, 3.3%). (See Figures 4.10, 4.11, 4.12).

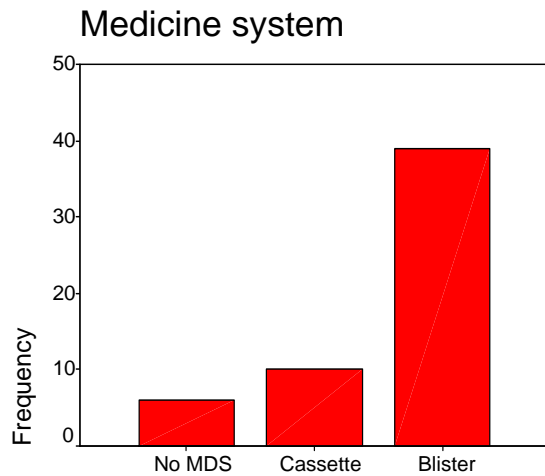


Figure 4.9: Medicine system

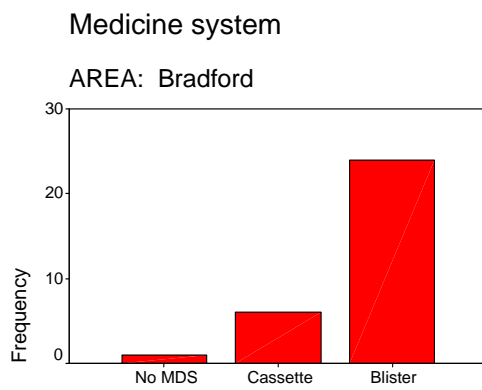


Figure 4.10: Medicine system - Bradford

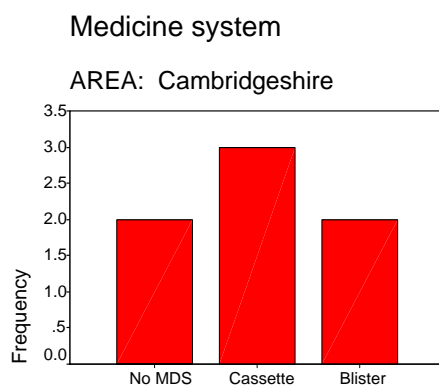


Figure 4.11: Medicine system - Cambridgeshire

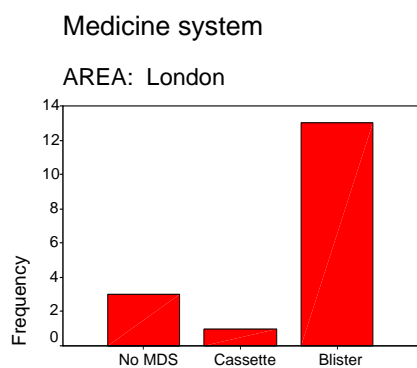


Figure 4.12: Medicine system - London

The majority of care homes were serviced by one pharmacy (mean 1.5, range 1-4) (Figure 4.13). Again, there was some variability between areas. Care homes in the London and Cambridgeshire areas were more likely to be serviced by more than one pharmacy than those in Bradford (see Figures 4.14, 4.15, 4.16).

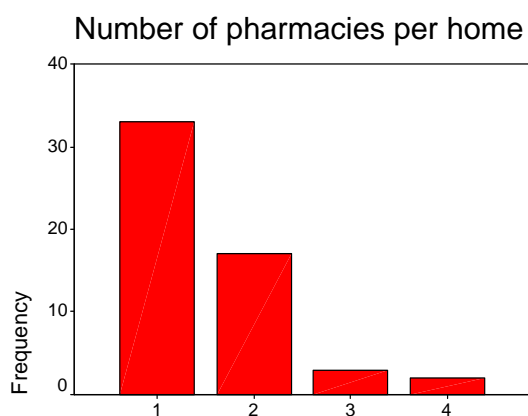


Figure 4.13: Number of pharmacies per home

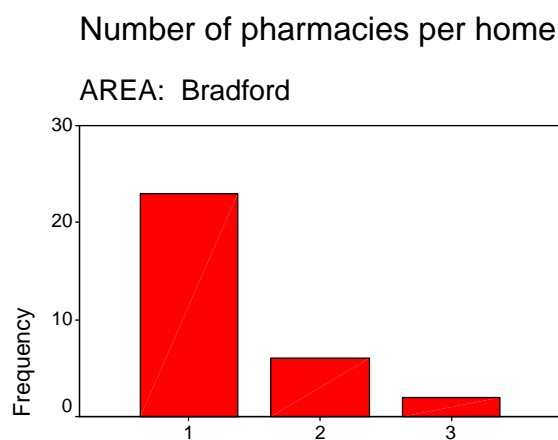


Figure 4.14: Number of pharmacies per home - Bradford

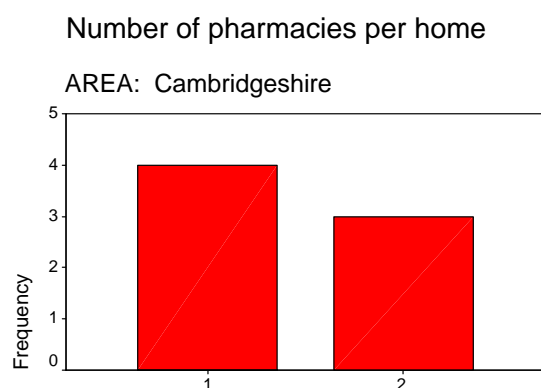


Figure 4.15: Number of pharmacies per home - Cambridgeshire

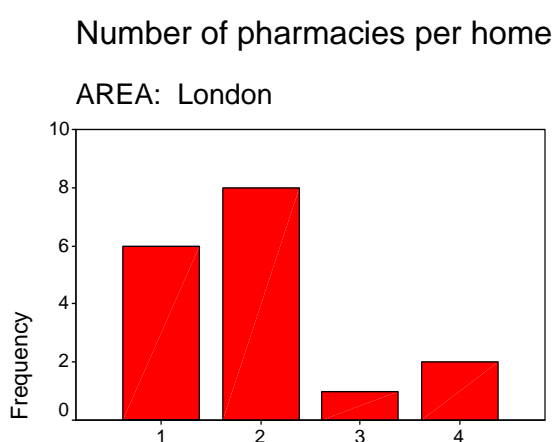


Figure 4.16: Number of pharmacies per home - London

4.2 Prevalence and typology of medication errors

Overall

In total, 178 of 256 residents (69.5% 95% CI 63.5-75.1) had at least one medication error. There was a mean of 1.9 (95% CI 1.64-2.17) errors per resident (Table 4.2). Overall, there were no statistically significant differences between areas in the number of residents with an error or the mean number of errors per resident. However, there was a statistically significant difference between areas in the prevalence of medication errors by opportunity for error ($p=0.007$).

The adjusted odds ratio (OR) for a medication error (prescribing, monitoring, MAE or dispensing) in residential residents versus nursing residents was 1.31 (95% CI 0.93-1.84),

however, this was not statistically significant at the 5% level after adjusting for age, sex and medication delivery system.

4.2.1 Prescribing errors

One hundred residents (39.1%, 95% CI 33.0-45.3) had one or more prescribing errors, totalling 153 prescribing errors (in one case, two prescribing errors were found in one medicine). The mean number of prescribing errors per resident was 0.60 (95% CI 0.48-0.71), with Bradford, London and Cambridgeshire having 0.67, 0.57 and 0.42 prescribing errors per resident, respectively; these differences were not statistically significant. The prescribing error rate by opportunity for error was 8.3% (95% CI 7.1-9.7), the breakdown by areas was Bradford (9.8%), London (7.4%) and Cambridgeshire (6.1%); again no statistically significant difference was found.

Table 4.3 shows the typology of prescribing errors. The most common type of prescribing error, accounting for 87.6% of the total, were 'information incomplete' (37.9%); 'unnecessary drug' (23.5%); 'dose/strength error' (14.4%) and 'omission' (11.8%).

4.2.2 Monitoring errors

27 residents (10.5% 95% CI 7.1-15.0) had a total of 32 monitoring errors in 218 prescribed items that required monitoring with the mean number of monitoring errors per resident being 0.13 (95% CI 0.08 – 0.17) and there being 14.7% (95% CI 10.3-20.1) errors if looked at by the number of drugs requiring monitoring (Table 2). This means that around 1 in 7 such items is subject to error. In total, there were 147 residents who were prescribed a medicine that required monitoring and 18.4% (27) of these had an error. There was considerable variation between areas with 75% of monitoring errors occurring in London, resulting in 0.23 monitoring errors per resident in this area. This compares to a figure of 0.03 for both Bradford and Cambridgeshire. Nearly one third (30.8%) of medicines deemed to require monitoring in the London area were not being monitored. The higher rate of monitoring errors in London was statistically significant.

The great majority of monitoring errors (90.6%) resulted from a failure to request monitoring (Table 4.4). Monitoring errors by drug type is given in Table 4.5.

4.2.3 Medication administration errors (MAE)

57 (22.3% 95% CI 17.3-27.9) residents had a total of 116 administration errors (Table 4.2). In one case, two administration errors were found during the administration of one item. The mean number of medication administration errors per resident was 0.45 (95% CI 0.32-0.58). Cambridgeshire had the lowest administration error rate per resident (0.23), followed by Bradford (0.40) and London (0.58). However, there were no statistically significant differences in medication administration errors between areas. The prevalence of administration errors by opportunities for error was 8.4% (95% CI 7.0-10.0) overall.

Nearly half [49.1%] of all administration errors were 'omissions' and just over one fifth (21.4%) were 'wrong dose' (Table 4.6).

There was no statistically significant difference in MAE by residents' principal delivery systems ($p=0.36$).

The odds of a MAE occurring were higher in residential care residents than nursing care residents, however this just failed to reach statistical significance at the 5% level (adjusted OR 1.77 95% CI 0.96-3.25 $p=0.063$) [adjusted for age, sex and medication delivery system].

Table 4.7 shows medication administration errors by type of care and medication delivery system. The higher risk of administration errors in residential residents compared to nursing residents was largely attributable to more 'omissions' (38 versus 19) and 'wrong doses' (18 versus 7). Of the 81 medication administration errors occurring in non-MDS, the most common preparations were inhalers (34.6%), liquids (27.2%), solid oral dosage forms (24.7%) and eye drops (11.1%).

There was a statistically significant difference in the odds of a MAE between delivery systems when analysing individual errors ($p=0.008$; age and sex not significant). This was driven by an increased odds of error in non-MDS versus MDS. The OR of a non-MDS error (relative to blister) was 3.16 (95% CI 1.43-6.95 $p=0.0036$). Comparing the two MDS systems, there was no statistically significant difference (cassette vs. blister OR 1.27 95% CI 0.30-5.34 $p=0.74$).

4.2.4 Dispensing Errors

94 residents (36.7% 95% CI 30.8-42.9) had a total of 187 dispensing errors with a mean of 0.73 (95% CI 0.56-0.90) dispensing errors per resident (Table 4.2). In 12 cases, 2 dispensing errors were found in one dispensed item and in one case, three dispensing errors were found in one dispensed item. The dispensing error rate by opportunity for error was 9.8% (95% CI 8.5-11.2).

Labelling errors were found in 7.3% of dispensed items, content errors in 2.3% and clinical errors in 0.21% (Table 4.8).

There was a statistically significant difference between areas in the number of residents with a dispensing error, with Bradford having the highest rate ($p=0.004$). Similarly, there was a statistically significant difference between areas in the prevalence of dispensing errors by opportunities for error, again with Bradford having the highest rate ($p<0.001$). However, there was no statistically significant difference between areas in the mean number of dispensing errors per resident (Table 4.2).

The most common labelling errors were 'other labelling error' (29.4%), 'no label' (16.6%) and 'instructions incorrect' (13.4%). 'Timing error' (8.0%) and 'deteriorated drug' (5.4%) were the most common content errors (Table 4.8).

There was a statistically significant difference in the odds of a dispensing error by residents' principal delivery system ($p=0.0053$, adjusted for age and sex). This was due to those residents receiving their medicines principally in a cassette having an increased risk of error (cassette adjusted versus blister OR 2.88 95% CI 1.5-5.55 $p=0.0012$). The adjusted OR for non-MDS was 1.31 (95% CI 0.48-3.57 $p=0.59$).

Table 4.9 shows dispensing errors by medication delivery system. Of the 84 dispensing errors occurring in non-MDS, the most common preparations were solid oral dosage forms (27.4%), liquids (25.0%), inhalers (21.4%) and creams (16.6%).

There was a borderline statistically significant difference in the odds of a dispensing error when analysing individual errors by delivery system ($p=0.056$) but no significant effect of sex or age. This was driven by the higher odds of a dispensing error with the cassette

system (cassette vs. blister OR 2.53 95% CI 1.12-5.72 $p=0.022$). Non-MDS was similar to blister (OR 1.03 95% CI 0.57-1.87).

4.2.5 Linked Errors

Seven prescribing errors were linked to administration errors and eight prescribing errors were linked to dispensing errors. There were 15 administration errors linked to dispensing errors.

Table 4.2: Error prevalence

	Type of error				
	Prescribing	Monitoring	MAE	Dispensing	Overall
No. of residents with an error [n=256] (%;95% CI)	100 (39.1%; 33.0-45.3)	27 (10.5%; 7.1-15.0)	57 (22.3%; 17.3-27.9)	94 (36.7%; 30.8-42.9)	178 (69.5%, 63.5-75.1)
Cambridgeshire	10/31 (32.3%, 16.7-51.4)	1/31 (3.2%, 0.1-16.7)	5/31 (16.1%, 5.5-33.7)	7/31 (22.6%, 9.6-41.1)	17/31 (54.8%, 36.0-72.7)
Bradford	50/121 (41.3%, 32.4 - 50.6)	7/121 (5.8%, 2.4-11.6)	26/121 (21.5%, 14.5-29.9)	57/121 (47.1%, 38.0-56.4)	89/121 (73.6%, 64.8-81.2)
London	40/104 (40%, 20.1-48.5) p=0.64	19/104 (18.3%, 11.4-27.1) p<0.01	26/104 (25%, 17.0-34.4) p=0.56	30/104 (28.8%, 20.4-38.6) p=0.004	72/104 (69.2%, 59.4-77.9) p=0.13
Mean no. of errors/resident [n=256] (95% CI)	0.60 (0.48-0.71)	0.13 (0.08-0.17)	0.45 (0.32-0.58)	0.73 (0.56-0.90)	1.91 (1.64-2.17)
Cambridgeshire	0.42 (0.16-0.68)	0.03 (0-0.10)	0.23 (0.02-0.43)	0.58 (0-1.17)	1.26 (0.52-2.00)
Bradford	0.67 (0.47-0.87)	0.06 (0.12,0.34)	0.40 (0.23-0.58)	0.85 (0.62-1.08)	1.98 (1.62-2.35)
London	0.57 (0.41-0.73) p=0.39	0.23 (0.13,0.34) p<0.01	0.58 (0.33-0.82) p=0.22	0.63 (0.35-0.92) p=0.42	2.01 (1.56-2.46) p=0.20
No. of errors/opportunity for error (%; 95%CI)	153/1837 (8.3%; 7.1-9.7)	32/218 (14.7%, 10.3-20.1)	116/1380 (8.4%, 7.0-10.0)	187/1915 (9.8%, 8.5-11.2)	488/5350 (9.1%, 8.4-9.9)
Cambridgeshire	13/213 (6.1%,3.3-10.2)	1/29 (3.4%, 0.1-17.8))	7/124 (5.6% 2.3-11.3)	18/236 (7.6%, 4.6-11.8)	39/602 (6.5%, 4.6-8.8)
Bradford	81/824 (9.8%, 7.9-12.1)	7/111 (63%, 2.6-12.6)	49/605 (8.1%, 6.1-10.6)	103/780 (13.2%, 10.9-15.8)	240/2320 (10.3%, 9.1-11.7)
London	59/800 (7.4%, 5.7-9.4) p=0.09	24/78 (30.8%, 20.8-42.2) p<0.001	60/651 (9.2% 7.1-11.7) p=0.40	66/899 (9.6%, 8.3-11.0) p<0.001	209/2428 (8.6%, 7.5-9.8) p=0.007

MAE = Medication Administration Errors; All intervals are 95% confidence intervals; p-values are tests for differences across areas
 With small numbers a continuity correction was used, and cross-checked with a bootstrap p-value

Table 4.3: Typology of prescribing errors

Typology	Number of errors (%) Cambridgeshire	Number of errors (%) Bradford	Number of errors (%) London	Number of errors TOTAL
Contraindication	1 (7.7)	3 (3.7)	1 (1.7)	5 (3.3)
Dose/Strength error	1 (7.7)	17 (21.0)	4 (6.8)	22 (14.4)
Drug incorrect	-	-	1 (1.7)	1 (0.7)
Duplication	-	1 (1.2)	-	1 (0.7)
Frequency error	-	1 (1.2)	4 (6.7)	5 (3.3)
Info incomplete	7 (53.8)	23 (28.4)	28 (47.5)	58 (37.9)
Interaction	-	1 (1.2)	-	1 (0.7)
Omission	-	11 (13.6)	7 (11.8)	18 (11.8)
Timing error	-	2 (2.5)	-	2 (1.3)
Unnecessary Drug	1 (7.7)	22 (27.2)	1 (22.1)	36 (23.5)
Other Prescribing error	3 (23.1)	-	1 (1.7)	4 (2.6)
Total	13 (100)	81 (100)	59 (100)	153 (100)

Table 4.4: Typology of monitoring errors

Typology	Number of errors (%) Cambridgeshire	Number of errors (%) Bradford	Number of errors (%) London	Number of errors TOTAL
Not requested	-	7 (100.00)	22 (91.7)	29 (90.6)
Results not acted upon	1 (100.0)	-	1 (4.2)	2 (6.3)
Requested not done	-	-	1 (4.1)	1 (3.1)
Total	1 (100)	7 (100)	24 (100)	32 (100)

Table 4.5: Monitoring errors by drug type

Drug/Drug group	Frequency of monitoring errors (%)
Diuretics	17 (53.1)
ACE Inhibitors	5 (15.6)
Amiodarone	4 (12.5)
Levothyroxine	3 (9.4)
Lithium	2 (6.3)
Glitazones	1 (3.1)

Table 4.6: Typology of administration errors

Typology	Number of errors (%) Cambridgeshire	Number of errors (%) Bradford	Number of errors (%) London	Number of errors TOTAL
Omission	3 (42.8)	26 (53.1)	28 (46.7)	57 (49.1)
Wrong dose	1 (14.3)	11 (22.5)	13 (21.7)	25 (21.6)
Timing error	-	4 (8.3)	-	4 (3.5)
Unprescribed drug	-	1 (2.0)	6 (10.0)	7 (6.0)
Deteriorated drug	-	3 (6.1)	7 (11.7)	10 (8.6)
Drug incorrect	-	1 (2.0)	-	1 (0.8)
Other	2 (28.6)	2 (4.0)	1 (1.6)	5 (4.3)
Extra doses	1 (14.3)	1 (2.0)	3 (5.0)	5 (4.3)
Formulation error	-	-	2 (3.3)	2 (1.8)
Total	7 (100)	49 (100)	60 (100)	116 (100)

Table 4.7: All administration errors classified by type of care and medicine delivery system

Typology	Nursing resident (%)	Residential resident (%)	Cassette (%)	Blister (%)	Non-MDS (%)	Number of errors TOTAL (%)
Omission	19 (48.7)	38 (49.4)	5 (55.6)	18 (69.2)	34 (41.9)	57 (49.1)
Wrong dose	7 (17.9)	18 (23.3)	-	3 (11.5)	22 (27.2)	25 (21.6)
Timing error	3 (7.7)	1 (2.3)	-	1 (3.8)	3 (3.7)	4 (3.5)
Unprescribed drug	2 (5.2)	5 (6.5)	-	1 (3.8)	6 (7.4)	7 (6.0)
Deteriorated drug	5 (12.8)	5 (6.5)	4 (44.4)	3 (11.5)	3 (3.7)	10 (8.6)
Drug incorrect	1 (2.6)	-	-	-	1 (1.2)	1 (0.8)
Other	2 (5.2)	3 (3.9)	-	-	5 (6.2)	5 (4.3)
Extra doses	-	5 (6.5)	-	-	5 (6.2)	5 (4.3)
Formulation error	-	2 (2.6)	-	-	2 (2.4)	2 (1.8)
Total	39 (100)	77 (100)	9 (100)	26 (100)	81 (100)	116 (100)
% of total	33.6%	66.4%	7.7%	22.4%	69.8%	100%

Table 4.8: Typology of dispensing errors

Typology	Number of errors (%) Cambridgeshire	Number of errors (%) Bradford	Number of errors (%) London	Number of errors TOTAL
Labelling error				
Additional warning(s)	-	11 (10.8)	-	11 (5.9)
Dosage incorrect	-	4 (3.9)	3 (4.5)	7 (3.8)
Drug strength incorrect	-	2 (1.9)	-	2 (1.1)
Drug name incorrect	-	-	4 (6.1)	4 (2.1)
Instructions incorrect	6 (33.2)	14 (13.7)	5 (7.7)	25 (13.4)
No label	-	28 (27.3)	3 (4.6)	31 (16.6)
Other labelling error	10 (55.6)	17 (16.7)	28 (42.4)	55 (29.4)
Patient name incorrect	-	4 (3.9)	-	4 (2.1)
Subtotal	16 (88.8)	80(78.2)	43 (65.7)	139 (74.4)
Content error				
Deteriorated drug	-	2 (1.8)	8 (12.2)	10 (5.4)
Dose/strength incorrect	-	1 (0.9)	1 (1.5)	2 (1.1)
Drug incorrect	-	1 (0.9)	-	1 (0.5)
Extra dose(s)	-	-	1 (1.5)	1 (0.5)
Formulation error	-	3 (2.9)	3 (4.5)	6 (3.2)
Frequency error	-	3 (2.9)	1 (1.5)	4 (2.1)
Missing dose(s)	1 (5.6)	-	1 (1.5)	2 (1.1)

Omission	-	1 (0.9)	2 (3.0)	3 (1.6)
Timing error	1 (5.6)	10 (9.7)	4 (6.1)	15 (8.0)
Subtotal	2 (11.2)	21 (20)	21 (31.8)	44 (23.5)
Clinical error				
Contraindication	-	1 (0.9)	-	1 (0.5)
Interaction	-	1 (0.9)	-	1 (0.5)
Other clinical error	-	-	2 (3.0)	2 (1.1)
Subtotal	0 (0)	2 (1.8)	2 (3.0)	4 (2.1)
Total	18 (100)	103 (100)	66 (100)	187 (100)

Table 4.9: All dispensing errors classified by medicine delivery system

Typology	Cassette	Blister	Non-MDS	Number of errors TOTAL
Labelling error				
Additional warning(s)	-	7 (16.3)	4 (4.8)	11 (5.9)
Dosage incorrect	1 (1.6)	2 (4.7)	4 (4.8)	7 (3.8)
Drug strength incorrect	2 (3.2)	-	-	2 (1.1)
Drug name incorrect	-	2 (4.7)	2 (2.4)	4 (2.1)
Instructions incorrect	5 (8.2)	1 (2.3)	19 (22.9)	25 (13.4)
No label	-	-	31(37.3)	31 (16.6)
Other labelling error	40 (65.6)	3 (6.9)	12 (14.4)	55 (29.4)
Patient name incorrect	-	4 (9.3)	-	4 (2.1)
Subtotal	48 (78.7)	19 (44.2)	72 (86.7)	139 (74.4)
Content error				
Deteriorated drug	-	10 (23.3)	-	10 (5.4)
Dose/strength incorrect	1 (1.6)		1 (1.2)	2 (1.1)
Drug incorrect	1 (1.6)	-	-	1 (0.5)
Extra dose(s)	-	1 (2.3)	-	1 (0.5)
Formulation error	-	1 (2.3)	5 (6.0)	6 (3.2)
Frequency error	1 (1.6)	2 (4.6)	1 (1.2)	4 (2.1)
Missing dose(s)	1 (1.6)	1 (2.3)	-	2 (1.1)
Omission	2 (3.2)	-	1 (1.2)	3 (1.6)

Timing error	5 (8.2)	8 (18.6)	2 (1.2)	15 (8.0)
Subtotal	11 (18.0)		10 (23.2)	44 (23.5)
Clinical error				
Contraindication	1 (1.6)	-	-	1 (0.5)
Interaction	1 (1.6)	-	-	1 (0.5)
Other clinical error	-	1 (2.3)	1 (1.2)	2 (1.1)
Subtotal	2 (3.2)	1 (2.3)	1 (1.2)	4 (2.1)
Total	61 (100)	43 (100)	83 (100)	187 (100)
% of total	32.6%	22.9%	44.4%	100

4.3 Harm

It was intended that any actual harm would be assessed using the scale developed by Bates (see Section 2.6 Chapter 3). However, no actual harm was detected from the identified errors. Harm from medicines, particularly if they should be monitored but are not, can develop slowly (hence intervention can be very effective). Patients who have suffered harm of any severity are also likely to have been admitted to hospital, or have died. Had the purpose of this work been to study harm, it would have been designed differently to capture these events, however the focus of this study was the prevalence of error.

It is possible to predict the harm that would result from errors. We have previously used generalisability theory to predict the harm that would result from medication administration errors, and validated it by the blind assessment of errors which had known outcomes.⁷¹ Generalisability theory calculates the number of assessors required to get a reliable result. In the present study, we have extrapolated the use of this scale to other types of error. The scale is from 0 (no harm) to 10 (death), with 0-3 being considered 'minor', >3-<7 'moderate' and 7-10 severe. Table 4.10 shows the potential harm scores as assessed by the expert panel. The mean harm scores for prescribing, administration and dispensing errors were 'low' (2.6, 2.1, 2.0 respectively) and for monitoring errors it was 'moderate' (3.7). None of the ranges of errors include 0, and the highest score was 6.6 for a dispensing error. The distribution of monitoring errors is very unusual, with a tight range and low standard deviation; the lowest score being at the upper end of 'minor', at 2.8.

Five examples of errors of each different type are presented below.

4.3.1 Prescribing errors

Case 1

Atorvastatin and ramipril were prescribed prior to a hospital admission, resident had hypertension and had previous stroke. Following discharge from hospital both medicines were discontinued erroneously and the resident was not receiving both medicines 18 months later. (Mean harm score 4.4 and 4.8 for omission of atorvastatin and ramipril respectively)

Case 2

Glimepiride tablets prescribed “3mg daily” by GP for Type 2 diabetes. The diabetic specialist clinic had recommended it be increased to 4mg daily as resident’s glycosylated haemoglobin (HbA1c) remained elevated at 9.7% (target <7.5%). The dose had not been increased by the GP and there was no record in the medical notes to indicate this was deliberate. (Mean harm score 5.2)

Case 3

Tramadol capsules 50 mg prescribed “one to be taken **up to** four times a day” for chronic foot pain, resident also taking warfarin for long term DVT prophylaxis (Tramadol can enhance the effect of warfarin). International normalised ration (INR) checked regularly with erratic results ranging from 0.9-4.5. (Mean harm score 5.8)

Case 4

Amiodarone tablets 200mg prescribed “one daily” commenced in 2001 for atrial fibrillation. Two hospital communications indicated that the amiodarone had been stopped during the admission to hospital as the resident was found to be in sinus rhythm. The amiodarone had not been discontinued by the GP and there was no indication in the medical notes that the continuation was deliberate. (Mean harm score 5.2)

Case 5

Donepezil 10mg tablets prescribed “one daily” for dementia. Following a review from hospital specialist a letter to the GP indicated Aricept® (brand name for donepezil) should be stopped. The donepezil had not been discontinued by the GP and there was no indication in the medical notes that the continuation was deliberate. (Mean harm score 1.8)

4.3.2 Monitoring errors

Case 1

Bumetanide 1mg tablets prescribed “one daily” for heart failure for at least 3 years, however urea and electrolytes had never been checked in this time by the GP. (Mean harm score 4.6)

Case 2

Lisinopril 5mg tablets prescribed “one daily” for hypertension for a resident with an estimated creatinine clearance of 19ml/min. A potassium level had been checked one year ago and had revealed a high potassium level 5.8mmol/l (range 3.5-5mmol/l): no action was taken. (Mean harm score 5.8)

Case 3

Lithium carbonate 250mg tablets prescribed “one daily” for bipolar affective disorder. The lithium level was last checked 13 months ago. (Mean harm score 5.2)

Case 4

Amiodarone 200mg tablets prescribed “one daily” for atrial fibrillation. Thyroid function tests were last checked 9 months ago, when Thyroid Stimulating Hormone (TSH) was 12.9 mIU/l (range 0.3-5.5 mIU/l) and T₄ (thyroxine) was 18 nmol/l (range 50-151 nmol/l) and no action had been taken. (Mean harm score 5.8)

Case 5

Furosemide 40mg tablets prescribed “one twice a day” for knee oedema, urea and electrolytes were last checked two years ago. (Mean harm score 3.8)

4.3.3 Medication Administration errors

Case 1

Casodex® (bicalutamide) 150mg tablets “one daily” were prescribed by the hospital for prostate cancer and this prescription was continued by the GP generically as bicalutamide. They were administered simultaneously for two days resulting in the resident receiving an overdose. (Mean harm score 1.5)

Case 2

Fluoxetine 20mg capsules were prescribed “one daily” for depression and not administered for 6 days as drug not in stock. (Mean harm score 3.0)

Case 3

Beclometasone 200 inhaler prescribed “two puffs twice a day as directed” for asthma. Although an Aerochamber® was available for the resident it was not used. The resident had poor inhaler technique and was not encouraged to rinse afterwards. (Mean harm score 3.4)

Case 4

Bendroflumethiazide 2.5mg tablets prescribed “one each morning” for hypertension. This was discontinued due to low serum sodium of 127 mmol/l (range 135-145 mmol/l), however it remained on the current Medication Administration Record when the next monthly drug supply was made and hence continued to be administered. (Mean harm score 4.6)

Case 5

Glyceryl trinitrate patch prescribed generically “5mg/24 hours take HALF daily” for ischaemic heart disease. A patch was cut in half and applied to the resident’s chest despite the fact that the contents were leaking out. The patch dispensed was Transiderm Nitro® brand which is a reservoir patch and is unsuitable for cutting. (Mean harm score 4.6)

4.3.4 Dispensing errors

Case 1

Alendronate 70mg tablet prescribed “once weekly” for osteoporosis. The pharmacy indicated on the Medication Administration Record for this to be given at the same time as calcium and all other medicines. No warning labels on pharmacy label or Medication Administration Record to indicate “Take before food” or “Follow printed instructions”. Alendronate should be taken on an empty stomach at least 30 minutes before breakfast (or other oral medicine); and remain upright for at least 30 minutes after taking the medicine. (Mean harm score 3.6)

Case 2

Casodex® (brand name for bicalutamide) 150mg tablets dispensed from a hospital prescription and later bicalutamide 150mg tablets dispensed from an FP10 for the same

resident. No evidence to indicate the care home had been informed by the pharmacy that these medicines were identical. (Mean harm score 3.0)

Case 3

Lorazepam 500micrograms/5ml suspension prescribed “5ml at night as required” to settle at night. Pharmacy labelled indicated “Lorazepam 500mg suspension” but with no strength specified. The repeat prescription directions were “5mls at night as required” however pharmacy label stated “Take 5ml when required”. No additional warning labels were included on the pharmacy label. (Mean harm score 3.6)

Case 4

Tramadol 50mg capsules dispensed “one to be taken **up to** four times a day” as prescribed despite the fact that the resident was taking warfarin regularly (see case 3 in prescribing errors for more details). (Mean harm score 5.8)

Case 5

Aspirin enteric coated 75mg tablets dispensed instead of zopiclone 7.5mg tablets as a 7 day supply in a cassette dispensing system. (Mean harm score 5.0)

Table 4.10: Potential harm

	Type of error				
	Prescribing	Monitoring	MAE	Dispensing	Overall
Mean harm score* (SD; range)	2.6 (1.4; 0.2-5.8)	3.7 (0.8; 2.8-5.2)	2.1 (1.3; 0.1-5.8)	2.0 (1.2; 0.2-6.6)	2.6 (0.8;0.1-6.6)
Cambridgeshire	2.5 (0.9; 1.4-3.8)	5 (- ; -)	2.1 (0.3; 1.4-2.4)	1.5 (0.6; 1.0-3.6)	
Bradford	2.9 (1.5; 0.2-5.8)	3.5(0.7; 2.8-4.6)	2.9 (1.3; 0.2-5.8)	2.3 (1.4; 0.4-6.6)	
London	2.2 (1.3; 0.6-5.8)	3.7 (0.8; 3-5.2)	1.4 (0.9; 0.1-3.8)	1.5 (0.8; 0.2-3.6)	

SD = Standard Deviation; *Assessed by 10 point scale (0 = no harm; 10 = death) (Dean and Barber 1999)

Chapter 5

The Causes of Errors I: Analysis of identified errors

5.1 Introduction

In this section we seek understanding of why the errors we have documented occurred.

In this chapter we investigate the causes of errors and in Chapter 6 we extend this to evaluate the dispensing process and monitored dosage systems in particular. In this introduction, before presenting the methods and results in detail, we give an overview of the theories of human error which were used as the theoretical framework.

When attempting to understand the causes of error both the individual and the system, or context in which the individual works, need to be considered. Reason's organisational accident model²⁸ incorporates both individual and system factors and has been adapted by into a framework specific to healthcare by Vincent et al.²⁹

The actions of the individual are the focus of two general models. These are: Rasmussen's²⁷ Skill - Rule - Knowledge (S-R-K) Model; and Reason's²⁸ generic error-modelling system (GEMS). The Skill-Rule-Knowledge Model distinguishes between three types of actions. Skills refer to automatic, familiar, well-practised actions, e.g. an experienced driver; Rule refers to rehearsed routine patterns that require some conscious thought or effort; and Knowledge refers to new tasks, where there are no existing rules or actions to refer to. This type of action requires a lot of conscious thought and effort, e.g. when first learning to drive a car. Reason extended Rasmussen's Skill, Rule, Knowledge (S-R-K) classification of actions to identify types of errors. Skill-based errors are those where the individual is conducting a task in which he or she is skilled, gets interrupted and then makes an error. Reason refers to these as slips or lapses. The other two types of errors, which Reason labels 'mistakes' refer to planning or problem-solving failures. Rule-based errors refer to the misapplication of a good rule, e.g. prescribing one drug but writing the dose of another, similar type of drug or similar sounding drug. Knowledge-based errors occur in novel situations, with the use of inaccurate or incomplete information and where the person is subject to biases.

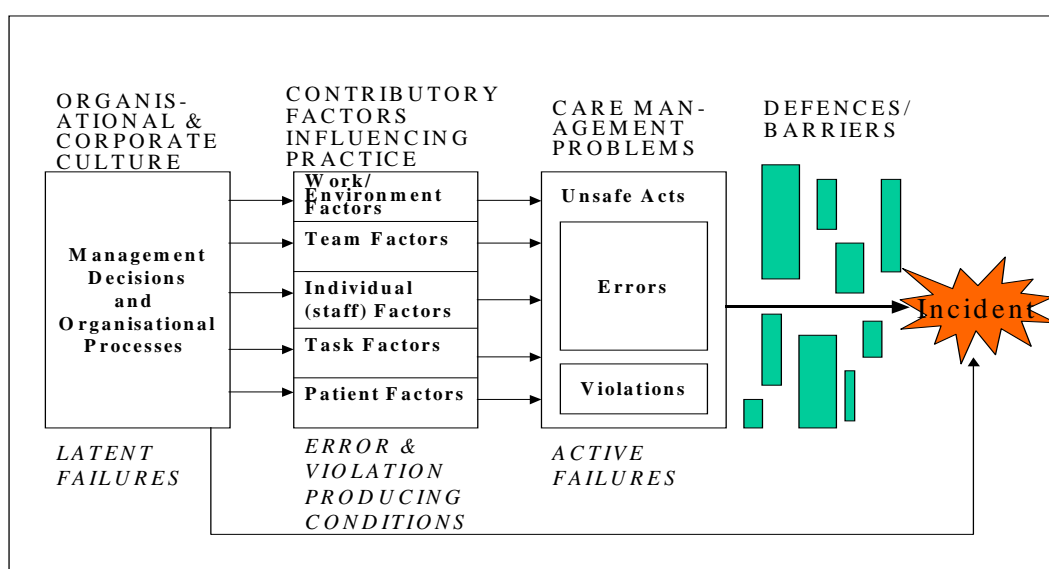
In addition to errors, Reason also distinguishes between different types of violations. Violations are distinguished from errors in that they are done deliberately, i.e. with conscious effort and the individual is aware they are violating a rule or protocol (Reason 1990). Types are: Routine violations, where corners are cut at every opportunity; Optimising violations, where actions are made to further personal rather than strictly task-related goals; and Necessary or situational violations which are acts that seem to offer the only path available to get the job done as rules/procedures are considered inappropriate for the current situation.

System factors are taken into account in Reason's Organisational Accident Model⁷¹ by making a distinction between active failures and latent conditions. Active failures are defined as errors and violations, described above; the 'unsafe acts' carried out by those working directly with patients, e.g. general practitioners, nurses, pharmacists, etc. These actions can have immediate adverse consequences. In contrast, latent failures are systems failures which can lay dormant for a long time, only becoming evident when they combine with other factors to break through the system's defences. These latent failures are committed by those away from the immediate healthcare area, such as designers, high-level decision makers, managers and maintenance personnel. These failures are influenced by various factors which may have economic, political, or practical constraints..

Based on the error theories described above Vincent and colleagues created a framework for the analysis of adverse events and critical incidents in healthcare. This framework includes active failures, error and violation producing conditions, and latent conditions. In particular the framework considers the following factors when assessing the causes and contributory factors of each incident: the patient's characteristics, including their condition; the individual member of staff; the nature of the task itself; the environment in which they work; the healthcare team, including communication and supervision; and the organisational factors that influence the work environment and conditions, such as policy and economic decisions (latent conditions or failures). The framework we use is illustrated in Figure 5.1

Figure 5.1: Adapted Organisational Accident Causation Model incorporating both Reason's and Vincent et al.'s framework for the analysis of critical incidents and adverse events.

(Permission to re-print applied for.)



Both Reason's model and Vincent et al.'s framework have been cited and used in a wide range of specialties and areas including primary care,^{72,73} surgical^{74,75,76} and medical⁷⁷ procedures, radiotherapy⁷⁸ as well as presentation of case analyses, and publications about errors and safety in general (e.g. Graves;⁷⁹ Laing;⁸⁰ Waring⁸¹). There have also been a range of publications about medication related errors and safety issues using these methods including electronic prescribing (Bell et al;⁸² van der Sijs et al⁸³), paediatric medication (Stebbing et al;⁸⁴ Ghaleb et al;⁸⁵ Walsh et al⁸⁶), prescribing for older patients (Cresswell et al⁸⁷), drug-related admissions (Howard et al⁸⁸), analysis of malpractice claims (Rothschild et al⁸⁹), community pharmacy (Szeinbach et al;⁹⁰ Knudsen et al⁹¹) and intravenous issues (Husch et al;⁹² Taxis and Barber⁹³). The framework has been used as a tool for the investigation and analysis of critical incidents and adverse events (Vincent et al⁹⁴) and has been incorporated into a record review methodology (Woloshynowuch et al⁹⁵). As such it can be, and indeed has been, applied to various methods including interviews, observations and reviewing documents.

Reason's model and Vincent's framework are the dominant explanatory models of errors in healthcare. We have experience of using them before to explain medication errors (Dean et

al⁹⁶) and they would appear to be suitable for the data generated, so we had no hesitation in adopting them for this study.

In order to understand and assess the causes of error we need to establish the following: what happened and how it happened, then we can assess why it happened. The question of 'what happened' has been answered in the quantitative section of the report. The question 'how it happened' was addressed using human error theory^{27,28} as described above. Some errors may not be easily classified into one or other error type using this taxonomy by those assessing errors, particularly without knowing exactly what type of action is being executed at the time. This will not only depend on the task, but also the level of experience and expertise of the individual, and the context in which the individuals are working at the time such as the level of interruptions, distractions, etc. The question 'why it happened' was assessed (as far as possible) using Vincent et al.'s²⁹ framework for the analysis of risk and safety in medicine to attempt to identify the immediate conditions that enable the errors to occur as well as the underlying or root causes of error.

5.2 Methods

Information about the causes of errors came from several sources: interviews about specific errors, interviews about past errors and problems in general, observations of administration and dispensing, and field notes.

Interviews: We had originally intended to speak to people about specific errors, soon after the error had happened, as we have done with prescribing errors in hospital.⁹⁵ This was possible for administration errors, which were observed by a researcher, and could be discussed in a sensitive way at the time. In addition to the above in some cases a team leader, deputy manager or manager was also interviewed. However prescribing errors were found in the records and had commonly been made in the past; what is more it was often difficult to get to speak to, and in some cases to identify, the prescribing doctor. Most doctor interviews were therefore about problems with prescribing to care homes in general. Doctors were also hesitant to give face-to-face interviews because of time constraints and many of their interviews were conducted over the telephone.

Observation: Nurses and care assistants were observed while administering medicines and records were made in field notes. In all cases our approach was as naturalistic as possible, given such observation and recording represented implied criticism in a sensitive area. In interviews we let the conversation flow, however the questions were structured according to the analytical framework. Interviews were taped and transcribed when possible, however this was not always the case (25/59 error specific interviews and 20/22 general interviews transcribed) and additionally the researchers made notes which they expanded on after the interview.

Errors were analysed using Reason's framework^{28,70} as described in the Introduction to this chapter. Error producing conditions were divided into patient factors, task factors, individual factors, team factors and work environment factors.²⁹ Latent factors contributing to errors were also identified. Often there was insufficient information to definitively say whether the error was the result of a slip, lapse, mistake or violation. Because we want to show the way in which various factors relate to each other in the formation of errors we have chosen to illustrate our points with case summaries rather than decontextualised quotations.

In all cases interviews were read by several members of the team and the findings discussed at regular group meetings. For the analysis each case was read by two members of the team experienced in qualitative research. Errors were assessed from interviews as well as confirmed using case records and other available documentation such as staff rota or field notes. One member categorised the data and the second read and critiqued the analysis. Together they synthesised the findings reported below. Additional sources of information drawn upon were detailed notes made about the characteristics of each home, and field notes made by the researchers on their visits to the homes.

5.3 Results

59 interviews were conducted relating to 66 administration errors, 34 dispensing errors, 18 prescribing errors and 8 monitoring errors. Further general interviews were carried out: 11 with pharmacists and 11 with GPs.

In the following sections the results are shown in the following order: administration errors, prescribing and monitoring errors, and dispensing errors.

5.3.1 Administration errors

Patient Factors

Some patients in the care homes lacked both knowledge of their medicines and physical independence. Lack of patients' awareness of their own medication was common and could be considered to have contributed to the majority of administration errors (see case 1). In addition, physical difficulties such as arthritis, difficulties in breathing and difficulties swallowing made the administration of medicines and inhalers more difficult, making errors more likely to occur (see case 4). Some patients suffered from dementia or exhibited challenging and aggressive behaviour. Where patients did take a more active role in their medicines this was often based on negative beliefs about medicines, e.g. fears of being poisoned or believing that medicines should not be taken on an empty stomach. Such beliefs contributed to medication not being taken as prescribed. In some cases had the patient's relative acted as an advocate for them we would have expected errors would have been avoided.

Location of patients during the drug round was a further contributing factor. For example, some patients were asleep when the medication was being given and others changed rooms in the middle of a drug round, which caused confusion. Being one of the last patients on the drug round was also an error producing condition in some cases.

Changes to medicines, especially those that occurred in the middle of the monthly medicines ordering cycle and recent admissions to hospital were identified as error producing conditions.

Task Factors

Task factors included factors related to the medicines and devices themselves and lack of use of protocols for administering them. Location of medicines was an identified factor in homes across the UK. Some medicines could not be placed in the MDS system e.g. liquids, sachets or those unstable in the system (see case 1). This contributed to them being omitted.

This was further exacerbated where medicines outside of the MDS system were placed together on the drug trolley rather than in individual patient trays or where medicines had to be kept in the fridge and were therefore not kept on the drug trolley at all. Some medicines outside the MDS were shared between patients in the majority of homes, e.g. bottles of lactulose, in order to save room on the drug trolley and therefore could not be put into individual compartments. In some cases where medicines were omitted, the medicines were in the wrong place e.g. inside the wrong packet or the wrong person's medicine drawer. Where medicines were in a multi dose Nomad system, individual tablets could not be identified so care home staff were unaware if they had given them or not. In other cases the medicine had not been reordered and so was not available to be administered. Errors in ordering occurred in some cases when medicines did not fit into the monthly cycle, e.g. one bottle of 500ml lactulose being insufficient for the whole month, the prescription being a week out due to prescription changes during the month or changes occurring after the monthly order had taken place (see case 2).

Special directions required for medicines contributed to some errors, e.g. medicines which needed to be taken on an empty stomach (see case 3) or those which were not supposed to be dissolved. The former was made difficult as medicines rounds took place during meal times in some homes (see case 3). Inhalers were complex to administer, contributing to errors (see case 4).

Lack of following systematic protocols contributed to errors. In particular the protocol of administering medicines by systematically following the MAR chart was rarely used (see case 2). In some cases the MDS system was not in the same order that the sequence in which the patients were sitting in the room, and this also contributed to omissions. In addition, there was often no system in place to remind the carer if a medicine had not been given in systematic order and needed to be given later.

Other error producing conditions were more specific to particular cases. In one case lack of the necessary equipment to administer medicine contributed to an error. In another a tablet got stuck inside a Nomad system and therefore was omitted.

Individual factors

Lack of knowledge of the member of staff administering the medicines contributed to administration errors in all sites involved in this study (see cases 3 and 4). Specifically, lack of knowledge of inhaler technique was identified in many cases (see case 4). In addition, lack of knowledge of the required timing of medicines in relation to food or other medicines was also noted at all sites (see case 3).

A range of other factors relating to the individuals administering the medication were identified. In some cases carers were inexperienced (see cases 2 and 4), tired (see case 1), unwell or generally stressed. Being at the end of a shift was also an error producing condition identified. Lack of motivation to administer medicines from a MAR sheet, rather than relying on memory contributed to errors in several homes (see case 1). English was not the first language of a carer in one home and she therefore had difficulty in communication. In another home, staff had an individual approach to patient care and altered medicines that are available over the counter to suit the patient e.g. altering the dose of laxatives. This meant that there were technically errors as the dose given deviated from the prescribed medication.

Team factors

The Medication Administration Record (MAR chart) is a form produced by the pharmacy and copies are shared between the home, pharmacy and doctor's surgery. In theory it should serve as an accurate record of all medication being taken as well as communicating any changes in medicines so that the same records are held by all three parties. However, inaccuracies in the MAR charts contributed to administration errors in care homes at all sites. Discontinued items were often left on the MAR chart, making it difficult to use. This was partly caused by care homes not returning the MAR charts to pharmacies, and hence not communicating changes in medication (see case 2). These changes are therefore not reflected in the following month's MAR chart produced by the pharmacy. Even where information was supplied it was not always accurate. This was due to the pharmacy copy being a carbon copy and irrelevant information sometimes came through to the copy in question as a result of pressing on top of the chart of another patient. Where handwritten

changes were made on MAR charts during the month, if these were not communicated to the pharmacy and the GP did not update their own records, they were missed in some cases.

A number of other difficulties occurred with MAR charts. In some cases two MAR charts were produced for the same person and each had different information on. For example, in one case the branded name was written on one MAR chart and the generic name on the other. This contributed to an overdose being given. The MAR chart also differed from the instructions on the label in some cases. In other cases, the MAR chart was unclear.

When care home staff did attempt to use the MAR to look for which medication to administer they tended to administer what has previously been signed for as being administered. Therefore, if a medication was missed once it was likely to continue to be missed.

Other team factors within the home itself also contributed to errors. Lack of supervision meant that problems were allowed to continue (see cases 1, 3 and 4). There was a general culture within homes of relying on verbal rather than written communication (see case 2). Therefore, in some cases staff did not always gain the information they needed. Care home staff were reliant on others to have completed tasks for them to be able to administer medicines accurately. For example, where medication had not been ordered by those responsible, the person responsible for administering it could not do so.

Likewise, if the pharmacy dispensed the wrong product this led to the wrong medication being administered. A more common contributing factor, however, was in the information supplied to the home from the pharmacy. In some cases, pharmacists lacked understanding of the information that care home staff would need and assumed they would have a large amount of knowledge concerning medication. For example, assuming that they would know that alendronate should be given separate from other medication.

Administration errors were linked to prescribing errors in some cases, for example where insufficient quantity was prescribed for the month or where a prescription was omitted. In other cases, they were linked to records at the GP surgery being inaccurate, for example repeat medication not being placed on the repeat list. In yet other cases GPs had agreed to a

change of medication at the home but had not updated their own prescription records, so that where the home had made the change it appeared as an error.

Finally in one case care home staff had not acted on information been given by a patient's relative, perceiving it as unreliable.

Work environment factors

The physical conditions within the work environment contributed to errors. Examples of such conditions included homes being hot and airless, having unpleasant smells, being poorly lit or being noisy (e.g. from television or care home residents moaning).

In addition, there were shortages of space in many care homes (see case 4). There was a lack of space for the drug trolley in some homes. This meant that the drug trolley had to be left in the corridor in some cases and the staff administering the medication had to walk from each patient and back to the trolley to obtain the medication. In other cases, lack of space meant that the drug trolley could not be opened completely. In one home one drug trolley had to be shared between two nurses. A more frequent problem was lack of space on the drug trolley itself resulting in a cluttered trolley where items were hidden from view.

A further error producing condition identified in all areas observed was staffing problems. This was particularly problematic during the morning round. During this round a large number of medicines generally had to be given by few staff (see case 1). In some cases the member of staff administering the medicines was also carrying out other tasks during the round such as washing, dressing, serving breakfast, acting as receptionist, carrying out managerial roles and holding the keys (see case 1). There was pressure to complete the drug round in order to complete other work and to make sure a big enough gap was left before the lunchtime round. Care home staff were constantly interrupted by residents, other care home staff, personnel from outside the care home e.g. delivery drivers and the telephone (see case 1). Care home staff did not always have designated times for ordering medication and had to fit this round their other work (see case 2). In addition staff often worked long shifts in some cases (12 hours).

In one specific home there had recently been a change of management leading to redundancies, resulting in a stressful atmosphere. In addition, there was a shortage of basic equipment such as medicine spoons at this home.

Latent factors

Latent conditions contributed to the error producing conditions described above. In some cases management policy led to difficulties. For example, in one home there was a policy not to give out medication during meal times without accompanying policies to ensure medication could still being given out systematically (see case 1). In the majority of cases, the latent conditions identified indicated lack of adequate policies to support staff. For example, lack of policy to achieve an optimum work environment, lack of development of protocols for systematic administration of medicines. Policy to ensure staff in place and arrangements to cover absentees was also lacking. Although some training for staff was in place, this was not enough to ensure competency in the task of administering medicines (see cases 2, 3 and 4). Refresher training was lacking in some cases. In other cases, training in specific knowledge areas such as administration of inhalers was absent.

In addition, communication problems between care home, pharmacy and the GP surgery were not adequately addressed. For example, where ordering errors had occurred and supplies had run out there was no fall back system in place for obtaining the medication quickly, and on occasion patients went several days without their medication. Supply to homes is based on a monthly basis. Although there were systems in place for dealing with interim prescriptions for acute items needed (e.g. antibiotics), there were inadequate systems for dealing with changes to medicines already being dispensed monthly. Most medication was prescribed/dispensed to be given in the morning which is the busiest time of day in the care home. For medication where time of day administered is not important, there was no arrangement for this to be given at other times of the day.

These conditions were linked to those higher up in the system in some cases. Difficulties in staffing were linked to recruitment difficulties which were ultimately linked to budget constraints (see case 1). Low salaries of nurses employed in care homes compared to NHS institutions and the lack of training opportunities can lead to difficulties in recruiting and

retaining staff. In addition, managers (who were sometimes the only nurse present) were unable to have a hands on approach because of their own administrative workload which needed to be completed.

The MDS systems themselves were latent factors contributing to errors. For example some medicines are not compatible with the MDS system, contributing to omissions. This is discussed further in the section on dispensing below. In addition the common belief that the MDS is a safe medication system may be contributing to behaviour. There is some evidence that people may reduce their vigilance to error if they believe a system to be safe.

The above data came predominantly from staff who had made errors and had the specific circumstances fresh in their mind. This sort of data is generally taken as being richer and more complete than interviews about causes of medication errors in general. However, it is notable that when interviewing GPs about the causes of prescribing and monitoring errors in homes, their general comments corroborated several of the issues raised above. Two GPs brought up another cause of administration errors: that some homes would not use local pharmacies to supply newly prescribed medicines – this could result in a delay of several days before the medicines were available to be administered.

Case 1: Administration Error: Omission of ferrous fumarate syrup

Error Producing Conditions

Patient characteristics

Patient had dementia. Therefore, lack of knowledge concerning medication

Task factors

Liquid medications cannot be packaged in MDS

Difficulty signing the MAR chart during the drug round due to lack of space

MAR chart was generally difficult and time consuming to use.

Individual factors

Lack of motivation of nurse to follow procedures (e.g. following MAR chart). Prefers to rely on memory (this is linked to task factors as established procedures are not effective).

Very tired by end of the drug round.

Team factors

Lack of effective supervision

Un-supported team, particularly attitude of the Area Manager (see latent factors below)

Work environment

Only 1 nurse on duty (apart from deputy manager who did drug round for other floor today – not norm).

Nurse taking on managerial role e.g. has to sort out problems with food.

Lots of interruptions during drug round.

Nurse works 12 hour shifts

All patients have dementia.

Latent Factors

Policy that medicines cannot be given whilst patients are eating breakfast makes it more difficult to administer medicines in a systematic way and at the correct time of day.

Difficulty in recruiting trained staff (possibly linked to financial constraints)

Area Manager has a blame attitude towards errors

Case 2: Administration error: Bendroflumethiazide meant to be discontinued but re-started after 2 weeks (at the beginning of the following month's cycle)

Error Producing Conditions

Patient characteristics

None identified

Task factors

Medication re-ordered before discontinued as medication re-ordered 2 weeks in advance

Individual factors

Lack of experience of nurse who checked in the medication against the previous MAR (been working at this home less than 2 months)

Nurse was not working on the same floor when the change of medication occurred so would not have received verbal handover about this change

Team factors

Previous MAR sheets are not always returned to pharmacy so the pharmacist may not have known it was discontinued. Pharmacy are not confident of the accuracy of information recorded on the part of the MAR sheet returned to them as it is a carbon copy and may have just come through from someone pressing on top of the MAR sheet of the previous patient.

At the home, the culture of communication is reliance on verbal rather than written records (although this change was recorded in care plan, daily communication sheet and GP record sheet).

Work environment

No designated time at home for nurses to check in medication. Long job that needs to be fitted in between other routine work. Interruptions while carrying out checking task.

Latent Factors

Large amount of paperwork may make it impossible to check all records before ordering/administering medication.

Lack of training

Case 3: Administration error: Flucloxacillin and penicillin V given after food instead of on an empty stomach

Error Producing Conditions

Patient characteristics

Patient eats frequently and rarely has an empty stomach

In pain during the evening drug round

Task factors

Evening drug round is during dinner.

All evening medication placed together in Nomad for the evening slot.

Individual factors

Lack of knowledge that flucloxacillin and penicillin V should be given on an empty stomach (taking with food reduces the amount of antibiotic which gets into the system)

Team factors

Lack of supervision to check gave medication at the right time

Lack of tablet id on Nomad

Work environment

None identified

Latent Factors

Although staff receive some medicines training, there is a lack of training about the importance of timing of medications

Case 4: Administration error: Salbutamol and beclometasone administered through the aerochamber incorrectly.

Error Producing Conditions

Patient characteristics

Lack of ability to use aerochamber

Task factors

This is a complex device to use

Individual factors

Lack of knowledge about inhalers and how to use aerochamber

Carer newly initiated to giving medicines

Team factors

Lack of effective supervision to ensure carer competent in the use of inhaler devices (although she was observed doing the drug round until it was felt she was competent to give medicines)

Lack of knowledge of deputy manager in inhaler technique (although she has successfully completed 2 different medication courses and worked in care homes for 17 years).

Pharmacy staff failing to ensuring care home know how to administer inhalers.

Work environment

Lack of space for trolley in dining room means that it needs to be left in the corridor, and so carer needs to go backwards and forwards from the dining room to the trolley.

Latent Factors

Although basic training about medication/ MAR charts given, there is a lack of training in the use of inhalers.

5.3.2 Prescribing and monitoring errors

As it is almost impossible to interview GPs immediately after the occurrence of prescribing and monitoring errors, this section is predominantly based on the analysis of interview data relating to general error producing conditions.

Patient factors

A recurring theme (as it was in the cause of administration errors) was that patients in care homes differed from other primary care patients. GPs identified that patients in homes were generally very ill and had multiple pathologies. They had poor memory and were therefore unable to give relevant information to the doctors (see cases 5-8). One doctor expressed the view that as patients in care homes did not manage their own medicines, it was not possible to prescribe medicines on a when required basis as often as for other patients. In addition, doctors identified that as most were permanently housebound, they had a lack of access to services that would be available to the ambulatory population such as dieticians and specialized chronic disease management nurses in some cases. Doctors did not have full access to diagnostic equipment and most did not have access to records when visiting homes, as opposed to when patients visit the surgery.

Other factors contributing to errors included patients being treated in secondary care (see cases 7 and 8) or having been transferred from another care home (see case 6) (also see team factors). In addition, patients' dislike of medicines or blood tests contributed to some errors (see case 5)

Task factors

Information technology was viewed by GPs as a limitation when prescribing in care homes and this contributed to several errors (see cases 5 and 7). Lack of computer prescribing software terminals at the care homes meant that doctors did not have access to full patient medical records. They had to rely on paper notes kept at the home or a print out of minimal information taken from the surgery. In addition, difficulties were identified with information technology at the surgery. Reminders about monitoring tests that were due and drug allergies came up in a screen with many other reminders and so could be easily

missed. Signing prescriptions was seen as a time consuming and not very productive process.

Individual factors

Individual factors relating to errors were rarely identified but lack of specific knowledge contributed to some errors. An example would be lack of knowledge by a hospital consultant about his specialist area of medication (see case 8).

Team Factors

Management of the care home workload varied between practices. In two research areas an allocated GP serviced the care home and made regular planned visits. Some practices had a rota so that one GP would service the home for sometime (e.g. 3 months, 2 years) and then another would take over the role. In some practices which serviced more than one home, each home was allocated to a separate GP. However, in the majority of Bradford practices visits were only made on request and were treated like any other home visits. Where possible, a GP familiar with the patient would visit but this was not always possible due to workload constraints or another GP already making visits in the same geographical area.

Administration staff at the practice had a large role in care home management. Each practice had one or two prescription clerks who generated all the repeat prescriptions for the doctors to sign. GPs stated that these clerks also had responsibility for updating records from hospital letters and discharge summaries in some cases. One doctor stated that it was therefore their responsibility to highlight monitoring tests that were due and that these were often missed.

Doctors expressed concern that it could take up to 4 months for patient's medical notes to be transferred between practices. Patients often changed practices when they were admitted to care homes resulting in a time lapse before GPs had access to their medical history. This contributed to several prescribing errors (see case 6). The notes came through after patients had had their new patient checks and one doctor was of the opinion that they were never thoroughly reviewed.

GPs discussed staffing issues at care homes which caused difficulties in some cases. Two doctors expressed concern over shortages of staff and one of these also discussed the large turnover of staff; others reported that staff had little expertise or that it was very variable between homes. One GP discussed the difference between care homes where staff were acting in the capacity of a concerned relative and nursing homes where staff had medical training. Another stated that even within nursing homes, the nurses were not as highly qualified as in other settings. A lack of skills specifically stated as problematic included the lack of ability to assess patients to determine whether or not a GP visit was necessary and the lack of training to perform blood tests. Lack of experienced staff was linked to low remuneration by several GPs.

A range of difficulties with consultant letters and discharge summaries were identified from the interview data and interface communication contributed to several errors (see cases 7 and 8). Firstly, the information was not always sent to the GP, e.g. it was sent to the home only or to the wrong GP. When it was sent to the correct GP it was significantly delayed in some cases. Information about the discharge was incomplete in many cases. Specific examples of missing information reported included the reason a medication had been stopped or the follow up action required by the GP. GPs reported querying it in some cases. As it was not possible to query everything an assessment of whether there was an obvious reason for it being stopped was made. These difficulties were not specific to care homes and occurred with all patients.

Some GPs reported that they received no support from the PCT. In contrast other GPs reported they could deploy staff such as district nurses, psychiatric care nurses, community matron and a support practice pharmacist. The London homes no longer had access to a phlebotomist, as the PCT had cut the service.

Two doctors in one research area identified a difficulty where homes did not use local pharmacies, so it could take several days to get interim medication delivered.

Work environment factors

The work environment factor contributing to the largest number of errors was high workload of the GP, including a large number of letters and telephone calls each day (see

cases 5-8). This meant that there was insufficient time to optimally carry out tasks such as medication review and updating records following visits to care homes or hospital communications. In one case, prescribing for a patient the doctor was unfamiliar with contributed to an error.

Latent Factors

A range of organisational issues were identified. First is information and communication. GPs have become accustomed to prescribing with the aid of electronic records and the associated prompts and error checks. These are not available when they prescribe to patients in care homes. Nor does there appear always to be sufficiently functional communication between practices in primary care, nor between hospital doctors and GPs. Second, and related, is the way some GP practices manage, resource, and implicitly prioritise, prescribing. For example whether non-clinical staff who deal with repeat prescribing and other medicines related issues always have the appropriate skills and are appropriately monitored. Finally there is the way in which PCTs provide resources (ie prioritise) for functions that support patients who generally can not leave a home and need extra monitoring.

Case 5: Monitoring error: Haemoglobin test requested following prescription of iron tablets but no blood results were received by the surgery.

Error Producing Conditions

Patient characteristics

Patient unaware of her medicines

Patient sometimes refuses medicines

Task factors

No computer or other type of systematic reminder; reliance on arrival of test results to prompt necessary action; assumption that haemoglobin is normal in absence of results

Individual factors

Doctor's perception that this test would be unimportant in comparison to other blood tests such as potassium.

Team factors

Conflicting written records. Home diary ticked to say bloods have been taken but no record of blood having been taken in patient's daily record sheet.

Refusal of lab to tell home whether or not they have received samples when home contacts them. Therefore home assumes tests normal unless any other information received.

Work environment

Large number of blood tests carried out by the surgery making it impractical to follow up all tests.

Large home making it impractical to follow up all blood tests.

Latent Factors

No alert on the computer system for haemoglobin tests.

Culture is such that the lab do not cooperate when such information is requested

Case 6: Prescribing error: Omission of hydroxycobalamin and folic acid

Error Producing Conditions

Patient characteristics

Patient transferred from another home resulting in a change in GP surgery.

Patient unaware of medication she is currently taking and is slightly confused.

Task factors

GPs only see medical notes if they specifically request them.

Difficult to elicit accurate information from patient. There is no other reliable source of information available at the time.

Individual factors

Admin staff who summarise new patient's medical notes have no medical training.

GP very stressed when took the call from the home regarding the repeat prescription.

Team factors

Delay in obtaining patient's notes from previous surgery. GP surgery has to issue a repeat prescription before the old notes have arrived.

GP recorded an ambiguous message 'review with notes' instead of 'needs a review with notes' The next GP to authorise the medications was a different GP so he could have misinterpreted what the first GP meant. As a result repeat prescriptions were never checked against the medical notes.

Work environment

GP has to answer 10-15 calls in 20 minutes, making it easy to press the wrong button on the computer.

Latent Factors

Lack of time for GPs to adequately deal with phone calls.

System for receiving notes from previous surgery was inadequate.

Lack of resources meant that untrained staff transcribed medical notes

Case 7: Prescribing error: Glimepiride dose not increased as recommended by hospital specialist

Error Producing Conditions

Patient characteristics

Patient lack of knowledge of medication

Patients in care homes are often unaware or do not remember changes to medication and therefore cannot inform doctors themselves.

Task factors

When doctors visit care homes they cannot make computer changes during consultations.

Information from hospital consultants were not available when GP visited the patient in the care home

Individual factors

None identified

Team factors

Consultants' letters are very long, repeating history GP is already aware of. Changes to medication are not highlighted.

Work environment

Doctors' workload: GPs receive 20-40 letters per day

When doctors visit care homes they often have to see 8 patients in an hour so they often do not have time to review medications

Latent factors

Lack of resources: one doctor employed by PCT to manage a few homes who would then have more time to spend with patients and follow up issues

Case 8: Prescribing error: Wrong dose of co-careldopa prescribed.

Error Producing Conditions

Patient characteristics

Lack of knowledge of medication

Patient treated by consultant as well as GP.

Task factors

Large number of different preparations of Sinemet (brand of co-careldopa) available.

The product that the consultant recommended to the GP had been discontinued.

Accepted practice of using brand and generic named prescriptions

Individual factors

Lack of knowledge of consultant and GP that Sinemet LS had been available but had been discontinued.

Team factors

Consultant was unaware that he had recommended a discontinued product.

Consultant recommended medication by brand name.

GP could not find recommended product (Sinemet LS) in British National Formulary and therefore assumed that there had been a dictation error and that the GP had meant Sinemet Plus.

Lack of checking with consultant

Work environment

GPs do not have much time to spend on individual letters and therefore did not read it thoroughly and follow up issues in detail.

Latent Factors

Communication process between consultant and GP.

Discontinued medication dose

Generic and brand names of medications

5.3.3 Dispensing errors

This information was drawn from interviews and observation in the homes and in dispensaries. As with the GPs, we could not interview the person who made each error.

Patient Factors

Patients' medication regimes were not always compatible with the MDS system and this contributed to some errors (see case 11).

Task factors

Information technology contributed to several dispensing errors. Lack of automation of warnings or formulation of medication being placed on the label led to this information being omitted in some cases. For some medication, this lack of automation was linked to warnings not being legally mandatory but only being suggested as counselling in the BNF. A warning system from pharmacists of all potential interactions, both minor and major, was included in software packages, with the same level of alert, and this led to it being more difficult to identify major interactions.

The MDS system also contributed to errors. Only one label could fit on some of the systems. This led to warnings being omitted where they could not all fit onto one label (see case 12). In addition, MDS systems were not easy to use where medication was not taken every day of the month (see case 11).

In addition, the appearance of medication and its packaging were identified as error producing conditions. Products were confused where packaging of different products looked similar. The difficulty of identifying white tablets in an MDS system also contributed to errors (see case 10). Generic medication changed its appearance from month to month, leading to further identification difficulties (see case 9).

The prescription itself was also a contributing factor. Where changes to a prescription had occurred, these were not always actioned where the label was simply printed from the PMR. Medication being prescribed for unlicensed use was an error producing condition in one case.

Filling and checking MDS systems was described as a tedious process. The protocol for filling MDS systems contributed to the type of error which occurred. If MDS systems were filled from the prescription but not the MAR, this contributed to errors of medication being put in the wrong time slot. However, if they were filled from the MAR rather than the prescription, changes which had been missed at the labelling stage would be less likely to be picked up at the filling stage.

Individual factors

A range of individual factors contributing to dispensing errors was identified. In one pharmacy staff experienced low morale and other staff reported feeling hungry, tired and unwell while dispensing the MDS (see case 12). Lack of experience of the dispenser or pharmacist in care home systems also contributed to errors in pharmacies (see case 9). However, the most common lack of knowledge was not with the systems themselves but the level of support that care home staff needed and the motivation to provide this support. One pharmacist expressed the view that she was not responsible for ensuring care home staff administered medication correctly (see case 12). In other cases, pharmacy staff simply assumed that if patients were taking long term medication, care home staff would already know how to administer it or that they would ask if they had any queries. These findings link with those identified when interviewing care home staff, where lack of information from pharmacies contributed to administration errors.

Team Factors

Lack of individual knowledge of the needs of care home staff can be viewed in a wider context of the communication difficulties between the pharmacy and home that were identified from interview data. In some cases, pharmacy staff never visited care homes. Some pharmacy staff also expressed the view that care home staff were uncooperative. Language barriers added to communication problems where English was not the first language of care home staff.

Supervision within the pharmacy team itself was lacking in some cases. For example, dispensing errors were not always identified at the checking stage. When dispensers labelled medication, the pharmacist did not view the patient medication record and

information regarding interactions was not always transferred from dispenser to pharmacist. Information gaps between regular pharmacists and locums also contributed to errors (see case 10).

A range of other team factors contributing to errors were identified. These included discrepancies between records, records not being updated, manufacturing supply problems and lack of communication between the surgery and pharmacy.

Work environment

The work environment in the pharmacies was described as being busy and pressured, sometimes due to staff shortages. Staff reported experiencing constant distractions and interruptions. In one pharmacy there was no counter assistant which led to dispensers having to interrupt their work to serve customers. The dispensary was very noisy in some cases due to the phone and fax machine. In one pharmacy, only a small space was available for dispensing and checking.

Latent Factors

Company policy contributed to errors e.g. lack of training policy, policy dictating which brands to dispense and staffing issues. Wider policies were also identified as error producing conditions. For example, the large amount of paperwork which legally needed to be completed led to it being difficult to check it all accurately and generic prescribing has been encouraged without uniform shapes and colour of generics being developed. Characteristics of information technology systems and MDS systems were also identified in the analysis as contributing to errors. Dispensing had in some cases become an industrialised act, separated from the patient and their needs, and the patient's surroundings and the carers needs. Re-dispensing into MDS being an unfunded activity. MDS being wanted by homes.

Case 9: Dispensing error: Ramipril capsule described on Nomad label as yellow but green and white capsules are dispensed. The product is correct but, because another brand has been used, the description is incorrect.

Error Producing Conditions

Patient characteristics

None identified

Task factors

Different brand dispensed so looks different.

Individual factors

Pharmacist very inexperienced with care homes.

Team factors

Locum pharmacist is the most senior member of staff present and he has had little experience of care homes. There is no evidence that he has sought or been offered help from a manager or had any orientation training.

Work environment

Busy

Regular pharmacist on maternity leave. Very hectic work environment due to inexperienced staff.

Latent Factors

No standard shape, size and colour for drugs.

No evidence of training for locums unfamiliar with homes/ MAR chart system.

Case 10: Dispensing error: Aspirin e/c 75mg dispensed instead of zopiclone 7.5mg. Home informed pharmacy but mistake was not rectified.

Error Producing Conditions

Patient characteristics

None identified

Task factors

Tablets look very similar (both white and oblong) making it difficult to check

Packaging similar –same company

Individual factors

Tired as last patient of the day and repetitive task

Team factors

Lack of transfer of information about the error between pharmacist and locum who would be covering.

Work environment

Busy day, constant interruptions, had to keep stopping to serve customers

Small space for dispensing and checking,

No quiet space.

The day the pharmacist was informed of the error was her last day before going on holiday.

Latent Factors

Design of system makes it very difficult to check similar looking tablets in blisters.

Different tablets in similar packaging

No designated staff member for shop means the staff cannot focus on dispensing only.

There was only one area for dispensing.

Case 11: Dispensing error: Extra dose of furosemide dispensed
Error Producing Conditions

Patient characteristics

Furosemide prescribed on alternate days

Task factors

Difficult to pack on alternative days in MDS blister.

Individual factors

Not known

Team factors

Pharmacy do not know which days it is being taken.

Packing the blister is the last stage so has less checking than the other stages(labelling and selecting medication)

Work environment

Not known

Latent Factors

The MDS system is designed to be used for medicines taken every day.

The culture of checking is focussed on the earlier stages of the preparing and dispensing process

Case 12: Dispensing error: Missing warning labels on aspirin e/c.
Error Producing Conditions

Patient characteristics

None identified

Task factors

Cannot fit all warnings on one dispensing label and so some are printed onto a second label.

The MDS system only has room for one label

Individual factors

Pharmacist's assumption that if patients are on medication long term the home would not need reminding of the warnings.

Low morale

Feeling tired/hungry/unwell

Team factors

Management did not show appropriate level of concern

The team assumption was the same as the pharmacists

Work environment

Very busy pharmacy- short staffed

Do not take full break entitlement due to high workload

Pressure from others to get the work done quickly

Noisy due to fax and phone

Constant distractions and interruptions

Latent factors

Computer labelling system and MDS do not allow all warnings to fit on.

Short staffed due to staff off sick with stress in company as a whole. Personnel issues

Pharmacy manager not on site and generally not "hands on"

5.4 Summary

The purpose of this chapter is to provide understanding behind the data presented in the previous, quantitative chapter. We will draw the whole together in the final Discussion of this report. In this section our aim is simply to draw out some of the most significant findings from the qualitative work. We should add that these are some of the major themes reported and observed, however they are not definitively causal. For example it is common for someone at the end of their shift to feel tired. If they make an error they may report that they were tired and that this might have been a contributory factor, whereas in reality it was unrelated to the error.

5.4.1 *Administration errors*

When we followed up administration errors these are the factors which were raised at least some of the time. The patients have a high level of dependency which adds to the complexity of them receiving medicines, they may be very ill, immobile, demented and on a large number of medicines. Nor should we under estimate the role of medicines, which are heavily systematised and often need to be given with a high degree of precision. Here we see an interaction between the skill, training and management of staff and their failure to order or store medicines, to give medicines by the right technique (particularly inhalers), at the right time in relation to food; and their failure to follow the appropriate procedures. The MDS systems used in many homes also contributed. Some staff felt tired or unwell. Certainly the homes could be a challenging environment in which to work, and large medicines trolleys and often cluttered spaces contributed to error. Staff were often interrupted and, particularly on the morning round, there were often too many calls on staff (or too few staff). Finally, there were often communication problems. The Medication Administration Record (MAR) chart, a key communication between the home, pharmacy and GP, was often inaccurate and failed to communicate the correct information. There were also problems within homes; where there was a dependence on verbal communication; pharmacies and GP surgeries also contributed by not communicating accurate or sufficiently helpful information.

Latent factors included medicines not being given sufficient priority on occasions, the lack of policies and training, which at least partly reflected the difficulty in recruiting to these posts, the MDS and the rigidity of its monthly supply system, prescribing of drugs for administration in the morning, and the lack of adequate three way communication between the home, the pharmacist and the GP. Finally, there was a lack of ownership of the whole system by which medicines are prescribed, ordered, dispensed and administered. People managed their own part of the system without taking a whole systems view.

5.4.2 Prescribing and monitoring errors

Several of the issues raised during the study of administration errors were again raised by GPs with respect to prescribing and monitoring errors. The characteristics of the patients again contribute; they are often very ill, with multiple pathologies and associated therapies. Their immobility means they can not visit the surgery with its associated IT, measurement equipment, and associated services.

Several factors contributed to monitoring errors: poorly designed computer prompts, support staff in the practice not noticing prompts, staff in the homes not trained to take blood, and the lack of a local phlebotomist service. Another area of similarity was that there were concerns about staffing in some of the homes. These include staff shortages, rapid staff turnover, poor knowledge of some staff, some poorly skilled nurses, including their inability to decide whether a GP visit was required or to take blood. Poor remuneration was viewed by several GPs as the cause of these problems.

Other factors identified by GPs included poor communication: between GP practices, and from secondary care following patient discharge from hospital. The lack of the usual computerised prescribing system (with its comprehensive medical record and error trapping prescribing software), coupled with patients being poor historians, made prescribing more error prone. Management arrangements between the GP practice and home affected familiarity with the home and its patients, poor familiarity being more likely to produce errors. Lack of other services could also be linked to errors, such as lack of PCT services such as district nurses and psychiatric care nurses. Finally, GPs quoted their high workload, high volume of communication and lack of time as factors

5.4.3 Dispensing errors

While there were the usual staff issues (training, morale, tiredness etc) that can contribute to any error, many of the issues that emerged were related to MDS. For this reason we decided to study MDS further, and this is described in the next chapter.

Chapter 6

Causes of Errors - the dispensing process

6.1 Introduction

Most medicines for care homes are dispensed in monitored dosage systems (MDS), which package doses into individual spaces. This is generally dealt with in a mass assembly process.

Initially, we had assumed MDS was an evidence-based safe technology. After the first stages of analysis it became clear that we should not take for granted that the MDS is a good system and we decided to investigate it more deeply.

In order to gain a deeper knowledge of the dispensing process, in depth interviews were carried out with eight pharmacies in one location in the country and observation of dispensing processes were carried out in five of these pharmacies.

While we had investigated individual errors using Reason's framework (see chapter 5), we also wanted to study the technology in more depth and so chose to also adopt a different approach. Because MDS is a technology we used a technology evaluation framework, that of Cornford et al,³⁰ previously used successfully for a related area: the evaluation of an electronic prescribing, dispensing and administration checking system in hospitals.⁹⁷

Our approach to the evaluation of dispensing was informed by the socio-technical perspective which considers information systems as social and technical systems, and technology's characteristics and capabilities as being revealed through use.⁹⁸ This approach is reflected in the evaluation framework of Cornford et al³⁰ which we chose for this study (Figure 6.1), similar to that later proposed by the UK Department of Health to evaluate information technology.⁹⁹ The framework is structured as a matrix with Donabedian's model^{100,101} for evaluating quality of care (structure, process and outcome) as one dimension, and system functions, human perspectives, and organizational context as the other. The last three factors map onto Reason's framework – those of the functioning of the system, the users' perspectives and the organisational (Latent failure) perspective.

	System Functions	Human Perspectives	Organizational Context
Structure	Technical detail	Changed work conditions and implied requirements	Sustainability, opportunity costs, management needs, skill requirements
Process	Information processing; correct and valid	Human participation in tasks; social interaction	Altered delivery and practice
Outcome	Relevant, applicable, reliable	Quality of service, and outcomes	Effect in the world

Figure 6.1: Evaluation Framework. (Based on Cornford *et al.* 1994, fig. 3, page 499)

6.2 System

6.2.1 Structure

A variety of different software packages were used for dispensing medication to care homes in this study. Features which pharmacists identified as helpful included facilities to include allergies and warn the user if the patient was allergic to medication that was prescribed, information on how much of an item was dispensed in a monthly period and a reminder that prescriptions were due in from the home. Three pharmacies had recently changed systems to allow for the introduction of electronic transfer of prescriptions. Difficulties with the new system identified by pharmacists included problems in transfer of data from the old system, the tedious nature of making changes to patient medication records (PMR), lack of flexibility to include timing on MAR charts for medicines taken outside routine times e.g. four to five times a day and not automatically putting the correct time on MAR chart e.g. morning if labelled as one in the morning. However, one pharmacist had taken advantage of the new system to setup a direct link to the medical practice and was able to access patients' full medical records.

A range of different systems were used to pack medication including Boots MDS, Manrex, MTS Venalink, Medisure and non MDS packing. Four of the eight pharmacies used more than one system depending on the home or patient. The main differences between different MDS systems included whether they were single or multi dose, whether they were weekly or monthly and whether they were cold or heat sealed. Pharmacists using different systems identified the advantage that all tablets could be identified in single dose systems. Disadvantages included their bulky nature resulting in them taking up a lot of space and the time consuming process for pharmacy staff of popping out all the different tablets.

MDS dispensing facilities ranged from a large separate MDS dispensing room with five workstations to a dispenser dispensing on top of a pile of stacking boxes at the back of the main dispensary. Two of the MDS dispensaries had no windows and therefore only artificial light. There was generally good temperature control although a member of staff complained of feeling cold in one pharmacy. In another pharmacy, a radio was on in the dispensary.

6.2.2 Process

Many types of medication were not compatible with the MDS system. External items, liquids, reconstitutable sachets and large tablets such as Calcichew were not packed in the system by any pharmacists. In addition, medication which was unstable to light or heat or water was not packed in the MDS by the majority of pharmacies. An exception was that medication not stable to heat could be packed in cold seal systems. In addition, one pharmacist packed sodium valproate, which is hygroscopic, in the MDS as she believed little of the dose would be lost during the course of the month and that this is a lesser risk than if it was not packed within the MDS, in which case they thought it would be likely to be forgotten altogether. Medication which was not taken the same way everyday of the month, or where dosage varied during the month, was often packed outside the system. This included short courses of antibiotics, reducing dosage of steroids, weekly medication where the day of the week being taken was not known and warfarin (see case 11 for example of dispensing error) when attempted to pack within the MDS. Interim medications (or 'interims') were packed outside the system in many cases, usually as a normally dispensed item.

Other equipment was also not fully compatible with medication. It was difficult to split generic tablets with tablet splitters (when 'half a tablet' was prescribed, or a dose prescribed that could not be given as a whole tablet), with the two halves rarely being equal. One pharmacist reported that devices were available for popping tablets out of blisters but that these were cumbersome and were difficult to align with different sizes of blister. They were not used by any of the pharmacies observed. The same pharmacist also reported that he did not use gloves as tablets stuck to the latex. This appeared to be common practice, as gloves were observed to be used by only two personnel in total.

Other technical difficulties included the printer becoming unaligned (printing in the wrong position) when printing out MAR sheets and labels sticking to reminder cards making them 'gunky'.

6.2.3 Outcome

A Nomad is a multidose cold seal MDS system (described in the Introduction to the report). Identification is placed on the label (e.g. 'pink round tablet') in order to allow identification of individual tablets within the Nomad. One pharmacist stated that the identity on the Nomads was often inaccurate (also see case 9, Chapter 5) resulting from there being no standard shape and colour of a tablet and generics constantly changing. In some pharmacies, care was taken to ensure only one type of generic medication was used in each blister.

A large number of tablets were discarded after attempts to split them resulting in unequal halves.

Variation in MAR charts sent out to home was observed. In three pharmacies only medication supplied that month was printed on the MAR chart, whereas in three others all medication on the PMR was included on the MAR with a note, 'not supplied this month' when not supplied. There was also variation in whether all medication was placed on one MAR chart or there were separate charts for different items e.g. one for regular medication and one for medication to be taken only when needed. Medication on the MAR chart was in alphabetical order in most pharmacies. Allergies were printed on if they were known to the pharmacy. In one pharmacy 'dispensed in separate box' was printed on the MAR for

items dispensed outside the MDS. However, this could not be highlighted due to the absence of a colour printer. In another pharmacy it was observed that the MAR chart had faint print which was smudged in places. In the same pharmacy the MAR charts were sent in one continuous roll for the care home staff to separate. In a third pharmacy, the pharmacist said that the printer sometimes printed out two identical MAR charts resulting in 2 two being sent to the home.

Medication was sent out in blue bags or white boxes which included MDS, bulk medication and MAR charts. In one pharmacy the bags of fridge items were separately labelled as fridge lines. In two pharmacies patient information leaflets were also sent.

6.3 Human participants

6.3.1 Structure

The number of personnel involved with MDS ranged from one pharmacist and non qualified dispenser to a full unit with eight dispensers, including two accredited checkers and several delivery drivers. In units with several dispensers, they each had distinct roles, e.g. one was a key contact for the homes, another was in charge of all interims. Pharmacists' input varied. Generally the larger the unit and the more staff, the less pharmacists were involved in the day to day dispensing to homes. In two pharmacies dispensers dispensed without the presence of a pharmacist in the room.

Pharmacists had completed continuing education training packages relating to homes. Two pharmacists were also supplementary prescribers. Where dispensers were qualified, they had NVQ training. However, this did not include training on MDS, which was learnt 'on the job.' The accredited checkers had to precheck 1,000 consecutive items without missing any errors before being allowed to gain their accreditation. One checker was also a qualified pharmacist in another country. A health and safety training session was taking place on the day of the researcher's visit at one pharmacy.

Pharmacists expressed a range of views about MDS with some stating that they made it easier for care home staff to administer medication safely and systematically while others expressed more negative opinions. Two pharmacists were of the view that MDS were not safe as tablets could not be identified. One also said that when a tablet was dropped the

staff would not have a replacement. Another said that MDS encouraged staff not to look at the label. These pharmacists did not use the MDS and were generally negative about dispensing for the homes, with one stating that it was “not worth the aggravation”.

6.3.2 Process

Communication between pharmacy and surgery

Analysis of interview data showed that relationships between GPs and pharmacists were variable. The amount of contact between them varied. In some cases, GPs were the first point of contact if there were queries with prescriptions, although more commonly it would be the home who would be contacted first. One pharmacist said it was difficult to access the GP as he was very busy and she had not spoken to him for two months. Another pharmacist said that where there were several GPs at a practice involved with the home it was difficult to build a continuous relationship. In contrast, one pharmacist reported always trying to combine a visit to the home with a visit to the surgery.

Pharmacists’ input into GPs’ prescribing decisions also varied. One pharmacist reported carrying out medication reviews with GPs and going on ‘ward rounds’ at the homes. Another had a direct link to the surgery and carried out sessional work there. A third said that once you had a ‘foot in the door’ and demonstrated what pharmacists could do, it was easier the next time. However, some pharmacists were also of the view that some doctors did not want to work with pharmacists.

Pharmacists reported a range of difficulties that arose with prescriptions. Three pharmacists had difficulty obtaining a 28 day prescription from some doctors in order to fit in with the monthly cycle. One pharmacist said that doctors did not like to prescribe in advance in case changes occurred but that meant insufficient time to dispense the medicines for the start date of the next cycle. The same pharmacist also reported that doctors did not like to prescribe liquids, or branded tablets that were easier to split, as they were more expensive. Yet another pharmacist said that doctors sometimes prescribed half a tablet of a controlled release preparation. This is an error as these tablets have a complex structure so they release the medicine in a controlled way – this benefit is lost (and is potentially dangerous) if the tablets are split. Pharmacists also reported that mistakes occurred on

repeat prescriptions. They thought these were caused firstly by doctors not updating their records when prescriptions were handwritten at the homes and secondly when interruptions occurred when prescription clerks were issuing prescriptions.

Primary/secondary interface

Discharge information from a hospital was used to inform homes of changes that they should make when administering medication and to check that GPs had updated patients' prescriptions for the next cycle.

Receipt of discharge information varied between pharmacists and hospitals. One pharmacist had been proactive in phoning all hospitals that discharged patients to care home to ask them to fax discharge information to him. He therefore received discharge information before GPs and then sent it to them. Where discharge information was not received from the hospitals, it was sometimes received from the homes. One pharmacist requested it from the homes when large changes had been made to the medication and he suspected that they had probably had an admission to hospital.

Discharge information was reported as being often unclear by one pharmacist, who contacted the doctor/ hospital to clarify information.

One pharmacist stated that on some occasions when patients were admitted the hospital rang him to confirm what medication was being taken.

Communication between pharmacy and home

Communication between pharmacy and homes varied. One pharmacist reported that at some homes a continuous relationship was built with a key contact person at the home. However, at other homes staff turnover was high resulting in a lack of continuity. There was a range of experiences reported regarding the return of MAR sheets, indicating changes to patient's medication, from homes.

It became apparent from the analysis that the pharmacy communicated with the home concerning a range of medication related issues. During the repeat dispensing process, pharmacists reported that they telephoned homes when prescriptions had not arrived at the

pharmacy when expected or if there were queries on prescriptions. The home was often the first point of contact for queries. One pharmacist explained that the home had more up to date information if handwritten changes had been made during GP visits. Another pharmacist reported that dealing with queries was a time consuming process. Pharmacy staff reported that homes contacted the pharmacy if there were any queries once the medication had been received and checked in. Homes also contacted pharmacists to request equipment or to inform them of a new resident admission to the home. Occasionally homes asked for clinical information such as side effects. Where the key contact at the pharmacy was a dispenser they would refer clinical queries to the pharmacist if they were unsure of the answer.

A number of difficulties were reported to occur when communicating with homes. These included lack of understanding of the dispensing process, lack of transfer of all information, lack of trained staff at the homes with fluent English and loss of motivation of staff due to the work environment, tedious nature of the job and lack of interaction with new people. One pharmacist reported that the care home had recently been required by their management to photocopy all prescriptions and expected the pharmacy to assist with that.

Communication in relation to interims was carried out by fax in the majority of homes. One pharmacist explained that he did not take instructions verbally, in case there was a mistake. Another stated that he would only change directions if there was written evidence. The pharmacist with the direct link to the GP records did not need to rely on faxes. If the home told him antibiotics had been prescribed he could check the prescription by accessing the patient record.

Some difficulties were reported with interim prescriptions. One pharmacist said that homes requesting bulk items as interims rather than monthlies was annoying because these requests resulted in these items not being able to be dispensed as part of the planned routine. Another pharmacist was of the view that homes run out of 'PRNs' (medicines to be given as the patient needed them for specific symptoms, ie not a regular dose and hence an easily calculable number) too often and were probably giving them as repeat medication. Yet another pharmacist reported that different floors of one home faxed through their requests at different times of the day, resulting in multiple journeys for the delivery driver.

During a research visit to one pharmacy, the home informed the pharmacist that an interim prescription that they needed that day was at the GP surgery. However, the home gave the pharmacy out of date GP details and the pharmacist was then unsure who the patient's GP was.

Use of computer system to generate labels and MARs

The process of generating labels and MAR charts was observed in five pharmacies. In the remaining three pharmacies observation was not possible and data were collected by interview.

In four pharmacies labels and MAR charts were generated by dispensers and in four they were generated by pharmacists. One pharmacist explained that she liked to produce the labels herself as she then had complete control over the process. In pharmacies where the dispenser labelled the pharmacist did not view the PMR. In one pharmacy, the dispenser who printed out labels of all interactions identified by the computer software and attached them to the prescription for the pharmacist to access when checking.

Resources used when generating labels and MAR charts included prescriptions, patient medication records, and MAR charts returned from homes in the majority of pharmacies. In one pharmacy faxed interim sheets of changes made during the month were also referred to. In two pharmacies the British National Formulary (BNF) was referred to occasionally. In the pharmacy with the direct link to the GP surgery, the surgery's electronic medical records were accessed. In this pharmacy, the pharmacist reported that he generated 6 months supply of prescriptions which he asked the doctor to sign. Then every month he checked to ensure that there had been no changes before dispensing.

In six pharmacies labelling was done as a bulk process for all patients in each home. However, in one pharmacy labels were generated for one patient at a time, with the next patient's labels only being generated after the previous patient's medicines had been dispensed. The pharmacist perceived that this minimised the risk of a blister being filed with the medication for the wrong patient.

MAR charts were printed off at the same time as labels in five pharmacies. Other pharmacies printed them after all dispensing had been completed. In one pharmacy the dispenser came in early in the morning to print off the MAR chart before the shop opened. As there was only one computer and printer, no prescriptions could be dispensed whilst the MAR charts were printed. In two pharmacies the printing process was not straight forward as it took several attempts to line up the MAR chart correctly for printing.

Dispensing of MDS

As with labelling, observation took place in five pharmacies using MDS systems.

In six pharmacies there was a fixed routine for the dispensing of MDS. However, in two pharmacies, the pharmacist fitted in the MDS around his other work when the shop was quiet, doing a large amount at weekends. In four out of the five pharmacies where observation took place, there were a number of interruptions during the dispensing process, from walk in customers, telephone, other staff etc .

The personnel involved in the dispensing process varied between pharmacies. In two pharmacies the pharmacist carried out the whole process, where as in four others the dispensers were the only people involved. In two pharmacies the pharmacist selected the medication and the dispensers filled the blisters.

The information sources used for dispensing varied, with two pharmacies dispensing from the prescriptions, and three from the labels. MAR charts were referred to by dispensers in one pharmacy.

A range of procedures were used for selecting medication. In four pharmacies the medication was selected for the entire home before blisters were filled. In one pharmacy medication was selected for one patient at a time and in another medication was selected one item at a time, dispensed and put away before the next medication was taken out. The pharmacist in the last pharmacy argued that that this procedure minimised the risk of the wrong medication being placed in the blister.

The next stage of the dispensing process was filling the blisters. In the majority of cases medication had to be removed from another blister before being packed in the MDS. In

some pharmacies the medication was popped out directly into the MDS blister and then readjusted to ensure the correct number of tablets were in each slot. In other pharmacies, the tablets were popped out into the dispenser's hand and then put into one blister compartment at a time. Errors were observed to occur during this process with some compartments being missed or containing the wrong number of tablets. These were corrected by the dispenser as they did a final check that the blister was filled correctly before sealing. In one pharmacy, blisters were sometimes cut with scissors to make it easier to pop out the tablets. In another pharmacy the correct quantity was sometimes counted before filling the blisters, so if one tablet was left, the pharmacist knew there must be an empty compartment. Where tablets needed to be split, these were split with tablet splitters in two pharmacies and by hand in two others.

After the blisters had been filled, those that required heat sealing were sealed at this stage. Foil was placed on the blister before sealing. In three pharmacies the foil was folded and then unfolded to prevent it from curling up. In some cases, errors were noticed by dispensers after sealing. If the whole blister was wrong e.g. dihydrocodeine instead of codeine dispensed, the whole blister was redone. However, if only one compartment was wrong the foil was torn and then replaced with another small piece of foil and resealed. After heat sealing labels were stuck on the blisters.

In four pharmacies "prepacks" were used for items frequently dispensed instead of individually filling a blister each time. These are blisters pre-filled in a batch in the dispensary and kept in stock

The final stage in the dispensing process for blisters was to file the blisters in the correct coloured sleeve (according to administration time) and rack them in files (placing the blisters on a metal ring binder). In two pharmacies, the empty blister from the previous month was removed from the sleeve on the file and the new one put in. In another, the sleeves from the previous month were completely unpacked and repacked again. Blisters were racked onto separate files for morning, afternoon, evening and night time administration. In one pharmacy the pharmacist reported that medication which needed to be taken at a separate time to other medication was sometimes packed in a separate sleeve to emphasise this. The order of patients in the file was arranged according to the home's

requirements e.g. alphabetical order, room number order or order patients sat in the dining room. In some cases the filing did not take place immediately after dispensing e.g. in one pharmacy there was a shortage of space as blisters needed a lot more space when filed. In cases where blisters were prepared but not packed straight away a rubber band was placed around each patient's blisters.

Checking of MDS

When a dispenser rather than a pharmacist dispensed the medication, it was then checked by an accredited checker or a pharmacist. The pharmacist who dispensed some Nomads, said that he always filled these himself as it was impossible to check after someone else had dispensed it. Medication was checked solely by a pharmacist in four cases but in one case a clinical check of the prescription's appropriateness was carried out by the pharmacist after which an accredited technician checked the dispensed product (a similar procedure to that used in most hospital dispensaries). The accredited technician did not check interims. These were checked by the pharmacist. The checking process was carried out at different stages at different pharmacies. In two pharmacies checking occurred before blisters were racked and in three after blisters were racked. In two checking occurred before the printing of the MAR sheets and in two checking occurred after printing.

The checking process involved first checking the label and then the blister. In two pharmacies the checker held a pen and ran it across the blister to ensure all compartments were filled correctly. Blisters were turned over during the checking process to ensure they were correctly sealed. The identification of tablets in the blister was checked in different ways in different pharmacies. In one pharmacy it was checked against the original packs and in two others the dispenser had cut off information relating to the medication identity from the original pack and clipped it to the blister. In these pharmacies if the tablets were dispensed from a bulk pot, the dispenser showed the pot to another dispenser at the time of dispensing and this was not checked again at the final check. Items outside the MDS system were also checked. Liquids were smelt to confirm identity. In two pharmacies the prescription was also checked against the MAR chart: a pen was run across the MAR sheet with one hand and a finger run across the prescription with the other hand. In the pharmacy where a pharmacist carried out a clinical check, this involved "eyeballing" the

prescription and signing it. No reference was made to any other resources, such as the PMR. The accredited technician reported that she had identified clinical problems with prescriptions after the clinical check had occurred on some occasions.

Errors which were observed to be identified by checkers during research visits included wrong dose and filing for the wrong patient. When asked about errors commonly found when checking, checkers included wrong dosage, wrong coloured sleeve and labelling errors. Errors relating to the wrong product being dispensed were described as rare, although the accredited technician said that it was common for the wrong formulation of a product to be dispensed e.g. tablets instead of capsules. She said that labelling errors often occurred when changes had been made to the prescription but the old instructions from the PMR were printed.

During the checking process interruptions occurred, for example a telephone ringing or liaison with a delivery driver.

6.3.3 Outcome

Relationships with homes were described as good by the majority of pharmacists.

The MDS dispensing process was reported to be much more time consuming than other dispensing. One pharmacist stated that it took 3-4 times as long. The pharmacist who dispensed both Nomads and blisters said that the blisters were more time consuming and described it as a tedious cumbersome process. However, two pharmacists reported that although dispensing was more time consuming it was also more predictable than 'walk in' dispensing, as it was largely a repeat dispensing process, with interims being the only unpredictable part, therefore staffing levels could be planned. A range of views, some contrasting, regarding MDS dispensing were identified from interview data. For example one pharmacist said MDS dispensing gave little satisfaction whereas another said it aided staff development because of the different products seen.

6.4 Organisation

6.4.1 Structure

The number of homes to which pharmacies dispensed and the proportion of business generated from homes varied. For example, two pharmacies dispensed to one home each, whereas one dispensed to 76 homes. Homes were perceived as building up volume of prescriptions and therefore revenue and good will. However, the view was also expressed that it was easy to lose homes to large multiples. One pharmacist had agreed a one month notice contract with the homes.

When asked about payment, no pharmacists reported being reimbursed for providing medication in MDS. However, one had arranged to get weekly rather than monthly prescriptions in order to increase the number of items and therefore number of dispensing fees they were paid. Pharmacists were reimbursed for providing 6 monthly visits to homes in some cases. This contract included, giving advice about administration and storage of medicines and clinical governance procedures. Pharmacists were not reimbursed for carrying out medication reviews.

6.4.2 Process

Standard operating procedures were in place in pharmacies for dispensing to homes.

It became apparent from analysis of interview data, that pharmacists had a neutral to negative opinion of CSCI inspectors. Six had little contact with inspectors. Two pharmacists were of the view that inspectors had a fault finding approach and one of them expressed the opinion that it would better if inspectors helped homes to develop safer systems. He said that he would like to be present at the inspection and aid in this process. Pharmacists reported becoming involved when homes wanted to ensure they had all the correct paperwork in place for the inspection. One pharmacist said that helping homes to work with points identified on the report was good for relationship building. Inspectors contacted the pharmacies when problems were identified. These included having handwritten changes on MAR charts, putting medication on MAR charts which was not supplied that month and putting hygroscopic tablets within the MDS system. One pharmacist expressed concern over litigation as everything was documented even when

pharmacists did not have control over decision-making. Advice from inspectors was reported as being inconsistent from different inspectors and for different homes.

6.4.3 Outcome

A range of medicines and clinical services were reported by pharmacists as being provided to homes. The majority of pharmacists were of the view that they would try to meet all home requirements in order to retain business, whereas others were of the opinion that if the home wanted the service they had to meet the pharmacist's terms and conditions. Six of the pharmacies we visited offered MDS dispensing but two did not. All but one pharmacy delivered the medication to the homes. The number of interims dispensed was variable between homes. One pharmacy supplied most interims to the homes to which they supplied monthly medication. They ensured they got the trade by offering same day delivery provided the prescription was faxed to them before 10am.

Clinical services provided were variable between pharmacies. Six pharmacies provided training to care home staff on MDS and disease management. One pharmacist stated that he provided pharmaceutical care and addressed compliance issues. Three carried out some medication reviews or visited homes with the doctors and participated in 'ward rounds.' However, pharmacists also expressed the view that their skills were under utilised, that they could visit homes more often and could carry out detailed reviews for more patients. Pharmacists identified barriers to extending their role including lack of remuneration (including for locum cover) and communication problems.

6.5 Discussion

The dispensing process to care homes varied between pharmacies, in terms of the physical structure of the dispensary, the technology used (MDS and IT systems), dispensing procedures, volume of MDS dispensing and PCT contracts.

The MDS system was perceived as having advantages by some pharmacists. These included benefits to the homes, due to ease of administration of medicines. The predictable nature of dispensing to care homes was cited as an advantage to pharmacies, although this is not necessarily directly linked to the medication being dispensed in MDS.

However, many disadvantages of the MDS were also identified. Increased costs and reduced profitability of dispensing medication into MDS have been identified in previous studies.^{43,102} The time consuming nature of MDS dispensing and lack of remuneration were also raised pharmacists by participating in the current study. Previous research has also highlighted the lack of information available regarding stability of medication in MDS systems.¹⁰³ The current study found that pharmacists had to balance this limited information with the risk of medication being omitted completely – already the most frequent form of administration error. Variation in practice was observed. The study also demonstrated that it was not only the medication itself which may be incompatible but also the medication regime. MDS were most suitable for medicines which were taken every day of the month. More complex regimes, such as reducing doses of steroids, were perceived as very difficult to dispense in an MDS and were dispensed outside of it in most cases. It appears that MDS are not compatible for the more complex regimes, where it would be assumed they would be of most benefit. Difficulties of tablet identification were also identified, particularly within multidose systems.

Difficulties were also identified with other aspects of technology such as IT as well as with interrelationships between pharmacies, care homes, surgeries and CSCI inspectors. Relationships between pharmacies and CSCI inspectors were weak. There is potential for these relationships to be strengthened so that inspectors can work with pharmacists for patient benefit. In the cases of relationships between pharmacies and care homes and surgeries both strong and weak examples were seen. The extent to which pharmacies were prepared to accommodate the wishes of the care home was to some extent linked to the perception of the importance of maintaining the contract with the care home to the overall business. In some cases, good relationships were built where pharmacists neither dispensed in MDS systems nor delivered to the homes. The saving of time enabled these pharmacists to become involved with individuals' pharmaceutical care. However, these pharmacists did not perceive dispensing to care homes as an organisational strategy. Pharmacists wishing to build up a large volume of care home dispensing felt the need to offer an MDS service.

There was evidence that pharmacists were interested in providing extended clinical services to care homes but lack of remuneration and communication/relationship difficulties were acting as barriers. Many pharmacies were offering clinical services beyond that they were remunerated for within their PCT contract. However, the view was expressed that there was much scope for increasing their clinical role further. As shown above, the time consuming nature of dispensing in MDS systems may be one of the barriers to achieving this. The use of accredited technicians to check MDS medication was one strategy being employed to allow pharmacists to carry out clinical work while providing MDS services, but this was not widespread.

We realise we have studied MDS predominantly from the pharmacy perspective in this chapter, however that has not been done in this depth before. We have not specifically asked care home staff about it in the same way, and so some things they value MDS for are not included. An example would be that MDS gives care home managers the ability to easily audit that the right medicines had been given.

On the basis of the findings in this chapter, MDS is a technology that strongly structures pharmacists' work and may be a barrier to enhanced clinical services.

Chapter 7

Ergonomics

7.1 Aims

The aims of the ergonomics component of the CHUMS project were;

- To apply ergonomics user-centred design methods to understand the system and the factors that contribute to errors.
- To identify potential solutions.

The following sections describe the concept of user-centred design, the process of familiarisation with the existing system, analysis of error data collected during the main study, the identification and then investigation of three key priority areas.

A review of medication administration relating to care homes can be found in Appendix I. This review was conducted in order to guide the direction of the ergonomics investigation and to select appropriate methodologies.

7.2 User-centred design

User-centred design aims to place the user at the centre of the systems design process. By designing a system to take account of human abilities, likes and dislikes, it can better fulfil the needs of the individual operating within it. To achieve this goal, it is necessary to adopt design processes that facilitate the involvement of the final user of the system in its conception. Figure 7.1 illustrates the concept of user-centred design by identifying the layers of the system emanating from the user at the centre. As an example, if you consider a computer operator. The machine would be the computer (screen, keyboard, mouse etc); the workspace would be the computer workstation (desk, chair etc); the environment would be the room housing the computer workstation with factors such as lighting, heating, noise etc.; and finally the socio-technical system accounts for many wider issues such as the management structure of the company, company policies, the political environment within the host country, social pressures such as commitments/interests outside the work environment.

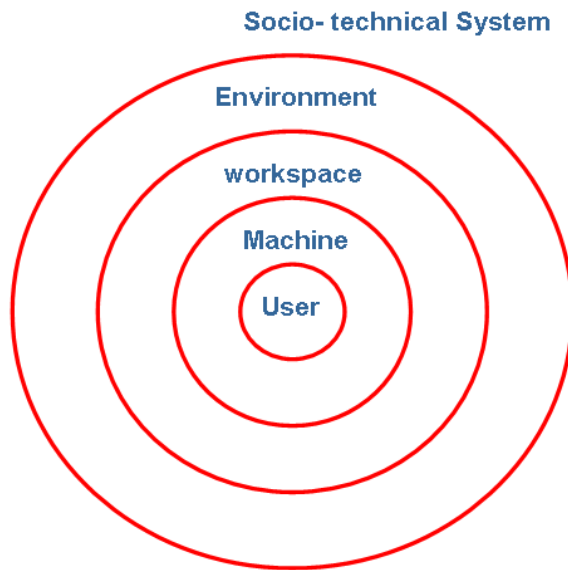


Figure 7.1: User-Centred design

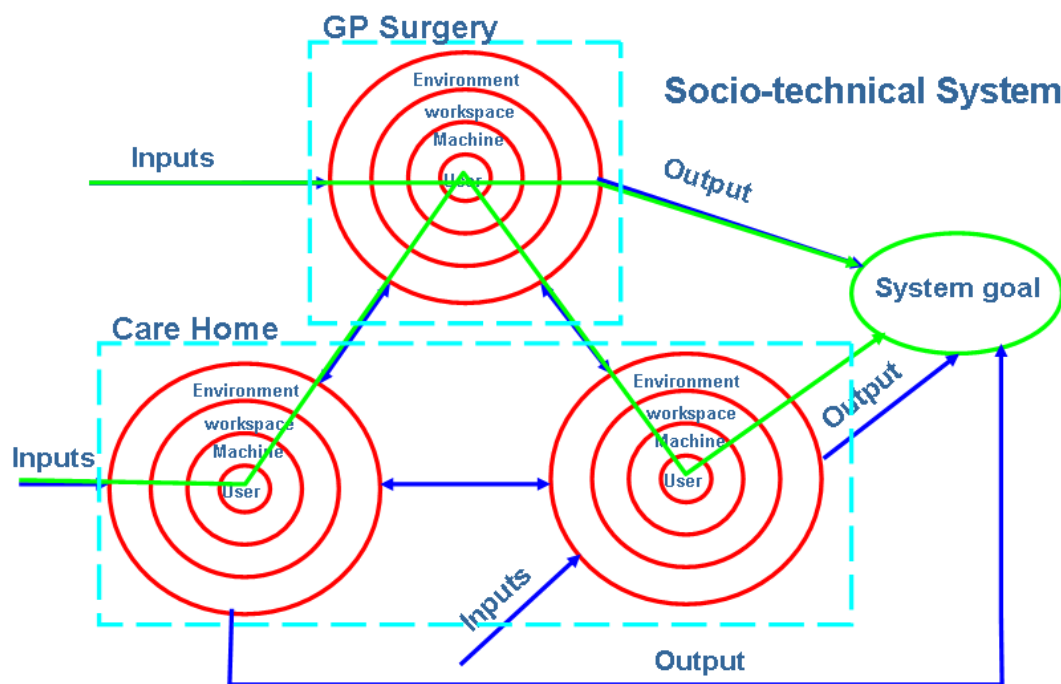


Figure 7.2: User-Centred design in a system framework

Figure 7.2 illustrates through a simplified example, how both individual and system wide factors are considered. In addition to the 'layers' identified in figure 1, figure 2 illustrates issues such as communication between individuals; communication between components of the system (e.g. care home, GP surgery etc.); inputs (e.g. a patient displaying symptoms of an illness) and outputs (e.g. prescribing/dispensing/ and administration of medicines) of

the system. The system goal in the example in figure 2 could be the safe administration of the correct medication to each individual to ensure the best treatment of their ailments. Alternatively, the goal could be described at a higher level as *'The attainment of the best possible quality of life for each resident in a care home'* with a sub-goal to achieve *'Safe and correct administration of medication'*.

In summary, the concept of user-centred design and hence ergonomics, is to place the user at the centre of the design process and facilitate user involvement in that process. Examples of user involvement in the design process include methods such as focus groups, semi-structured interviews walk/talk throughs and observations.

The aims and methods in this ergonomics study, map directly onto the systems-based user-centred approach to healthcare design, documented in the 'Design for Patient Safety' report, written by members of this research team and published by the Department of Health and Design Council.³¹ The aim could therefore be mapped onto the diagram in figure 3 as the *'Build the knowledge base'* and *'Define the requirements'* boxes. Once the requirements have been defined, the first iteration of the product design (in the inner box in figure 7.3) can be completed.

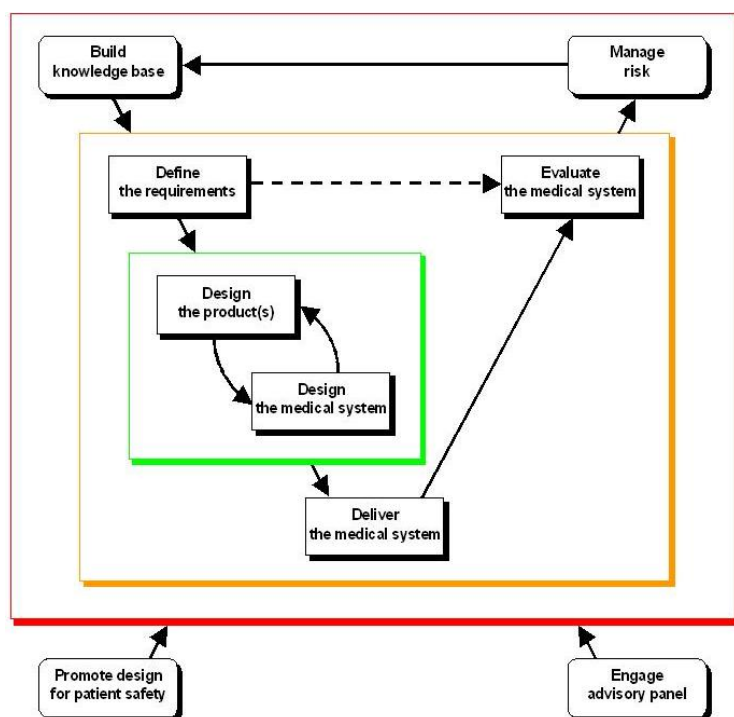


Figure 7.3: Systems-based user-centred approach to healthcare design (DofH 2003)

7.3 Familiarisation with the existing system

7.3.1 *Shadowing data collectors*

In this first stage of the ergonomics investigation it was considered important for the ergonomics investigator to gain a fuller understanding of the tasks, pressures and daily routine of the care home personnel. The ergonomics researcher visited a total of nine care homes, two GP surgeries and a community pharmacy during this period of familiarisation. The researcher was accompanied by a research pharmacist on each of these occasions, who was able to inform and provide specialist information to assist the ergonomist in understanding the work system in each location.

During each visit, the ergonomist observed the general environment within the care home, the tasks performed (including the scheduled drug round), and interactions between staff.

The outcome of this familiarisation stage was a fuller understanding of the working system, the environment and the daily demands on care home staff. The results of these visits were used to help construct the methods needed for the subsequent stages of the research.

7.3.2 *Pilot studies*

In order to help finalise a method of on-site data collection, and to further add to the understanding of the issues in the medication system a series of pilot studies were conducted. These consisted of visits to four homes in the Leeds/Bradford geographical area, and a visit to a large Bradford based pharmacy that regularly dispensed medication to around 45 homes in the local area.

The method at the care homes consisted of observing a scheduled drug round while making notes of events during the round. The observer also recorded ergonomic issues relating to the tasks performed, including aspects of the equipment used and the building itself (e.g. lighting, room layout, corridor widths).



Figure 7.4: A drug round in progress

The method adopted at the pharmacy consisted of a short introduction to the nature of the research followed by the pharmacist walking/talking through the typical 28 day cycle of supplying medication to care homes. An audio recording of the session was made to allow the ergonomist to clarify any uncertain areas in the processes followed, when comparing written notes taken on-site with the audio dialogue of the pharmacist.

7.3.3 Results from the familiarisation process

Systems diagram

Following the familiarisation stage, and the pilot studies, a simplified systems diagram was produced (Figure 7.5). This represents five main components within the system that links the care home to other health care providers, and the potential links between them. The diagram indicates the potential lines of communication in either direction between each component of the system. Solid lines represent the links; with dotted lines being used show the links between components not adjacent to each other in the diagram.

The 'Other' component represents staff and functions not linked with any of the other system components (e.g. visiting physiotherapists, family members, dentists etc).

This simplified systems diagrams was constructed to assist with the analysis of the CHUMS data and subsequently the identification of priority areas for further data collection and analysis.

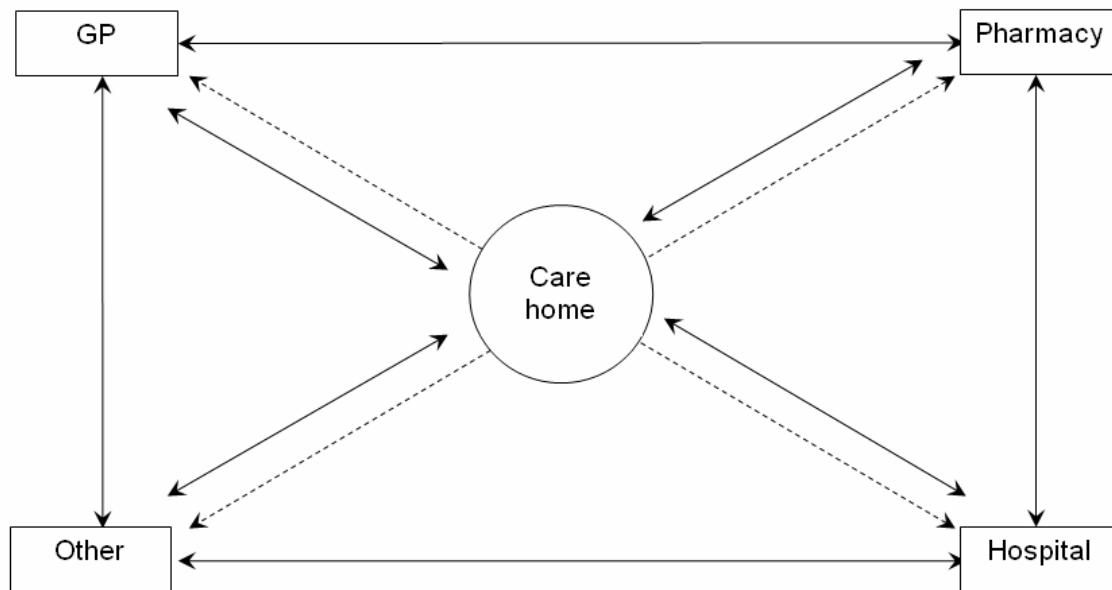


Figure 7.5: Figure Simplified systems diagram

Initial task analysis diagrams

A further advantage of undertaking the familiarisation process was that it enabled a task analysis diagram to be constructed for key tasks. These included the drug round and processes within the pharmacy.

Task analysis was selected to produce a 'description' of the existing care home medication system. Many task analysis methods use a hierarchical structure to some degree, and after a short appraisal of other available methods, Hierarchical Task Analysis (HTA) (Annett et al¹⁰⁴) was selected as the preferred method. The selection criteria included the following logic.

HTA permits a scaleable level of complexity depending on the characteristics of the system being studied. The nature of this study into medication within care homes was such that the complexity and level of analysis required was predominantly unknown; therefore HTA would adapt to match the needs of the project as the investigation progressed. The investigator would have the facility to choose the point at which tasks had been broken down to the component level required.

Secondly, as identified by Stammers et al.,¹⁰⁵ the most appropriate and valuable use of task analysis in general, is in the updating or modification of an existing system, as was the case

for care homes. They point out that as long as most elements of the system are likely to remain largely unaltered after any re-design, particularly those that are directly associated with the user, the majority of the task information obtained will be relevant to the new system.

Further discussion of methodologies adopted during the project, including task analysis, can be found in appendix I.

The resultant hierarchical task analyses are shown in figures 7.6 and 7.7.

The drug round procedure in figure 7.6 was based on visits to four care homes in the Bradford area during the pilot study. It illustrates all the tasks that could be clearly identified by the on-site observer and was further clarified by conversations with the care home staff involved. This 'initial' task analysis diagram formed the starting point for the studies of the drug round in the ergonomics investigation of key priority areas (see 7.4).

The dispensing procedure described in figure 7.7 was a result of a visit to a large pharmacy in the Bradford area during the pilot study. In a similar manner to the drug round task analysis, this formed the basis of further investigations of the key priority areas in section 4. It should be noted that the term 'Prime prescriptions' was one adopted by this particular pharmacy company.

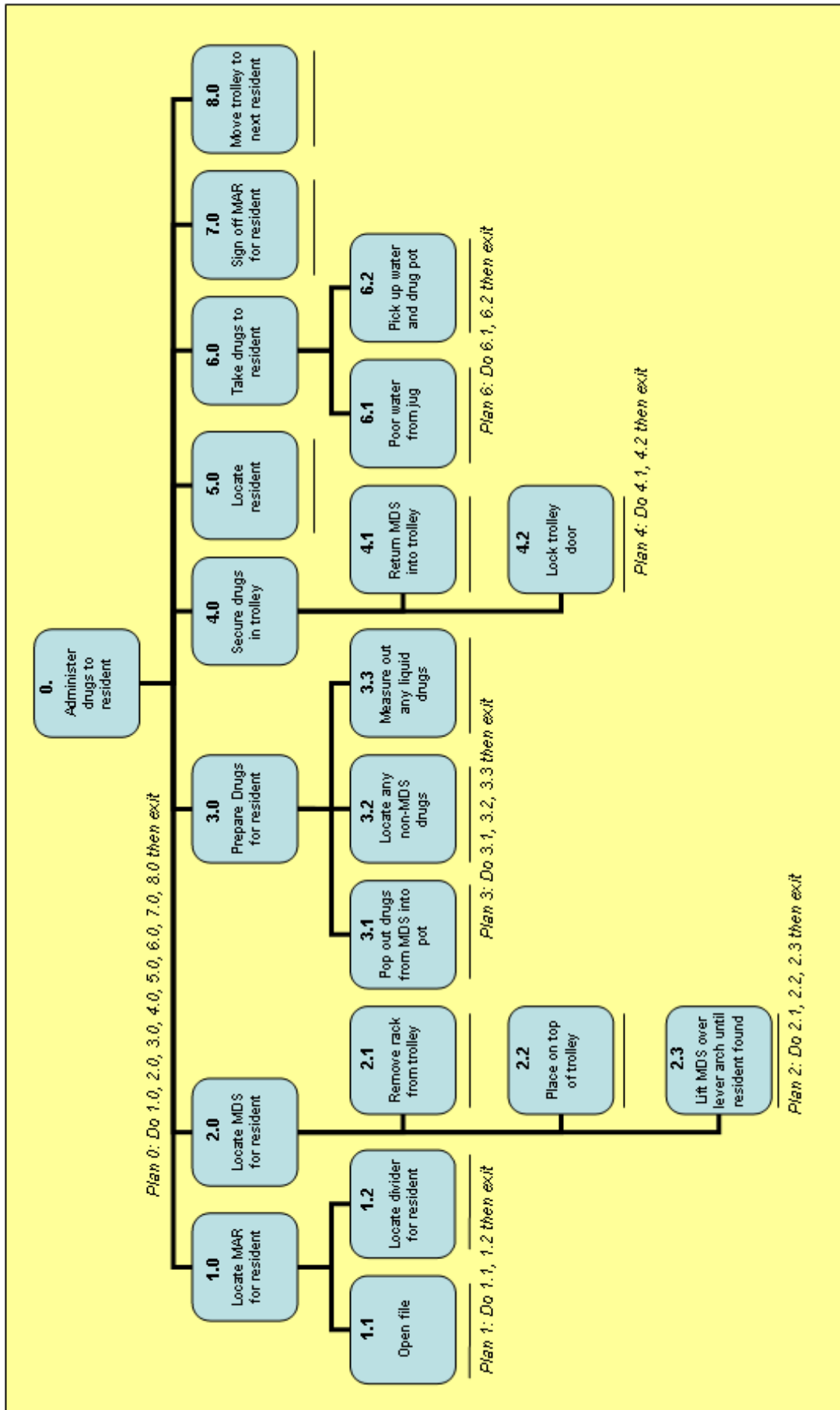


Figure 7.6: Drug round procedure

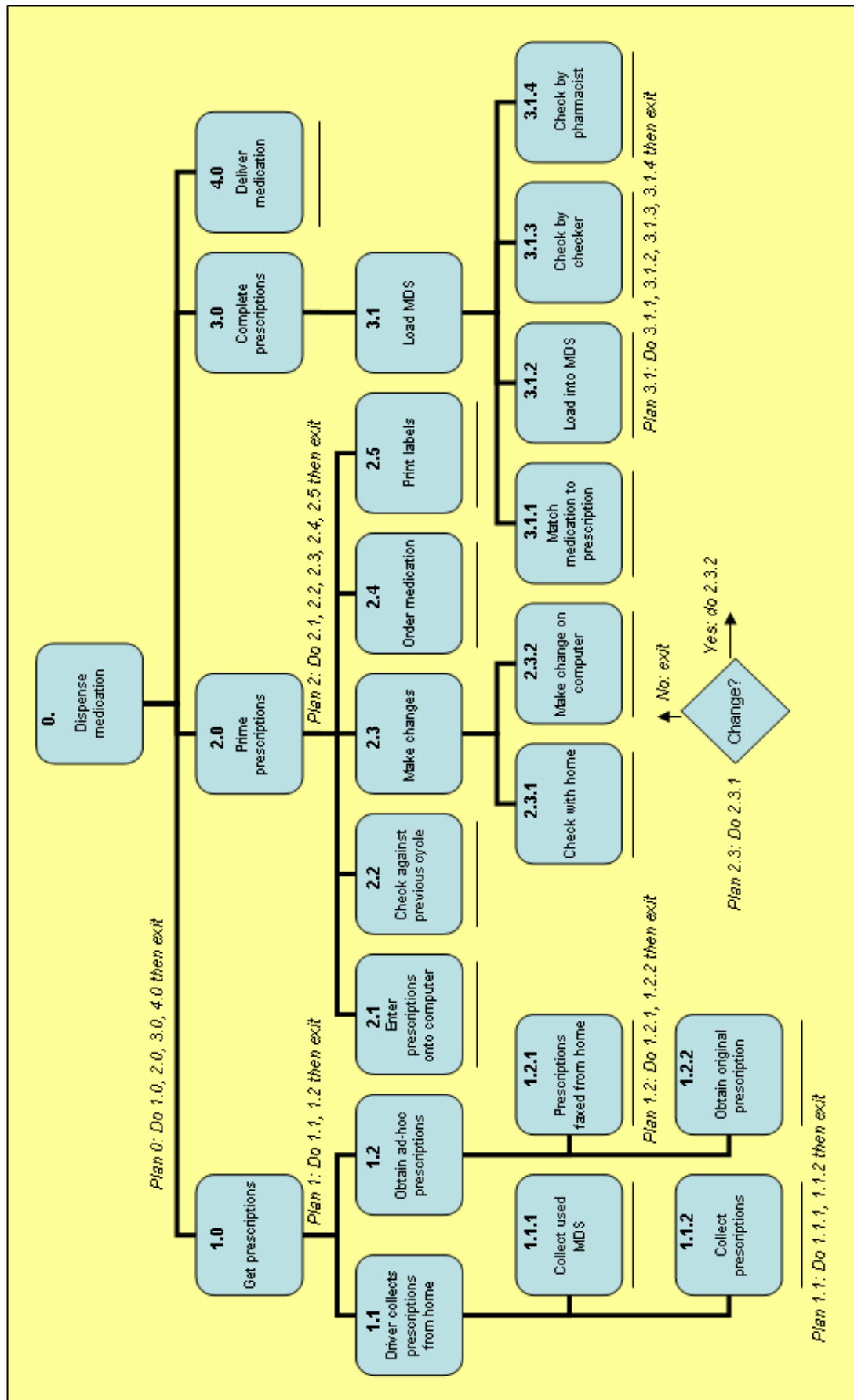


Figure 7.7: Dispensing procedure

7.4 Identifying key priority areas

7.4.1 Data analysis

Definition of the data set used for the analysis

The analysis was based on the 89 error reports. The errors were selected on the basis that they were *'more likely to have resulted in harm'*.

Each of the 89 error reports was based on the information filed by key project personnel during on-site data collection in care homes, pharmacies, and GP surgeries. These sometimes included semi-structured interviews with the staff involved. This information was then analysed to produce the 89 reports, using the framework developed by Vincent et al²⁹ for the analysis of risk and safety in medicine. This analysis attempted to identify and establish contributory factors in a number of categories as well as identifying possible latent factors. The categories included:

- Patient characteristics
- Task factors
- Individual factors
- Team factors
- Work environment
- Latent factors

Ergonomics Factors

In order to further analyse the 89 reports with the aim of focusing the ergonomics investigation, a number of factors were defined. A summary of these (with examples) is given below. The full list of factors can be seen in appendix J.

- Crossing system boundaries (25)
 - GP – Pharmacy
 - Care home – GP
 - Hospital – Care home

-
- Error location (5)
 - Pharmacy
 - GP Surgery
 - Care home
 - Hospital
 - Other
 - Object/task factors (28)
 - MAR (Discontinued drugs)
 - Drug round (Interruptions)
 - Drug trolley design
 - Medication packaging design

Ergonomics Analysis

Each of the 89 error reports was studied by the ergonomist, to assess which of the factors in 7.4.1 applied to each.

Figure 7.8 illustrates the occurrence of errors that appeared to have their origins in a particular component of the system (i.e. Care home, Pharmacy etc.). However, a full root cause analysis for each error was not feasible. Therefore, we have been careful to not make the assumption that the root cause was necessarily within a specific location. Nevertheless, the clustering of errors shown in figure 8 is useful for prioritising field observations.

No errors occurred outside the four components GP surgery, Care home, Pharmacy and Hospital. The majority occurred within two components, namely the Care home (45%) and the Pharmacy (37%). This finding was used to prioritise subsequent ergonomics observations.

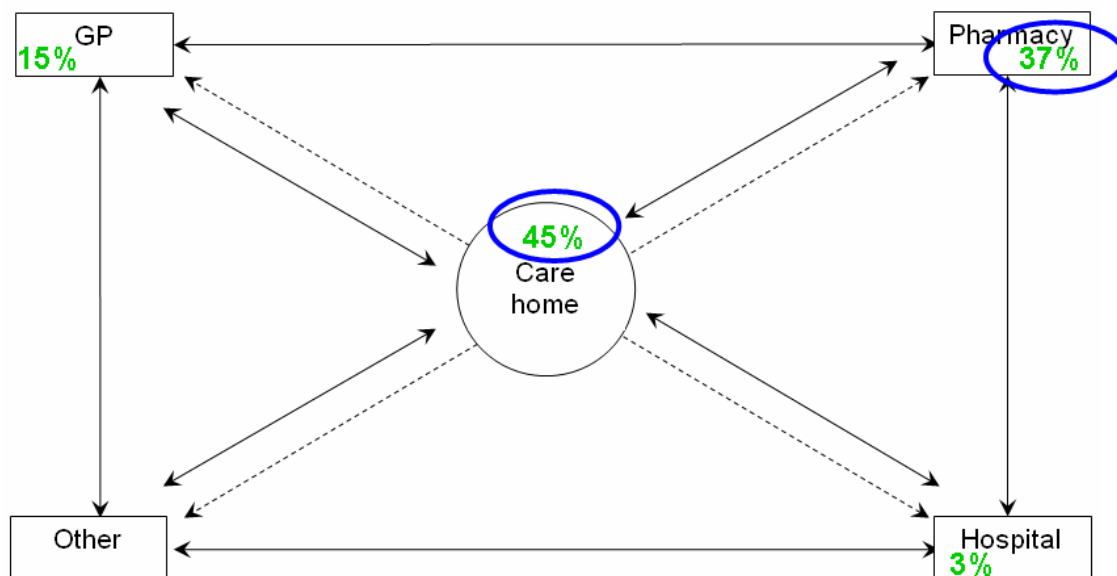


Figure 7.8: Within component statistics (error location)

Figure 7.9 presents statistics on the distribution of errors where at least one contributing factor related to communication issues. Where no figures are given, no errors were recorded where communication contributed to the error. Communication issues are split into two directions between any components, hence up to two figures are given on each line in the diagram. For example, the highest occurrence of errors are relating to communication from the pharmacy to the care home (37%). Whereas 13% of errors involved communication in the opposite direction. Transition between facilities was identified as a high risk time for medication errors by Pepper and Towsley.¹⁰⁶

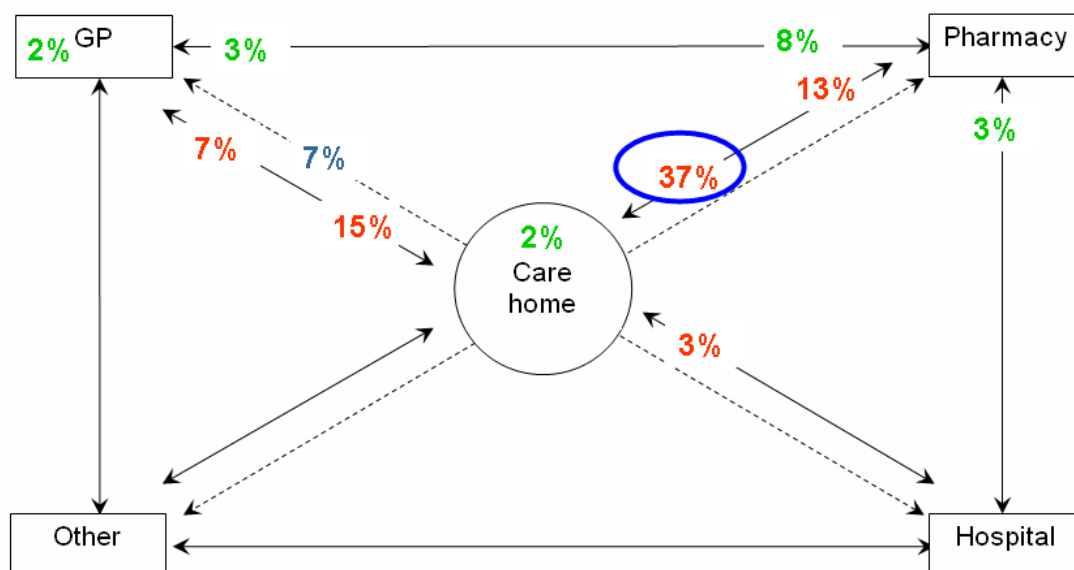


Figure 7.9: Errors including communication issues (crossing system boundaries)

Analysis of specific factors

Figure 7.10 presents the occurrence of object/task factors across all components of the system. Excluding issues associated with staffing (see below), MAR and drug round issues were prominent (represented in green). The bars represented as dotted lines indicate the breakdown of individual factors associated with the MAR and the drug round.

Staffing issues were not prioritised in this study but cannot be ignored. In a recent US study¹⁰⁷ it was found that quality of care was influenced to some degree by staffing characteristics, but that any improvement in quality could only be achieved by an improvement in many aspects of staffing such as staffing levels, worker stability, turnover and the use of short term agency staff. Had a full root cause analysis been feasible in our study, staffing would have been considered in depth. Our field observations suggest that staff numbers, skill sets and training may be important determinants and should be investigated further. However, it was felt that a larger impact on total number of errors could be achieved through identification of more specific factors and objects within the system.

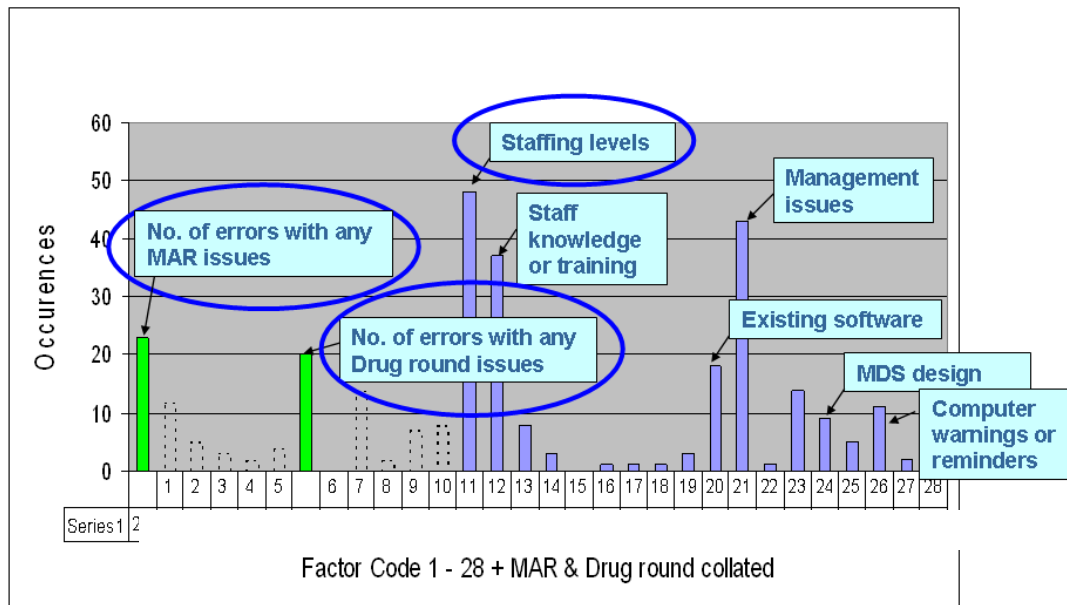


Figure 7.10: Object/Task factors (see appendix J for list of factors)

Figure 7.11 illustrates object/task factors in the care home alone. Again, excluding staffing issues, the prominent object associated with errors appeared to be the MAR chart and the prominent task, the drug round.

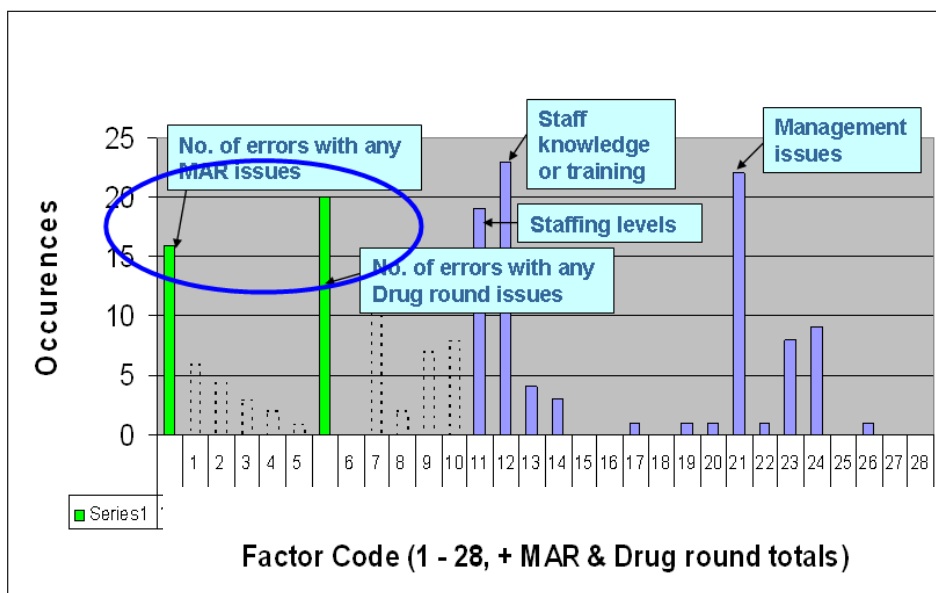


Figure 7.11: MAR and drug round issues within the care home

Figure 7.12 shows the breakdown in factors associated with the Medication Administration Record (MAR) chart. Where no specific factor was identified, although the MAR chart was

generally felt to have contributed, it was recorded as 'general'. In order to target the research, the largest identifiable factor was discontinued drugs remaining on the chart.

Discontinued drugs on the MAR chart are those items of medication that may have been administered in the past at some point, but are no longer being prescribed or administered.

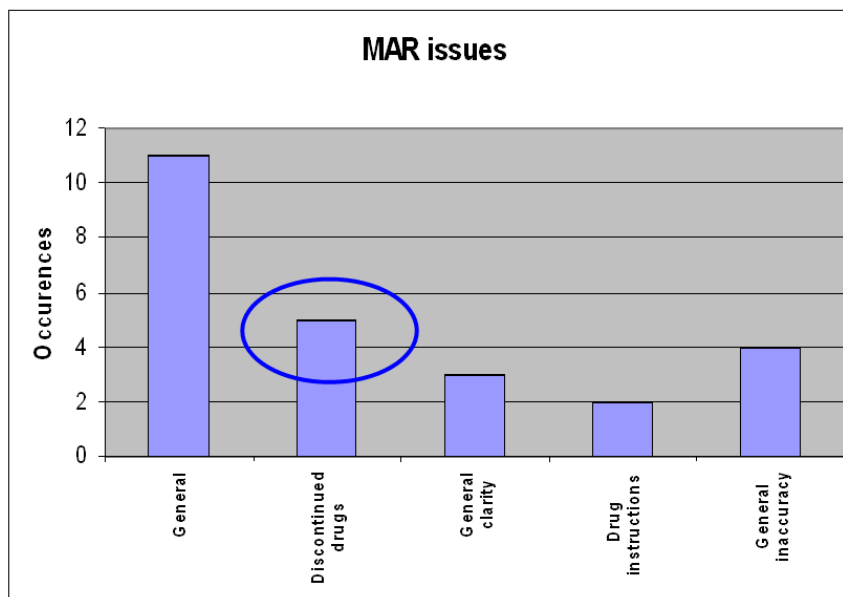


Figure 7.12: Significance of discontinued drugs on the MAR chart

Figure 7.13 illustrates the breakdown in factors associated with the drug round. It can be seen that the largest single factor was interruptions during the round.

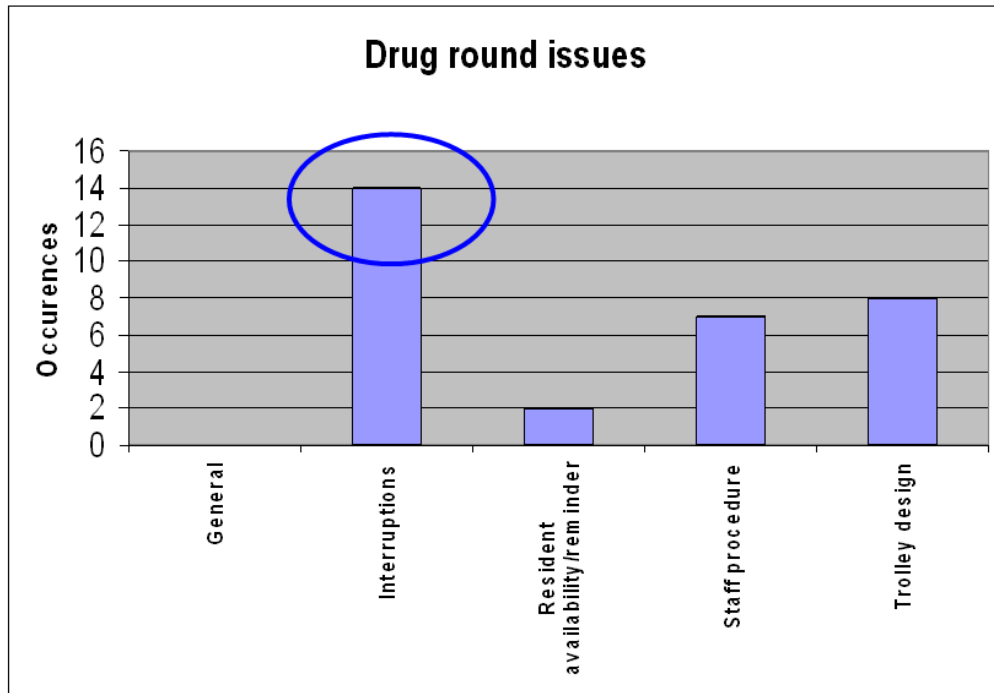


Figure 7.13: Significance of interruptions during the drug round

Figure 7.14 looks at object/task factors in the pharmacy alone. Similar to errors throughout the system, issues relating to staff were prominent. However, after discounting staffing issues (as discussed in 7.4.1 Figure 7.10); the next most significant category was computer software. This supported both comments made by staff, and the expert ergonomics observations during the pilot study at a large city pharmacy.

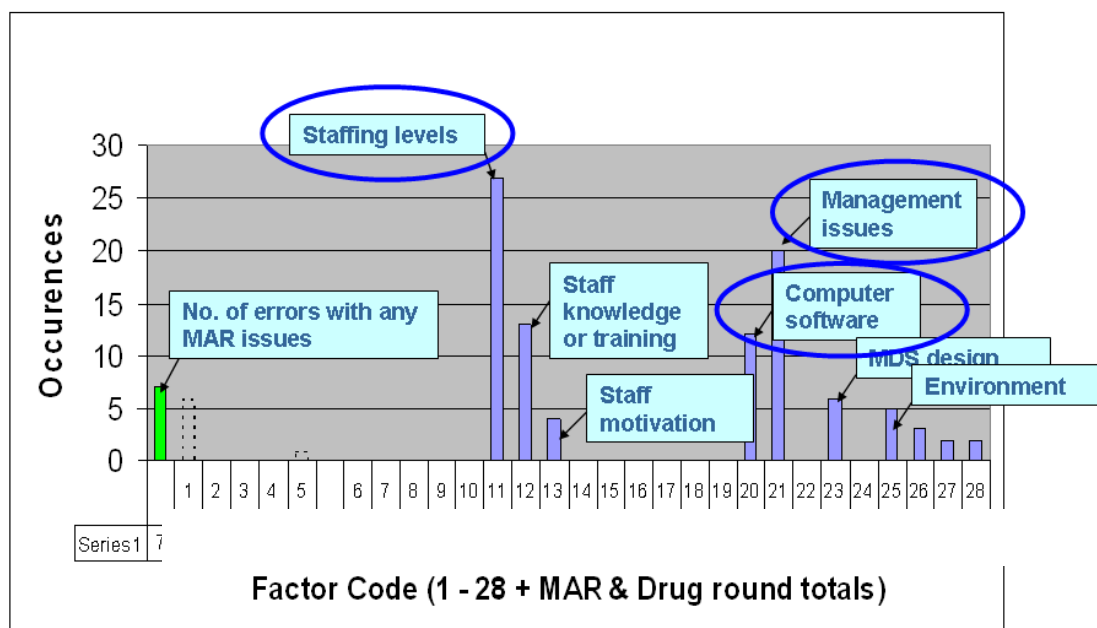


Figure 7.14: Computer software issues in the pharmacy

In summary, the following statements could be made at the conclusion of the analysis.

- A noticeable cluster of errors within both the Care Home and the Pharmacy (45% and 37% respectively)
- A noticeable cluster of errors associated with communication between the Pharmacy and the Care Home (37% Pharmacy to Care home, 13% Care home to Pharmacy)
- Staff (levels, training, motivation) and management issues were prominent throughout
- MAR and Drug Round issues were prominent in the Care Home (as well as staff issues)
- Main MAR issue appeared to be discontinued drugs
- Main drug round issue appeared to be interruptions
- Computer software appears to be an issue in the Pharmacy (excluding staff issues)

7.4.2 The priority areas

The following areas of priority were selected to match with the largest concentration of errors within the medication system, as recorded in the analysis of the 89 errors found on the CHUMS project. Focusing on these areas maximised the chance of reducing the overall total number of errors.

- The MAR chart, and in particular discontinued drugs
- The drug round, and in particular interruptions
- Communication between the Pharmacy and the Care home

These three priority areas represent three distinct types of problems; a physical object; a process; and crossing of component boundaries.

The above priority areas were used to direct the research effort in the latter stages of the project; however this did not preclude the inclusion of any other factors that may have been observed during the ergonomics data collection.

7.5 Investigating the key priority areas

7.5.1 Research questions

- Can the incidence of medication errors be reduced through improved or changed use of the MAR chart?
- What is the nature and extent of interruptions during the drug round?
- What can be done to minimise both the frequency and effect of these?
- Can the incidence of medication errors be reduced by changes to the bi-directional communication structure between the Pharmacy and Care Home?

7.5.2 Background

The Medication Administration Record (MAR) chart

A cluster of observed medication errors was identified in which one of the contributing factors was the MAR chart, and more specifically the number of discontinued items recorded on the chart.

The medication administration record or MAR chart is currently an integral part of the whole medication delivery system relating to elderly residents in care homes (It also has applications in other sectors of the health service, outside the boundaries of the current research project, for example hospital wards).

Briefly, the MAR chart records and distributes information on the medications administered to care home residents (in our case). One chart typically covers a 28 day cycle for one resident, at the completion of which a new chart is produced for the next cycle. MAR charts are archived for residents for three years after their death or departure from the care home. They are typically, but not exclusively, produced by the pharmacist. A typical MAR chart is illustrated in Figure 7.15. Figure 7.16 is an example of a completed MAR chart.

Name: _____ D.O.B.: _____
 Allergies: _____ Start Date: _____ Start Day: _____
 Period: _____

TIME	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Medication Details																												
Quantity																												
Received																												
by																												
Date																												
Start Date																												

Figure 7.15: A typical MAR chart

RESIDENT'S NAME: [REDACTED]

WEEK 1	WEEK 2												
DATE	DATE												
3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	GLIMECLAMIDE 5mg T	08.00											
2	METFORMIN HYDROCHLORIDE 500mg T	08.00											
3	PARACETAMOL 500mg T	08.00											
4	ASPIRIN 75mg T	08.00											
5	LORAZEPAM 1mg T	18.00											
6													
7													
8													

Figure 7.16: A completed MAR chart

There is a legal requirement for the existence and maintenance of some, if not all, of the information recorded on the existing MAR chart. There are practice guidance notes relating to the provision of printed MAR charts for use by community pharmacists. These are published by The Royal Pharmaceutical Society of Great Britain.³⁷

It is acknowledged by RPSGB that MAR charts are official records. To quote, ‘They are a formal record of administration of medicine and have been used as evidence in court cases’. The document also continues to state that care workers are highly dependent on the content and accuracy of printed MAR charts.

The drug round and interruptions

The medication error data collected on the CHUMS project identified a cluster of observed errors in which at least one of the contributing factors was associated with the drug round and more specifically interruptions during the drug round in the care home.

One of the daily tasks within a care home is to safely and accurately administer medication to those residents requiring it. Typically to achieve this, a home will conduct three to four ‘drug rounds’ each day. These normally take place in the morning, midday, early evening, and where required late evening.

The drug round will generally be conducted by one member of the care staff, and can typically take anything between 30 minutes and in excess of two hours (depending on the number of residents and the time of day). It is commonly designed to coincide with resident’s meal times, therefore allowing some residents to receive their drugs while in a single location. However, many residents will still be in their bedrooms necessitating staff in travelling around the home to locate them.

The large majority of homes in the study use a trolley to transport the medication and associated records around the home. A common design of trolley can be seen in Figure 7.17



Figure 7.17: Typical drug trolley used in care homes

A small minority of homes were observed to use a 'drug room' rather than the more common drug trolley. This is normally a small room or walk in cupboard, containing the same items carried on the trolley. The extra space available did permit a wider choice of layout.

Communication between the Pharmacy and the Care home

A cluster of observed medication errors was identified in which one of the contributing factors was bi-directional communication between the pharmacy and the care home.

The potential exists for either inaccurate or missing information between these two system components. Information to be communicated between the pharmacy and the care home include; administration instructions for medication (via medication labels and the MAR chart), medication no longer to be administered; changes in medication instructed by medical personnel during the typical 28 day cycle of medication supply etc.

7.5.3 Method

Aims

- To investigate the reason for discontinued items on the MAR (Medication Administration Record) (i.e. medication that is not required by, or prescribed for the resident but is still appearing as an item on the MAR chart.
- To collect data on interruptions during the drug round
- To describe the communication procedures between the care home and pharmacy (and vice versa).

Domain professionals focus group

In order to solicit as much user feedback in a relatively short space of time, it was decided to convene a focus group.

Focus groups are a recognised form of group interview involving one/two moderators who facilitate a discussion with around 5 to 10 group members. The lead moderator is required to keep the focus of the discussion on the pre-selected topic of interest. It will commonly

include an introduction to the topic to be discussed. They are more often applied to the evaluation of computer interfaces. A review of focus groups as applied to the user interface of advanced IT systems can be found in Christie et al.¹⁰⁸

The topic for this focus group was:-

'The MAR chart, its role in the medication system and the issue of discontinued items'.

The group consisted of six professionals associated with the entire system of caring for the elderly in care homes. The professions of the group members were as listed below.

- Care home manager
- Local GP
- Academic pharmacist
- Pharmacy manager
- Research pharmacist
- Care home nurse

The group was hosted at Leeds University and met for approximately three hours.

A short presentation was given by the group convenor to introduce the CHUMS project to those not already familiar with it.

To supplement the information to be elicited through the focus group discussion to follow, the group were given individual questionnaires to complete (Appendix K).

The main section of the meeting consisted of a semi-structured discussion in order to reach consensus on the response to a set of statements/questions. These were identical to those contained in the aforementioned questionnaire (Appendix K).

The entire focus group session was recorded and later transcribed.

In order to further understand the opinions of the group, a coding framework was devised and the transcript was subsequently broken down into relevant statements relating to the

coding structure. Both the transcript and the coding framework can be seen in appendix 3 and 4 respectively.

Field data collection at the Care home

1. Observations during a drug round

The ergonomist shadowed a member of staff during each full drug round. Using an observation table to record events, any interruptions were documented with time and other details being recorded. If further clarification on the nature of the interruption was required, the ergonomist asked the staff member to explain events in more detail.

2. Semi-structured interview

Immediately following the drug round, a number of questions (see below) were raised with the staff member in a semi-structured interview. They related to interruptions during the drug round, the communication between the pharmacy and the care home and MAR discontinued items.

Part 1 – Drug round interruptions

- How often do you conduct the drug round?
- Was today a typical round?
- What other responsibilities do you have on this shift?

In addition to the above questions, the ergonomist went through the list of recorded interruptions to clarify whether the interruption was beneficial, avoidable/unavoidable, and whether other staff could have dealt with it.

Part 2 - Communication

- What are the lines of communication you have with the care home (e.g. Fax, telephone, email, post, visits)?

-
- Could you complete the attached table for all categories of information transferred?
 - What information is not transferred from the care home to the pharmacy, but should be?
 - What information is not transferred from the pharmacy to the care home, but should be?

Part 3 – The MAR chart

- What is the primary purpose of the MAR chart?
 - What additional purposes (if any) does the MAR chart serve?
 - Could you complete the attached table for all information contained on the MAR chart?
 - Does the MAR chart fulfil its primary purpose?
 - Does the MAR chart fulfil its additional purposes?
 - What are the reasons for discontinued items on the MAR chart?
 - How are medicines not on the MAR chart catered for?
3. A semi-structured interview also took place with the care home manager (where practical). It covered the questions relating to the MAR chart and communication

Field data collection at the pharmacy

Walk/talk through

After an introduction to the CHUMS project, the pharmacy staff member was asked to talk through the processes that take place in one full cycle of administration to a care home.

Semi-structured interview

The following questions were discussed with the interviewee. They relate to both the communication between the pharmacy and care home and MAR discontinued items.

Part 1 - Communication

- How many care homes do you dispense to on a regular basis?
- What are the lines of communication you have with the care home (e.g. Fax, telephone, email, post, visits)?
- Could you complete the attached table for all categories of information transferred?
- What information is not transferred from the care home to the pharmacy, but should be?
- What information is not transferred from the pharmacy to the care home, but should be?

Part 2 – The MAR chart

- What is the primary purpose of the MAR chart?
- What additional purposes (if any) does the MAR chart serve?
- Could you complete the attached table for all information contained on the MAR chart?
- Does the MAR chart fulfil its primary purpose?
- Does the MAR chart fulfil its additional purposes?
- What are the reasons for discontinued items on the MAR chart?
- How are medicines not on the MAR chart catered for?

7.5.4 Results

The drug round and interruptions

It is important to define what was being measured to fully understand the data collected. The definitions below were generated to aid data interpretation.

- **Definition of an interruption**
 - An interruption is an event from any source, with the potential to interfere in the activity, physical or mental, devoted to the primary task
- **Specific definitions for this study**
 - An interruption is an event that requires the attention, verbal or physical, of the staff member performing the drug round
 - An event is activity, other than the drug round, that the staff member could be aware of visually or audibly
 - An unanticipated task is an operational task required but not planned for in normal drug round procedures

Figure 7.18 illustrates a typical data sheet used to record events during the drug round. It highlights the categories of data recorded.

Home P2	Nursing				
Teatime round					
Start time: 5:36 PM					
Finish 6:35					
Recorded interruptions					
Time	Request from	Communication	Accept/reject	Time off task	Comments
05:38:00 PM		Telephone	R		
05:46:00 PM	Staff	Voice	A	15 sec	She thought someone called her name
05:48:00 PM	Staff	Voice	A	2 min	Called away because resident wasn't well
06:04:00 PM	Resident	Siren	R		Called another staff member
06:05:00 PM	Staff	Voice	A	1 min	Asked to take a call
06:10:00 PM					Fetch water to lounge
General Observations					
Number	Description				
1	Helped by an NVQ trained carer. Takes dispensed meds to each room				
2	Takes two resident trays out at a time and places them on top of trolley				
3	Moves trolley to rooms. Narrow corridor and slopes				
4	Changed order to catch residents in sitting room				
5	Draw for each resident (NOT MDS)				
6	Bristol Maid trolley				

Figure 7.18: A typical data sheet recording events and observations during a drug round

A total of 15 drug rounds were studied. The findings can be summarised under the following three more specific research questions.

- The frequency of interruptions during the drug round
- The source of interruptions (e.g. Staff, residents, visitors etc.)
- The nature/purpose of these interruptions

Frequency of interruptions

- The average duration of a drug round was 44 minutes (range, 17 – 80 minutes)
- The average number of interruptions was 4.2 per hour (range 0 – 12 per hour)
- Two rounds had in excess of 8 interruptions per hour
- Seven rounds had less than 3 interruptions per hour

Source of interruptions

- The most common interruptions were from other staff (28 out of a total of 46)
- A total of 4 of the 46 interruptions were verbal requests from residents

The nature/purpose of interruptions

- 25 of these 28 staff interruptions were operational issues
- Only 4 of the 28 were relevant to the drug round

Other events included

- Audible alarms
- Telephones ringing, but not requiring a response from the drug round staff
- Panic button sirens not requiring a response from drug round staff.

In summary the majority of interruptions originate from other care home staff and that the majority of these relate to operational issues not relevant to the drug round. This suggests that further research into the distribution of duties among staff could result in fewer requirements for interruptions during the drug round.

Observations relating to all three priority areas

Figures 7.19 – 7.22 illustrate some of the observations made during the study of the three priority areas, superimposed on the task analysis diagrams created during the earlier pilot study. Variations in practices (Figures 7.19 and 7.20) can indicate adaptation of the system by the operators (i.e. care workers, nurses, pharmacists etc.) to produce a better output. Therefore these variations warranted close scrutiny to elicit useful information to guide future design.

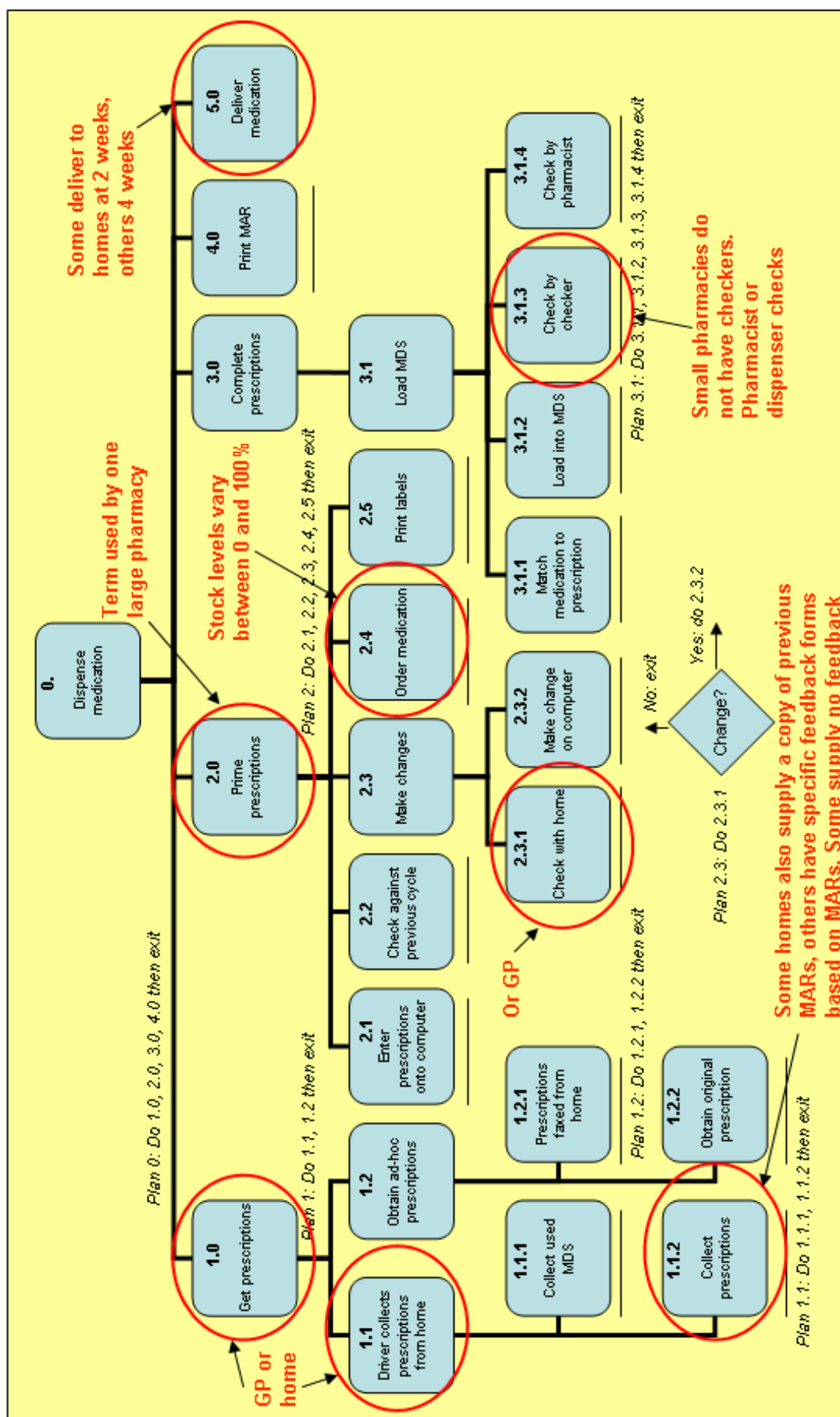


Figure 7.19: Variations in dispensing practices

0.0 Administer drugs to resident

Plan 0: Do 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0 then exit

1.0 Locate MAR for resident

1.1 Open file

1.2 Locate divider for resident

Plan 1: Do 1.1, 1.2 then exit

2.0 Locate MDS for resident

2.1 Remove rack from trolley

2.2 Place on top of trolley

2.3 Lift MDS over lever arch until resident found

Plan 2: Do 2.1, 2.2, 2.3 then exit

3.0 Prepare Drugs for resident

3.1 Pop out drugs from MDS into pot

3.2 Locate any non-MDS drugs

3.3 Measure out any liquid drugs

Plan 3: Do 3.1, 3.2, 3.3 then exit

4.0 Secure drugs in trolley

4.1 Return MDS into trolley

4.2 Lock trolley door

Plan 4: Do 4.1, 4.2 then exit

5.0 Locate resident

6.0 Take drugs to resident

6.1 Pour water from jug

6.2 Pick up water and drug pot

Plan 6: Do 6.1, 6.2 then exit

7.0 Sign off MAR for resident

8.0 Move trolley to next resident

Annotations:

- Staff often time drug round to coincide with meals so residents are in one room. Others visit each bedroom. Nursing care can mean resident is in own room** (points to 5.0)
- Often the trolley was only moved 2-3 times during a round. Sometimes not at all** (points to 8.0)
- Water jug and cups normally kept on trolley, but infrequently, water was distributed to rooms in advance** (points to 6.1, 6.2)
- Some staff use the flip out surface on the top of the door. Others place it directly on the main top surface of the trolley** (points to 2.2)
- If trolley is in communal area, sometimes it is not locked as it is in full view of the staff member** (points to 4.2)

Figure 7.21 illustrates those tasks observed to be potentially susceptible to interruptions. These tasks are as follows

- **Task 4.0 'Secure drugs in trolley'**

It was observed that the task of securing drugs in the trolley was repeated many times during a drug round. Whenever a care worker/nurse was required to leave the trolley the drugs needed to be secured to prevent access by residents.

In the event of an emergency interruption, the staff's response to the emergency could be delayed while the trolley was locked, or there would be potential for the trolley to be unlocked while the staff member dealt with the interruption.

- **Task 6.0 'Take drugs to resident'**

After the staff member has prepared the drugs for a particular resident (i.e. retrieved them from the MDS or measured liquids into a container) they then take the drugs to the resident in order to administer them. In some cases the resident will be relatively near, for example in the dining room along with the drugs trolley. In other cases the resident may be in their bedroom with the trolley remaining outside the room in the corridor.

In the case of an interruption, there is the potential for the medication to be misplaced, left unattended or incorrectly administered.

- **Task 7.0 'Sign off MAR for resident'**

It was generally observed that the staff member would sign off the MAR chart to confirm administration of drugs after returning to the trolley following medication administration to a resident.

If an interruption occurs during this stage of the task, an 'error' opportunity has been generated as the staff member may omit to sign off the MAR chart although the medication has been given.

- **Task 3.2 'Locate any non-MDS drugs'**

In some cases due to the nature of the medication, items will not be within the MDS system. Commonly such items are stored in the doors of the drugs trolley.

In the case of an interruption, if medication has been located ready for administration, then it needs to be made secure until the administration can be completed.

- **Task 3.3 'Measure out any liquid medication'**

Medicines in liquid form require to be measured out into a small container prior to administration to the resident.

In the case of an interruption, the measured medicine needs to be made secure.

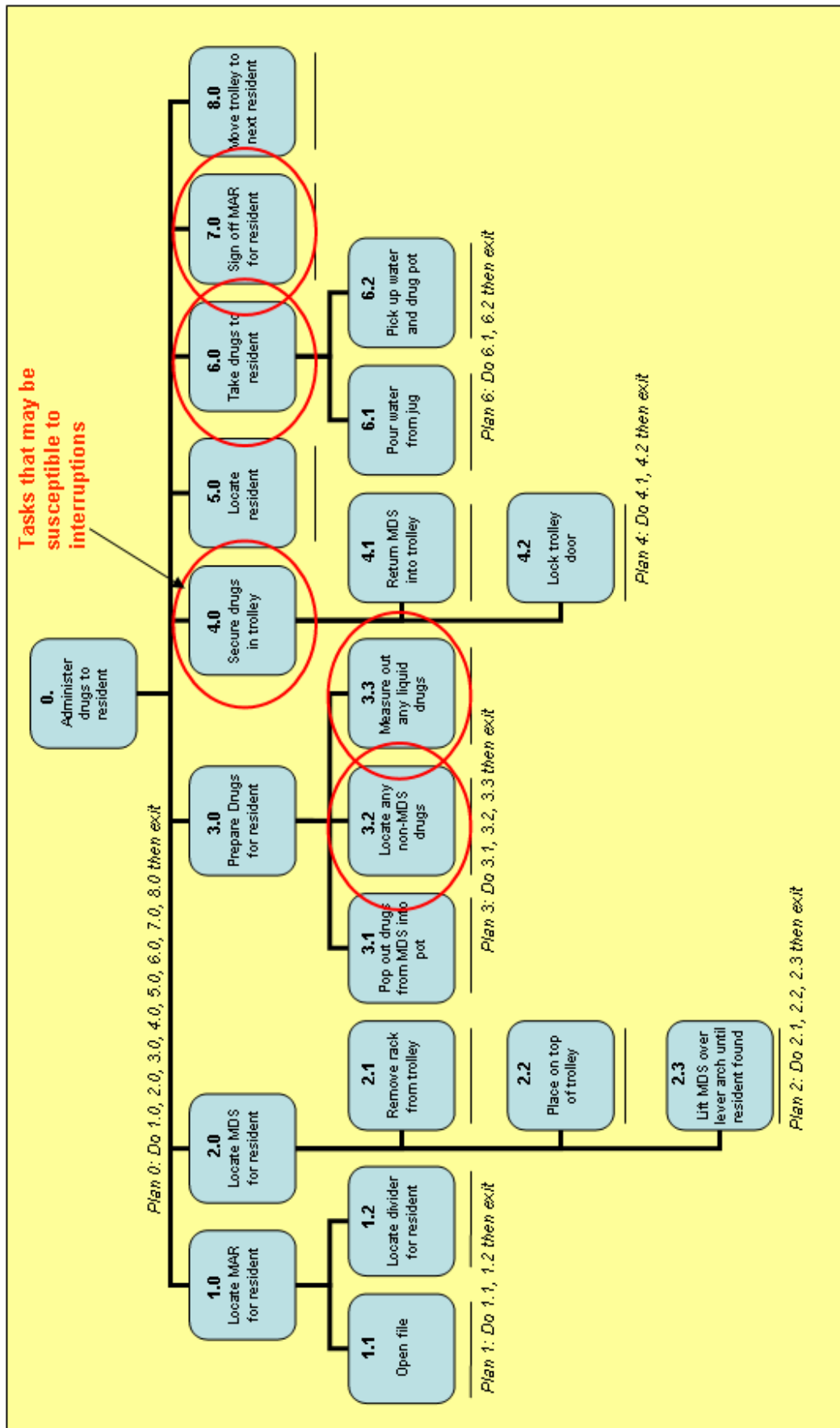


Figure 7.21: Drug round practices, interruption issues

Figure 7.22 indicates those dispensing tasks with communication links that are essential components if task completion is to be successful. They are identified as follows.

- **Task 1.0 ‘Get prescriptions’**

The pharmacy need to obtain the prescriptions prior to the start of a typical 28 day cycle of administration in the care home. In most cases, the home insists on seeing the prescriptions from the GP surgery before they go to the pharmacy for dispensing. This allows a check to be made on any missing, not required or incorrect medicines. However, in a small number of cases the prescriptions went straight from the surgery to the pharmacy. This may allow a greater number of errors in dispensing to occur.

- **Task 1.1 ‘Driver collects prescriptions from home’**

The prescriptions are generally collected from the care home by a driver employed by the pharmacy, although in some cases the care home take the prescriptions to the pharmacy themselves. By whichever means this occurs, there is a variation in the amount of feedback from the home to the pharmacy on events during the preceding medication cycle (typically 28 days). Information is needed by the pharmacy on medication that has either been changed or stopped for each resident since the last dispensing cycle. In some cases, the care home supplies a copy of the previous MAR chart, in other cases there is a second version of the MAR chart with columns for the care home to note changes that are intended for subsequent action by the pharmacy.

- **Task 1.2.1 ‘Prescriptions faxed from home’**

Most care homes used a FAX machine to send ad-hoc prescriptions during the medication cycle to the regular pharmacy for dispensing. A common issue raised by care home staff was that they didn’t normally get confirmation from the pharmacy that the prescription had been received. Additionally, there were occasions when, due to opening hours and distance from the home, a local pharmacy was used instead of the one handling the main medication cycle. On these occasions it was observed that there was often no documented procedure to inform the main pharmacy of the additional/changed medication.

- **Task 2.3.1 'Check with home'**

When the pharmacy goes through the process of preparing the prescriptions for dispensing (e.g. ordering medications, printing labels etc) they check the prescriptions against those dispensed during the previous cycle. When changes are observed they often need to confirm this change with the care home. The pharmacist normally does this by telephone. It was reported during interviews with the pharmacist, that one problem is that they can rarely speak to the same person at the home on each occasion. This can make it difficult to obtain definite confirmation that the changes are actually required and that it is not a problem with the prescriptions from the GP surgery. This is one potential reason for 'discontinued items' on the MAR chart, as the pharmacist may not be confident that the change is to be made.

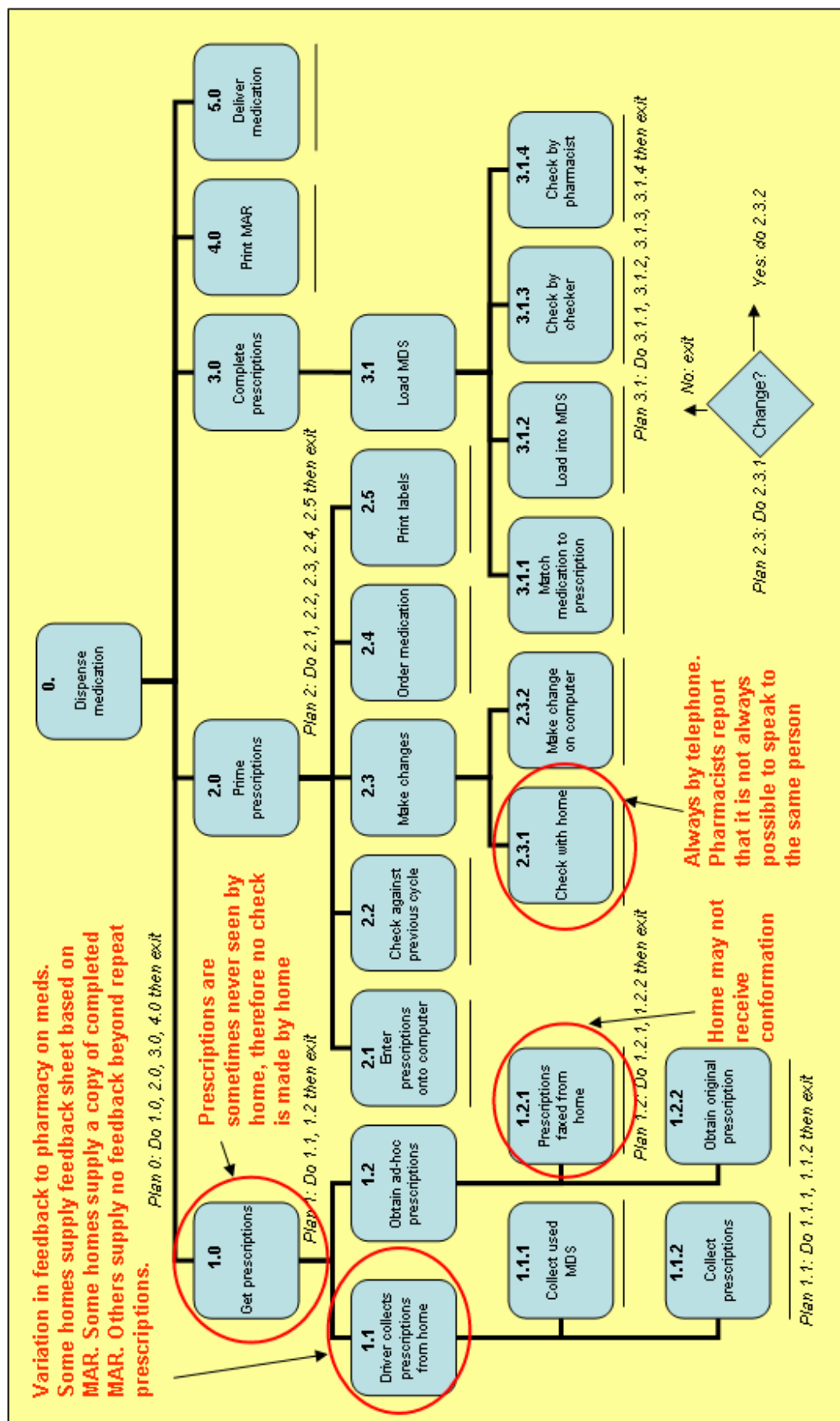


Figure 7.22: Dispensing practices, communication issues

7.5.5 Consequences and areas for action

In addition to the task observations and analysis, further ergonomics system factors were analysed. This identified a significant number of areas of concern that could directly or indirectly compromise the performance of the home with respect to medication administration. These areas are listed below.

1. Task Interruptions

- Staffing levels influenced interruptions
- Other duties required during round
 - Manager/assistant manager doing round
 - Nurse with responsibility for care staff supervision
- Training often low or absent
- Very few interruptions relevant to completion of the drug round (e.g. feedback on a residents reaction to earlier medication etc)
- Wide variation between homes, normally due to either difference in staffing levels and 'other' duties, or in the level of attention required by residents between care types (i.e. nursing, residential, dementia etc)

2. Physical ergonomics of the trolley design

- Lack of space on top surface
- Poor posture when lifting MDS out of interior
- Poor manoeuvrability
- Lack of storage 'pockets' to aid in organising non-MDS medication
- Top surface often too high for comfortable use/entry on MAR chart and sorting of MDS cards
- Often observed trolley being kept in one location during the round, not moved to resident
- In some cases mainly used just for secure storage, not portability

3. **Physical ergonomics of building design**

- Inadequate lighting for task
- Narrow corridors
- Poor ventilation
- Little natural light
- Inadequate elevators for trolley
- Emergency call systems poorly designed
- Contrast with some purpose built homes

4. **General**

- Need to secure medication in trolley between residents was time consuming, awkward to complete and distracting to the primary task
- Variation in how water was supplied to residents with medication (e.g. on trolley, already in rooms etc)

5. **Discontinued items**

- Observations suggested that this was not a widespread problem (this contrasted with the analysis of errors in the CHUMS project)
- In many cases there were no discontinued items
- Not often viewed as a problem by care home or pharmacy staff
- Design improvements could be made to reduce impact further
- Most pharmacies had procedures in place to reduce or eliminate the issue
- Scope to enhance existing procedures further through software re-design and communication procedures

6. **Communication**

- Normally reported by both pharmacies and care homes as reasonably good
- Main mechanisms used are FAX and telephone

-
- Possible weakness in the procedures and mechanisms available for care homes to communicate with pharmacy
 - Variation in the use of the MAR chart to feed back data on next drug cycle requirements
 - Some homes did not see prescriptions prior to dispensing by pharmacy
 - Both pharmacy and care home staff would like to see the scope for more visits by pharmacists and GPs to care home
 - Patient medical and medication information could be more comprehensive/suitable for tasks at both the pharmacy and care home

To further appreciate their implications, a table (Table 7.1) has been constructed that includes suggestions regarding the consequences of each issue and also possible actions to resolve each. It must be stressed that these are suggestions that might be explored and tested rather than being 'answers' to the problems raised. (Note: It was not possible within this study to provide and test solutions to the problems encountered.)

Table 7.1: Ergonomics systems problems, consequences and actions

Ergonomics systems problems, consequences and actionsCategory	Observation	Consequences	Suggested action
Staffing issues	Staffing levels	Insufficient staff available to deal with unexpected events during the drug round	Improve staffing levels. Two staff to conduct busy drug rounds
	Other duties required during drug round	Interruption of primary task to complete other duties (e.g. answering telephone or door. Dealing with staff management issues)	Review staff duties during a drug round. Temporary switching of duties during the critical time.
	Training often low or absent	Drug round staff unable to identify mistakes or required changes in medication. Unable to recognise physical symptoms either resulting from or requiring medication	Address training priorities specific to conducting a drug round. Ensure knowledge of common medications including their purpose and possible side-effects.
Trolley design	Lack of space on top surface	Difficulty in organising MAR charts and MDS systems. Spillages during drinking water dispensing. Limited room for measuring out liquid medication	Trolley re-design
	MDS location inside drug trolley	Poor posture required to either remove or return MDS file to the drug trolley	Re-design trolley interior to permit better location of MDS files. Review design of MDS file to facilitate better match with trolley interior
	Poor manoeuvrability	Trolley left further away from resident to avoid the problem. Potential posture problems while pushing/pulling	Re-design of trolley wheels. Consider recent developments in trolley design in other sectors (e.g. retail)
	Lack of storage 'pockets for non-MDS medication	Medicines stored in old margarine tubs, or loose in the trolley door	Re-design trolley interior to accommodate non-MDS medicines. Better use of door cavities
	Top surface often too high for comfortable use	Potential for mis-reading/completing of MAR chart, or mistakes in selecting correct MDS for resident	Use ergonomics standards to assess working height suitable for standing task. Re-design trolley to suit

Category	Observation	Consequences	Suggested action
Trolley design	Kept in one location during drug round. Not moved to residents	Trolley is being used as secure storage rather than a mobile facility	Consider use of a 'drug room' in particular homes. This allows better space for storage, filing, drinks etc.
Building design	Inadequate lighting for task	Inaccurate measurement of liquid dosages. Small increase in potential for mistakes on MAR or selecting MDS	Conduct lighting surveys in care homes. Consider localised task lighting, possibly integrated in trolley design
	Narrow corridors	Leaving trolley further from resident. Interference with other procedures in the home (e.g. residents moving around home. Staff movement)	Design input to new home builds. Establish standards for building conversions. Design narrower trolley
	Inadequate elevators for drug trolleys	Potential physical injury while manoeuvring trolley into elevator. Trolley left on ground floor	Establish criteria for lift design in new and converted buildings. Study into trolley dimensions to suit existing lifts
	Emergency call systems poorly designed	Distracting noise during drug round	Check volume and pitch against hearing characteristics of staff. Use of more visual signals
General observations	Variation in how water is supplied for residents during drug round	If transported with trolley, often resulted in spillages and used valuable space on the trolley top	Consider supplying fresh water to residents just prior to the drug round. This is already practiced at some homes
	Residents not able or unwilling to take medication at the time of the drug round	Doses can be missed and not discovered until the next round	Supply a checklist on the drug trolley that can act as a reminder to staff on completion of the round. Each resident could be ticked off when ALL medication has been given. This would also be an aid when the drug round has to be interrupted

Category	Observation	Consequences	Suggested action
Communication	Ad-hoc prescriptions are faxed to the pharmacy for dispensing	Homes often have no feedback to acknowledge that the prescription has been received. Time is wasted in contacting pharmacy to confirm	Introduce a procedure whereby faxes in either direction are confirmed immediately via a return fax or telephone call
	Often no formal way for the home to feedback information to the pharmacy on changes in medication since the last cycle	Can result in items being included on the MAR chart that are no longer required. Wasted time for pharmacy in checking with the care home to clarify missing prescriptions	Some homes already have a feedback form associated with each sheet of the MAR chart. This could be recommended across all homes.
	In some cases when a GP prescribes medication during a typical 28 day drug cycle, the home will obtain the medication from a local pharmacy and not the one used for the whole cycle. Information on these events is often not fed back to the main pharmacy	This results in the main pharmacy not having a comprehensive record of medication for particular residents. In isolated cases it could mean that the expertise of the pharmacy could be wasted in relation to possible interactions between medicines.	Introduce a procedure to ensure that any ad-hoc medication during the 28 day cycle is reported back to the main pharmacy for their records

7.6 Further Potential Systems Improvements

In addition to those areas identified in table 1, a number of key bottom-level actions from the task analysis diagrams presented in section 7.4.4 (Figures 7.19 & 7.20) were analysed using SHERPA (The Systematic Human Error Reduction and Prediction Approach).¹⁰⁹ This method and the reason for its selection are described in Appendix I (section 4.0).

Table 7.2 documents the results of the analysis. The columns and their contents are described below.

- Column 1 – Task step

This is the reference number for the bottom-level task and in this instance can be found in Figures 7.19 & 7.20

- Column 2 – Error Mode

Error types are categorised into action, checking, retrieval, communication, and selection errors. Each error type has a number of associated error modes. These are given codes. Action errors are coded A1 – A10, checking errors C1 – C6 etc. A full list of error modes can be found in appendix 5 (Table 1)

- Column 3 – Description

An outline description of the potential error

- Column 4 – Consequence

A prediction of the consequences of the error

- Column 5 – Recovery

This column indicates whether or not the error can be recovered. If the error can be recovered by performing another task step in the task analysis diagram, then it is referenced here. If it is not possible to recover the error then column 5 is left blank

- Column 6 – Probability

This column indicates the probability of the error occurring and is categorised as low (hardly ever occurs), medium (has occurred once or twice) and high (occurs frequently)

- Column 7 – Remedial measures

Column 7 (the last column) indicates measures that could be taken to reduce errors. These would require further investigation and assessment of suitability before implementation. They are based on sound ergonomics theory and practice.

Table 7.2: SHERPA Analysis

Task step	Error mode	Description	Consequence	Recovery	P	Remedial measures
4.2 (Fig 7.21)	A8	Drug trolley not locked while left unattended	Drugs obtained by wrong resident	None	L	Simpler (self-locking) mechanism for doors. Clear visual indication on top of trolley.
7.0 (Fig 7.21)	A9	MAR chart not fully completed for resident. Not all drugs administered recorded as complete	Dose missed or given twice	None	L	High-level checklist to be completed after each resident and on completion of round. Additional tasks should be identified if/when reviewed
1.2 (Fig 7.21)	A1	Can take a long time to find resident divider in MAR chart file	Disrupts flow of drug round. Places staff under greater time pressures. Task then more likely to be interrupted. Can lead to general errors	None	L	Improved ordering of residents in file. Better labelling
3.3 (Fig 7.21)	A4	Too much or too little drug measured out	Wrong dose given to resident	None	L	Better corridor/room lighting. Clearer marking on measuring container. Recovery procedures may be picked up through review or observation by others

3.2 (Fig 7.21)	A1	Cannot locate non-MDS medication in trolley	Either missed dose or delay to drug round. Places staff under greater time pressures. Task then more likely to be interrupted.	None	L	Better trolley design, permitting clear labelling of loose medication with residents name
1.2.1 (Fig 7.22)	I1	Prescription not received by pharmacy	Missed or late dosage given to resident	None	L	Procedure requiring pharmacy to acknowledge receipt of FAX
2.3.1 (Fig 7.22)	A9	Confirmation of changed/completed medication not fully obtained from care home by the pharmacy	Items supplied that are not required	None	L	Improve mechanism for feedback to pharmacy on changes since last cycle. Recovery procedures may be picked up through review in the longer term
4.0 (Fig 7.22)	I2	Items no longer being administered are included on MAR chart	Can lead to missed administration due to unclear MAR	None	L	Review pharmacy software interface design to allow items to remain on record, but not on MAR. Recovery procedures may be picked up through review in the longer term

7.7 Discussion

7.7.1 Existing system

The ergonomics findings have focussed on three areas deemed to be priorities. These areas were established during the study as trends in the data pertaining to the medication errors were observed during the epidemiological phase of the CHUMS research.

The chronology of the investigation and the availability of resources (including access to care homes) meant that decisions regarding priority areas had to be made before all the epidemiological data were available or had been analysed.

Areas for ergonomics investigation were chosen, therefore, on a combination of criteria. The first was that a higher incidence of errors appeared to be associated with them (based on the epidemiological evidence at the time of the decision) and the second criterion was that the issues chosen should give insights into three of the essential components of any socio-technical system, namely communication (both written and verbal), physical design and problems associated with critical task completion.

In this discussion, key findings from each area are re-iterated. Following this, a fuller discussion is provided on the potential benefits of the extended implementation of ICT in this sector.

Critical Task Completion

Successful completion of tasks is dependent on many factors within the system. One critical task has been studied in this research, namely administration of medication during the drug round within the care home. In many regards, the system used mirrors that found in most acute hospital ward settings. However, in many critical ways it differs from this system, perhaps most notably in the availability of appropriately trained health care professionals within the immediate system.

The drug round was observed in many care homes and at different times during the day. Most drug rounds were interrupted by other tasks with up to 12 interruptions per hour occurring. The source of these was, most often, other staff. This would suggest that a review

of all staff duties during the drug round period might be initiated to further understand why requests from other staff were so frequent. It might also be that planned 'breaks' within the drug round might be required if qualified personnel undertaking the drug round are needed for other 'non-urgent' tasks.

There is also a need to ensure that staff undertaking the drug round have the required knowledge and experience to conduct drug administration in a safe and reliable manner. This may include greater attention to ensuring each has knowledge of common medications, including their possible side effects, and an understanding of how high current rates of error appear to be.

The use of the drug trolley has many limitations and may be contributing to the likelihood of errors occurring. The design of the trolley appears to have changed little over a long period of time. This is in spite of vast differences in the extent of medication that patients / older residents are likely to be receiving currently. Urgent re-design of trolleys or other systems for storage (notably for MDS) and administration of medication to reflect this current need should be sought.

Some homes prefer to administer medication from a fixed location, for example a small drugs room/office. This appears to offer many advantages and reduced likelihood of interruption. For those homes where this is an option such examples of improved practice should be encouraged. That said, all such interventions will require further evaluation as too few were observed in this study to enable conclusions regarding efficacy to be reached.

The physical design and layout of care homes appears to have benefited little from ergonomics knowledge. Evidence in the form of too low lighting levels (making reading of medication information and MAR charts potentially difficult), corridors that prevented passage of trolleys, poor design of emergency call systems, and elevators that were too small to accommodate drug trolleys all suggested little systematic development or application of design criteria for care homes. This appears to be a relatively straightforward area for advancement and the design/architectural community should be urged to advance this area (perhaps with the help of the National Patient Safety Agency.)

7.7.2 Future systems and information technology (IT)

Historical perspective

At the 'birth' of the UK National Health Service, there was no widespread availability of computing technology, and the service grew and expanded for many years utilising a paper based system of records. However, during the preceding twenty years, there had been a worldwide acceptance that computing and information technology (IT) can or should make a contribution to the administration/operation of health services. From a review of the literature, it was clear that the extent, pace, strategy, and quality of implementation varies from country to country.

Progress on IT within the UK

In the UK, the strategy centres on the 'Connecting for Health' project (*NHS 2005*). This is a £6.2 billion government initiative spanning some 10 years, due for completion in 2014. It is intended to connect over 100,000 doctors, 380,000 nurses, and 50,000 other professionals. The components of the system are;

- NHS Care records service
 - Electronic care record for every patient
- Choose and Book
 - Electronic booking service
- Electronic Transmission of Prescriptions (ETP)
- National Network (N3)
 - IT infrastructure and broadband
- Contact
 - Central email and directory service

Connecting for Health (CforH) has generated a significant quantity of negative press in recent months, most of which appears to be related to acceptance by the users, of early implementations of some of the new systems. The need to gain the support and

commitment of not only senior management, but front line staff and users was recognised as a potential weakness in CforH by Humber.¹¹¹ He cites the BMA's demand for greater involvement in the programme¹¹² as a sign that the incorporation of some important user groups had, at the time (i.e. May 2004), been poor. More recently there have been signs that the earlier warnings from the BMA had not been heeded. In a press release in June¹¹³ the BMA, in response to the National Audit Office report¹¹⁴ stated "The report criticises the National Programme for not doing enough to engage with healthcare workers using the system, a sentiment shared by the BMA". In fact a year earlier a study and report prepared by QinetiQ for the National Audit Office¹¹⁵ found that in its sample of project processes, most had been executed 'fully' and as recommended by recent international standards^{116,117,118} with the exception of 'stakeholder requirements definition' which they rated as 'partially' compliant with the standards. QinetiQ made recommendations for 'improvement opportunities'. In actual fact, the National Audit Office report¹¹⁴ is broadly complimentary about the management and execution of the project in the majority of areas, with the exception of "winning the support of NHS staff and the public".

Many of the problems appear to relate to compatibility with computer hardware and software already adopted by many GPs surgeries and pharmacies. The need for CforH to link with such existing platforms has caused additional problems and delays not apparently anticipated at the outset of the project.

There does seem to be general agreement on the need and importance of a coordinated adoption of IT in the UK Health Service. Humber¹¹¹ states that without a national programme for IT "Equitable health care free at the point of need, financed through taxation, would be unsustainable and the rising costs prohibitive".

Progress on IT in Australia

In Australia the government has launched the 'HealthConnect' project. Considerably less direct government funding is going into this initiative (\$128 million over four years), as the project is intended as a facilitating and steering body, helping smaller clusters of hospitals and GP surgeries across Australia to independently adopt new IT technology that will ultimately link together at a National level. Australia has a larger proportion of its health

service in the private sector, and therefore the government's role is as a steering body. The general philosophy seems to be to trigger organic growth by helping local clusters to implement the basic infrastructure first. For example, the Australian government has invested around \$60 million in a 'broadband for health' program. This offers local health service providers a grant to implement industry standard broadband services within their establishments, as long as they fulfil certain criteria to qualify. The aim is to ensure that ultimately all health service providers across Australia will be connected to a common, and nationally compatible, broadband service. This will then form the foundation for further national IT implementations.

Focus on IT for care homes in Australia

Interestingly, although we could find no direct reference to the IT needs of care homes for the elderly within the UK Connecting for health project, the needs of this sector feature centrally within the Australian government's initiatives. Their government department itself is entitled 'The Department for Health and Ageing', and promotes major schemes dedicated to the aged care sector. One such scheme is 'e-Connect'. Quoting the Australian governments web site, e-Connect is designed to "create an enabling environment to leverage the use of IT to improve efficiency, quality of services and care delivered to older Australians".

In June 2006, the Australian Minister for Ageing, Julie Bishop, announced a one-off payment of \$1,000 per resident for residential aged care providers. The payments, which will total \$152 million, are to help aged care providers take advantage of new technology, improve their business practices, and increase staff training, particularly in dementia care.

Under the e-Connect initiative, there is a project named 'Clinical IT in Aged Care'. The cited goal for this project is to investigate how "clinical IT applications or tools can support and improve care standards for residents in aged care homes". Within this project a number of pilot studies have been implemented. Of particular note is aged care provider Lyndoch Warrnambool Inc.¹¹⁹ This case study describes the implementation of a wireless care management system into a large aged care facility in the South West of Victoria. Lyndoch supplies care to a total of 194 residents. The government report claims a high level of staff

and management satisfaction (no mention of residents satisfaction!). The research project was completed in February 2006.

Further trials through the Australian e-Connect project include electronic prescribing in aged care, as reported by Perkins et al.¹²⁰ This trial has studied the use of electronic prescribing and generation of medical charts. It involved the use of an existing GP clinical package in aged care homes. These were also installed in GP practices. The study looked at remote access by GPs, of medication information stored at the care home. Preliminary findings reported in Perkins et al.¹²⁰ have identified some problems, but these were mainly minor logistical issues. The main limitations of the trial were identified as the nature of the selection of GPs (self-selected), and that these probably represented a population sample that was particularly enthusiastic about the technology. At the time of writing, no final results could be sourced.

Progress on IT in the USA

In the United States of America (USA), President George W Bush, in 2004, launched an initiative to facilitate electronic health records for 'most' Americans by 2014. Interestingly, the same as the target completion year for the UK Connecting for Health programme. The US government has established the American Health Information Community (AHIC), being a committee comprising of both public and private representatives. The role of AHIC is to make recommendations to the president on achieving his stated goal. As the US does not have the equivalent of the UK National Health Service, the US government uses its influence to encourage the availability of affordable health insurance to vulnerable groups such as the elderly. According to statements from The Whitehouse (www.whitehouse.gov), the government is 'supporting' several health IT projects.

It will be interesting to see how the US private health care sector reacts over the next decade to government pressure to adopt IT in their operations. It is likely that market forces will drive health suppliers to 'stay ahead of the competition' through the application of new technology. It will be the central governments intention to ensure compatibility of platforms across states.

Focus on IT for care homes in the USA

The US government supports the availability of health care specifically for veterans through the Department of Veterans Affairs. On their web-site (www.va.gov) they state that their goal is to “streamline and modernize the information technology (IT) environment throughout the Department of Veterans Affairs (VA)”. It would appear from this, that this particular section of US society may well have access to IT based health care ahead of the general public.

It can be observed that the UK Connecting for Health (CforH) management, through their web-site (www.connectingforhealth.nhs.uk), point to the US Veterans Health Administration (VHA), as having the worlds largest functioning health information technology system. The computer system is known as VistA (Veterans Health Information Systems and Technology Architecture). The system is in place and operating in over 1200 care establishments across the USA. It includes a ‘computerised patient record system (CPRS). This, at the time of writing, was understood to include records for 8.5 million veterans. CforH believe that the US Vista system demonstrates that a single national health record ‘can work’.

Compatibility and cooperation worldwide

Another issue arising is the possibility of not only being able to access patient records across one nation, but to be able to do the same across the globe, and for many years. One such initiative is OpenEHR.¹²¹ This is a not-for-profit international collaboration between University College London (UCL) and Ocean Informatics Pty. Ltd., in Australia (www.openehr.org). Its goal is to make available open architecture standards internationally in order to encourage development of EHR systems with a common IT format. Through this initiative they hope to “Make the interoperable, life-long electronic health record a reality”.

One way forward in ‘global’ standardisation, would be to agree the content of an electronic patient record. To this end, ASTM International¹²² recently released a standard specification for a “core set of patient data that follows patients as they receive care”. The data includes the patient’s health status, treatment, allergies, medications and tests. Additionally, it

contains identification data, family health history, insurance, advance directives, care plan and care provider.

The future for IT in health care

There seems to be many hurdles yet to negotiate before a fully implemented Nationwide, if not worldwide IT system is implemented in the various Health Services. However, Blair¹²³ editor of Health Management Technology (Nelson Publishing Inc.) in a recent note from the editor made an interesting observation, suggested to him by Simmi P. Singh (vice president of Cognizant Technology Solutions). He proposed that a quicker route would be to supply patients with a 'credit card' style plastic card, which would store a range of basic medical information needed at the point of care. He believes that it would only required the familiar magnetic strip and not even the more recent 'chip' technology. He describes a situation where a patient would walk into a surgery and the doctor's receptionist would swipe your medical card through a reader which would then generate an 'electronic thumbnail sketch' of your current medical records. This way, the treating doctor would have important information on such things as allergies, recent medication etc. before suggesting any new treatments.

Chapter 8

Discussion

8.1. Introduction

We start by recognising the enormous support that care homes gave to this study. It was a challenging study to participate in, and we had a pleasing acceptance rate by the homes – 72% of those we approached took part, and many others were willing to do so, but could not do so within the timeframe of the study. We also came across some very dedicated people – care home managers who would not take more than two weeks holiday because they were worried about the ordering and delivery of medicines, and GPs and pharmacists who gave a personal service to a home, no matter what the time of day or night. We also found some examples of innovative and skilful practice, which we highlight later in the discussion. We take these as important markers of interest and commitment in this field, and as promising markers of a willingness to change. And change is certainly needed.

When we observed residents who were on medication, seven out of ten were subject to at least one type of error: prescribing, monitoring, medicine administration or dispensing. For each act of prescribing a medicine, dispensing it, or administering it, there was around an 8-10% chance of an error occurring; there was a 15% chance of a monitoring error.

Care home residents are among the most vulnerable people in society. Very elderly, often frail and immobile, many suffering some degree of dementia or other mental health problems and often with multiple pathologies, they are people who can often gain considerable benefit from medicines. In contrast, they are also some of the most vulnerable to side effects and to errors, and lack the advocacy and communication skills to report them. The very elderly have a reduced resilience to the challenges to the body that result from errors. Many of the errors we observed were negligible or trivial in their consequences, and we did not observe any cases of serious harm in the 256 residents we studied. However, if 1% of residents suffered serious harm, we might well miss it in a study of this size and design. We also saw errors which might impact on the quality of life and independence of the residents. The qualitative aspects of this study illustrate the

nature and contributors to many such errors, and we suggest some ways forward later in this chapter.

Table 8.1: Care Homes Use of Medicines Study – compliance chart

Statements in original research proposal	Comment
Aims	
(1) To establish the prevalence, types and underlying causes of medication errors, and the ensuing harm.	Met in full
(2) To develop solutions to reduce the prevalence of error	Met in full
Objectives	
To provide a typology of the errors.	Met in full
Objective To investigate the prevalence of different types of medication error (prescribing, monitoring, administration, dispensing, interface) with sufficient precision to: <ul style="list-style-type: none"> a. Indicate their relative frequency b. Identify the areas of greatest concern c. Allow sample size calculations for further intervention studies. 	Met in full
To apply the principles of ergonomics to: <ul style="list-style-type: none"> a. Analysing existing systems b. Understanding and mapping the medication pathway. c. Understanding and mapping the information pathways. d. Generating, evaluating and prioritising solutions. 	Met in full
Sample	
To get within +/-2% of a prescribing error rate of 10%, when between home variability runs up to a maximum of 6%, we need 100 homes, and 3 patients per home. Alternatively, we can use fewer homes if we increase the proportion included per home.	Partially met. Recruitment & study of homes, GPs etc took longer than estimated. As noted in original proposal we could have studied more patients per home, at fewer homes. Once in a home the marginal cost of recruiting extra patients is small, so we chose this option, finally recruiting 256 patients from 55 homes. We achieved our aim of +/- 2% precision in prescribing error rate with this sample size.

8.2 Prevalence of errors and comparison with other sectors

How does the prevalence of the errors we observed in homes compare with previous reports? We have focussed here on the UK literature, because error rates are very context dependent: they can be affected by many factors that are different in other countries, such as staff training, and systems of ordering, dispensing, delivering, distributing and paying for drugs. We have also taken into account that the way errors are defined and measured can make major differences to the results that are reported. For this reason we have focussed on observation-based research based on agreed (usually user defined) definitions of error; these are probably the best estimates we can get, and are comparable with the methods used in this study.

8.2.1 Prescribing and monitoring errors

There is relatively little information about the prescribing error rate of GPs in the UK; there is slightly more information on hospital doctors' prescribing errors, and we could not find any comparable UK data on monitoring errors in primary care. In our study 39% of patients had at least one prescribing error and, for any given prescribed medicine, the probability that there was an error in the prescription was 8.3%. This is similar to the 7.5% error rate of GPs studied in 2001,¹²⁴ which also, as with our study, found incomplete information on the prescription to be the commonest form of error. Studies of prescribing errors in hospitals, based simply on studying the medicines chart, showed a 1.5% error rate across a hospital,⁵⁷ however subsequent research found that studying the patient's notes as well in a study of a complex surgical ward revealed a three times higher error rate.⁵¹

Of the patients who had at least one medicine that required monitoring we found 18% were not being monitored properly; for every medicine that required monitoring there was a 14.7% likelihood that this would not be done. This was significantly more likely in London than elsewhere. We could not find any analogous studies on monitoring errors.

In summary, what little evidence there is would suggest the probability of a GP committing a prescribing error when prescribing for a patient in a care home is similar to that in general practice for each item initiated. However, our residents were prescribed an average of 7

items each, so the probability that a patient would receive an error is greater than if they were on fewer medicines.

8.2.2 Dispensing errors

Dispensing errors were found in 9.8% of the doses examined; 37% of residents had at least one error. This is a high percentage, compared to 3.3% of doses found in a study of 11 community pharmacies dispensing to ambulant patients (Franklin & O'Grady 2007), and less than 1% in hospitals (Beso et al 2005.) . Part of the cause of this high rate is the different ways in which medicines are repackaged and dispensed for homes; we explore this in depth later.

8.2.3 Administration errors

Medication administration errors were observed to occur to 22% of the residents we observed; 8.4% of individual administrations were erroneous. There are two comparators that could be used here: the administration error rate in hospitals, and that of people taking medicines when at home (called non-compliance or non-adherence). Since 1995 there have been 10 comparable studies of administration error in UK hospitals, covering a total of 28,426 administered doses and a number of ward based administration systems. The average error rate is 5% (range 3.0%-8.0%)^{52,54,55,125,126,127,128,129,130,131} suggesting the rate in care homes is high in comparison to hospitals. As is found in hospitals, around half the administration errors were omissions (medicines being out of stock, or staff missing medicines they should have given). In hospitals medicines are administered by nurses and, in our study, nursing care patients (who have medicines administered by nurses) received around half the administration errors of people in residential care, who have medicines administered by carers (although this just failed to reach statistical significance). Nursing care patients may therefore be closer to hospital patients in their error rates; this makes medicines administration in people in residential care all the more worrying.

It is harder to compare the 8.4% error rate with what happens when people are at home. We know that of patients who take medication for a chronic condition around 30-50% will not take their medication as directed,¹³² and that about half these cases voluntarily choose to stop taking the medicine, or adjust the way in which they take it.¹³³ However this has

limited relevance to people in care homes, many of whom are there because they can not cope with tasks such as medicine taking. In our study many were showing some signs of dementia and would not have been able to take their own medicines reliably.

8.2.4 Harm

Our methodology was designed to identify errors; a study to identify harm would have been designed differently. We used a method to predict harm, using a 0 (no harm) to 10 (death) scale. Monitoring errors produced the largest mean harm score (3.7), and the tightest range, with the lowest score being 2.8 and the highest 5.2. In some ways this is not surprising, in that medicines which are monitored are associated with some significant risk of toxicity, or the need to ensure efficacy. The high score and narrow range confirm that monitoring errors are an important group. Prescribing errors were the next most severe (mean 2.6, range 0.2-5.8). This is substantially lower than the mean score previously reported for prescribing errors in hospital in-patients, where mean scores of 4.2 and 4.6 were reported before and after computerisation, using the same scale of potential harm.⁵⁵

Dispensing errors and medication administration errors were the next most serious, and fairly similar (dispensing mean 2.0, range 0.2-6.6; administration mean 2.1, range 0.1-5.8), with a low mean score but showing examples of errors at the upper end of the 'moderate' range. A previous study of dispensing errors in community pharmacies reported a mean score of 2.4¹⁴⁴ and a recent study of medication administration errors in hospital in-patients reported a mean score of 2.7 for a paper-based administration system.⁵⁵ These mean scores are both similar to those reported in the present study.

8.2.5 Limitations

There are limitations to the statements we make about the prevalence of errors, their causation, and the extent of harm. First, the study required the consent (sometimes assent in the case of residents) of the home, GP and resident, in that order. If all three were not met then no data was collected. Clearly, those concerned about their practice would be more likely to refuse to take part in the study, leading to our results being underestimates of the severity of the situation. Similarly, in the ergonomics study, the choice of homes to visit was limited to those that were prepared to give access. We may therefore have been

excluded from those homes who felt threatened by the research. Having said that, we felt the response rate of homes (the highest response rate of all those that had to respond) was remarkably high, and gave us confidence. The team approached homes with a supportive attitude and were well received by and large.

Our sample of homes was not random and therefore the prevalence we found can not be said to be generalisable. On the other hand to ensure representativeness, it was based on a stratified sample derived from the national distribution of care home size, and designed to represent different areas of the country. Home size may be a significant factor as it relates to the organisation (very small homes tending to be family or small businesses, large homes tending to be large organised chains), which in turn is likely to affect the causes of error. The areas of the country were intended to represent urban, suburban and rural (including homes served by dispensing doctor practices). Our inclusion criteria for patients also need to be considered, as we only included patients on medicines, rather than all residents; in practice nearly all residents were on medicines. In addition, randomisation was applied to the choice of patients in each home.

The definition of errors is always contentious, and our goal was to avoid over specifying errors, and hence we used user defined definitions, as described in our methods. However we recognise that dichotomisation of complex judgements and situations into 'error' or 'no error' will always be the subject of active debate. The identification of errors inevitably has an element of subjectivity. However, we sought to minimise this specifically, some of our group have been studying medication errors for 17 years and we had several meetings, discussions and prepared a formal guide to help the assessors have a shared understanding. Once data collection had started we had regular meetings to discuss judgements in difficult cases.

The pharmacist assessors trained with each other to encourage uniformity. However each area of the country had a different pharmacist, and we can not rule out that differences between areas of the country reflect differences in the pharmacists assessing them. For this reason we have not focussed on 'geographical' differences in the discussion. When collecting evidence in homes, pharmacists observations may also have been affected by factors which affected home staff, such as distractions.

The validity of the analysis of the causes of medication errors was limited by the availability and access to information. For example, exhaustive interviews with medical practitioners in relation to the errors identified was not possible and the reliance on historical records may also carry bias and not reflect a true picture of all the factors contributing to the incident.

The presence of observers will have some effect on those administering medicines, and on the pharmacy staff when observed. There are two responses to this, theoretical and empirical. The theoretical response is that, using Reason's theory, we see that most errors, for our present purposes, can be divided into four groups.

- First are those errors that the practitioner has no control over – such as a medication not being administered because there was no stock.
- Second, the person knows what to do and inadvertently does the wrong thing, or forgets to do the right thing (slips and lapses). In these cases the act is unconscious and so is unlikely to be altered by an observer.
- Third, the person has a plan and enacts it, but the plan is wrong (a mistake); it is based on ignorance or incorrect understanding of something. As the practitioner thinks they are doing the right thing they would be unlikely to change it because of an observer. In our experience these errors are quite common in medication error.
- Finally there are 'violations', errors in which the practitioner consciously breaks the rules. In some cases the practitioner is happy to do so in front of an assessor as they believe their action reasonable; in other cases they may avoid violations because they are being observed.

The empirical response comes from our work studying nurses administering medicines in hospitals. In our experience of studying hospital nurses, observation has no effect on the error rates observed.⁶⁹ The majority of errors arise due to poor systems, lack of knowledge or unavailability of the correct medication, none of which can be affected by an observer's presence.

In some areas of the research (e.g. the ergonomics studies), areas of study have been prioritised based on the epidemiological data and on the current literature. This approach was driven by the need to use the research resources optimally, but this process of prioritisation may have led to other important areas of concern remaining unstudied. Thus this section should be viewed as examples of ergonomics systems issues rather than a complete or random selection.

During field visits, the researchers were only able to view specific shifts and drug rounds and the presence of an observer means the patterns of behaviour recorded and analysed during these 'site' visits may not be a full reflection of the practices occurring at other times.

Our work on harm is speculative in that we ask health professionals to speculate on the likely consequences of an error. As the study was not designed to identify harm, we have to estimate it. Errors often lead to harm over a long period of time, and so, following the identification of an error, often we can only try to predict the future. When harm is clear (usually because it is severe) it is likely to be acted on and so fall outside the remit of our study. If severe, it is likely to be identified and rectified, or at least treated, in the home or in hospital; sometimes it will lead to death. There are also limitations in our ability to assess harm from the sample size. To be 95% certain of detecting a 1 in 100 case of severe harm we would need a sample size of 300.; however our sample only included 256 residents. We also have to be aware that the method by which we estimate harm has only been shown to be valid and reliable for medication administration errors.

The statistical analysis is complicated by the tendency of errors to correlated within residents and within homes, and possibly within GPs and pharmacies, our analysis sought to address this, but there remains the possibility that some of our borderline significant findings may be false positives.

In the next section we link the quantitative and qualitative evidence. The qualitative evidence is based on a number of forms of input, which include the opinions of the researchers (elements of the field notes), which will have been affected by their world view. Those being interviewed knew the researchers to be pharmacists and that may have affected their response. Researchers making notes and later interpreting them may also be

associated with biases. In giving accounts of errors and system failures people will be likely to be presenting the account to show them selves in a reasonable light. There will also be several biases, such as hindsight bias.

8.3 Drawing together findings from quantitative & qualitative research

In this section we consider why the errors occur – drawing together the quantitative and qualitative studies. By understanding the causes of errors we can go on to suggest ways forward. First we look at specific types of error, then we go on to common elements independent of the type of error.

8.3.1 Contributory factors to prescribing and monitoring errors

The likelihood that any prescription for a medicine contained an error was 8.3%. The most common errors were that the information was incomplete (for example the dose or route missing) in 38% of errors, an unnecessary drug was prescribed (24%), the dose or strength was incorrect (14%) or a necessary drug had been omitted (12%).

Prescribing seemed to be performed under more uncertainty than was normal for a GP, generally because there was a lack of information or because information was incorrect. The following were reported in interviews:

- A common issue was that the residents themselves were often not accurate historians, or even able to describe their symptoms. This was sometimes compounded by staff who also may not have been able to give an accurate history.
- In some homes the residents would be seen by whichever GP was doing home visits that day, so the GPs often did not know the patient. This is a factor known to be a cause of error in hospital prescribing.⁹⁵
- Additionally, equipment and tests that might normally have been available in a surgery, or even by sending the patient to a hospital, were often not usually available as many of the residents were fairly immobile. Hence diagnosis was made under still greater uncertainty.

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- There were significant problems with residents who had been treated (or had treatment recommended) elsewhere – either another GP practice (in which case there could be delays of up to 4 months in transferring the notes of patients from one practice to another) or a hospital (as an inpatient or outpatient). It is well documented that there are often medication errors when residents are discharged to their own homes from hospital.^{138,139,140,141} This was certainly a common theme, as was an inadequate information flow following outpatient referral.
 - Finally, GPs pointed out that they were prescribing without the usual support given by their computerised prescribing and patient record system, which they would be referring to and using in a normal consultation in the surgery. Hence the patient history was usually missing, as was the drug interaction alert system at the time of prescribing. However most prescriptions for residents in a home were not hand written, as doctors made notes and went back to the surgery to prescribe.

Not all medicines require monitoring, however monitoring is necessary for some medicines that have a high risk of toxicity or where dosage needs to be adjusted. The harm score for monitoring errors was higher than for other forms of errors, which reflects the importance of this function. The most common monitoring errors were for diuretics (55%) and ACE inhibitors (16%). Morris et al¹³⁴ found 37% of “preventable drug-related morbidity” is associated with a lack of monitoring of drugs, with over ¾ involving ACE Inhibitors. Howard et al⁶ found that diuretics account for 16% of medicine related hospital admissions. Pirmohamed¹³⁵ found that after NSAIDs, diuretics were the second most common cause.¹³⁵

What was most marked about the monitoring errors was the geographical distribution: 75% of all these errors were from the homes in London PCTs, (although we were unable to understand why) and 91% of all monitoring errors were failure by the GP to request monitoring. Several factors contributed to failure to monitor – including the way in which the GP surgery was organised to identify and deal with the prompt to monitor, and deal with the results. However what emerged as a more significant problem was the issue of who took blood. We come back to some of these issues as latent errors later in the discussion. There are many factors which make the taking of blood for monitoring drugs an issue. In some areas there is a district phlebotomy service who can be called on to do

this. In some areas this service had been withdrawn on the basis that district nurses could do this, however some of them refused to do so, and one said she would only do it 'if the doctor asked nicely'. Nurses in homes can have problems retaining their competency and confidence, or may just wish not to take bloods. Some homes trained staff, at costs of £200-£700, however they were worried that, given the rapid staff turnover in the sector, these staff may leave. In some cases the GPs reluctantly took bloods themselves, which they found quite time consuming.

8.3.2 Contributory factors to dispensing errors

Dispensing errors were observed to happen to 37% of residents, and they occurred in 9.8% of cases where a drug should have been dispensed. Three quarters of these were labelling errors and a quarter were content errors. Dispensing to care homes is a complex field, as there are several ways of dispensing, the more complex of which are commonly thought to reduce errors and wastage. The three broad methods are :

- Normal dispensing into bottles or packs, with a label containing the resident's name and the dose instructions, as would be done for a patient living in their own home;
- MDS based on a "cassette" which contains all the relevant medicines for a certain day and time (e.g. Monday lunchtime)
- MDS based on blister packs in which, as described earlier, each dose of each drug is accommodated in a separate plastic blister which needs to be popped out to be given.

MDS systems were more common in Bradford than elsewhere; dispensing errors were more common in Bradford than elsewhere. Cassette MDS systems were associated with more errors than blister MDS systems, many of which seemed related to inadequate labelling of these systems (which should include a description of all the tablets for a given day/time). They often are not physically big enough to accommodate all the required labels. The dispensing error rates above are likely to be an underestimate, as the identity of small white tablets is impossible to verify: this is a popular form of tablet and we could not confirm their identities.

The practice of packaging all the medicines for a given patient/time/day (e.g. Mrs Smith, Monday, breakfast) has a long history in hospitals in the USA. Originally all the tablets for a patient/time/day were slipped into an envelope with the details on the front, so the nurse just had to ensure the patient took everything in the envelope at the right time. It was called unit dose and shown to be safer (fewer *administration* errors) than the then normal nursing practice in 1963.¹³⁶ A modified version of this practice is still in use in hospitals in the USA and is associated with a similar medication *administration* error rate to UK hospitals,¹²⁷ while having a higher *dispensing* error rate: at least four times that of a UK hospital if one compares Cina et al¹³⁷ with Beso et al.⁵³

When considering the extent of dispensing errors associated with MDS it is first important to reflect on the process which the pharmacists carry out – without any additional payment. MDS is used for solid oral dosage forms – tablets and capsules. These are now mostly supplied to pharmacies as 28 or 30 day packs, with each dose separately contained in blister pack strips of 7 or 10. These need to be popped out of the manufacturer's packaging, in which they were chemically stable and accompanied by a patient information leaflet. They then need to be arranged in the MDS device and, usually, checked by another person to ensure the right drug is in the right place. Because this is such a labour intensive and disruptive act in many dispensaries (but by no means all)) it is done in a special site, for example some companies have centralised MDS dispensing sites which serve several homes (the largest we saw provided for 76 homes). This allows skill mixing, batch processing and process control to improve the efficiency of this unfunded task and prepacks are often prepared for some commonly used drugs. The consequence of the repackaging is that the drugs are given an arbitrary expiry date of 8 weeks (<http://www.rpsgb.org/pdfs/mds.pdf>) and need to be re-labelled.

The process of filling MDS devices is therefore a cause of potential error, not experienced by most patients living at home nor those in hospital, which contributed to many of the dispensing errors we observed for MDS preparations. When MDS dispensing was done some distance from the home there was sometimes poor communication and a perceived delayed responsiveness. Often a different, more local pharmacy would be used for 'interims' – new medicines prescribed outside the usual MDS cycle; this added to the lack of

local knowledge of the home and residents by pharmacy staff (and vice versa). A good relationship, along with knowledge of the context of each others places of work, could lead to improved communication overall.

Not all medicines can be placed in an MDS, so there was also dispensing of other medicines as well in the usual, non-MDS form. This includes all liquids, inhalers, creams, eye drops, as well as tablets or capsules which are not stable outside of the blister packaging.

To give an idea of the extent of these activities we can extrapolate from the findings of this study and the statistic that in 2003 there were 12,871 care homes for older people in England.¹⁶ In our study we found that 86% of residents used MDS; that 40% of doses for residents using MDS were not from the MDS system, that there were a mean of 7 medicines per resident, and that there were an average of 39 residents per home. If we assume that the average dose frequency was twice daily, then that equates to up to 3.6 million doses popped out of a factory prepared blister pack by pharmacies across England every day.

The final cause of dispensing errors was the way in which the monthly order was made and kept up to date. Pharmacists tended to use two main sources of information when dispensing: the prescription and the returned copy of the MAR chart from the previous month. A MAR chart is generated as part of the dispensing process, the chart then goes to the home, where it is annotated during or at the end of its 28 day 'life', the home then return a carbon copy which the pharmacist can refer to in order to identify any medication changes. This may help to ensure that a prescription which has been discontinued is not re-dispensed (this discontinuation may not have found its way onto the prescription). However, conversely, it may have been changed on the practice computer system but not on the MAR chart. So MAR charts at some homes may not reflect the correct current prescription.

However, this carbon copy is not always returned to the pharmacy and often, when it is returned, may have poor legibility. Home staff and the pharmacists maintained they knew what should and should not be dispensed, however there was no proof, and much of the safety depended on the local knowledge of individuals, who could obviously be absent, or

on leave. A further problem is the difficulty that arises when a medicine is introduced or the dosage is changed mid-month. The way in which pharmacists deal with this common phenomenon varies.

8.3.3 Contributory factors to administration errors

An administration error was observed in 8.4% of the doses observed to be administered. Half the errors were omissions, and a fifth involved giving the wrong dose of the right drug. One cause was that 'as required' medication, such as lactulose, was shared between residents until it ran out, or that an 'original pack' (the container supplied by the manufacturer) was given but was insufficient for the required use over the 28 day time period. Another cause of omission was that nurses tended to administer looking at the MAR chart and, if the previous dose was omitted, they assumed for example that the medicine was out of stock and did not look for it. Failure to order medicines properly also led to omission errors.

The administration error rate was higher for people in residential care compared to those in nursing care. As most homes had both types of residents we assume these differences are probably due to the extra knowledge about medicines (from their training and experience) that nurses had, leading to safer medication administration. Having said that, the knowledge of some of the nurses was poor. For example one was observed giving an Aspirin 75mg dispersible tablet. These tablets are designed to disperse in water and hence stop an aspirin tablet dissolving at one spot in the stomach, with the concomitant risk of gastric irritation and, potentially, a gastric bleed. The nurse gave the tablet whole.

Interviews and observation revealed that often staff did not have sufficient training. This was particularly so in respect of inhaler technique, leading to residents not getting the benefits of the medicine concerned. Lack of knowledge about which medicines needed to be given in a special way in relationship to food was another source of error, which was compounded by most homes giving medicines always at the same times (usually at meal times), irrespective of any special requirements. In addition pharmacies sometimes failed to pass on appropriate instructions such as how to take the medicine with respect to meals.

On occasions low staffing levels and low motivation may have contributed to administration errors.

Working conditions when administering medicines may also contribute to error. Those identified in this study include distractions such as noise (e.g. alarm bells, residents moaning), smells, interruptions, poor lighting conditions and a medicines trolley that was cluttered, small and badly designed. Importantly, the MAR chart could be hard to read or inaccurate, with many medicines that should have been discontinued remaining on the MAR chart. One source of potential error reduction (or resilience) in a general hospital setting may be the patient themselves. In contrast, in the nursing and residential home setting, residents often could not contribute as they did not know what they were, or should be, taking.

Residents receiving a non-MDS medicine were significantly more likely to receive an administration error. It remains unclear whether this reflects that the MDS systems are inherently safer, or whether it reflects that, in homes using MDS systems, the medicines that could not be fitted into the system, such as inhalers and 'as required' medicines were also those that we observed more commonly associated with error, for example inhalers given by poor technique, or prn medicines that were out of stock. As mentioned above, pharmacies sometimes did not know how much of an 'as required' medicine to dispense, and some homes could have been better at reordering when stocks were running low.

8.4 Whole system assessment

In the previous section we have followed the traditional medicines related processes: prescribing, monitoring, dispensing and administering. We have measured the errors in each process and explored the causes of, and suggested contributors to, errors at each stage in the process. Previous researchers into medication safety in care homes have generally studied one process, however we have considered all of them. Using the model proposed by Reason (1990) we are able to identify significant latent failures within the system. Reason considers latent failures to be the higher level organisational and cultural issues that are

often the key factors in major industrial disasters. It appears that three of the most significant latent failures in this study are

- lack of ownership and understanding of the whole system,
- lack of valid information that is available to all concerned at the time that they need it,
- lack of sufficient recognition that health care is usually based on people moving to and between experts and centres that have appropriate resources. Care home residents can rarely move like this, and substantial resource is needed to move care to these residents - some of the most vulnerable in the community.

In this section, we discuss two other wider system issues, MDS and the drug round. Within these sections we also recommend ways forward.

8.4.1 Leadership and ownership

When looking at the whole system (prescribers, pharmacists, care homes and their staff, and the local commissioning bodies (PCTs in England)), what emerges strongly is that each element may feel it is doing its best, but no one is observing the wider picture or taking ownership of the whole system. In our view each home should have one person who provides leadership and takes ownership for the effective running of the whole medicines system in that home, and with the associated GPs, supplying pharmacists and the PCT. This person would not normally be a member of the home staff, but would be commissioned to provide the service. Because of their knowledge of medicines, and safe systems pharmacists would appear to have the skills to best fit this role. This suggestion is in accord with the recent white paper on pharmacy (DoH 2008) in which paragraph 3.80 states 'The Government considers that chief pharmacists of provider organisations, PCTs and other commissioners should have a lead role in ensuring that safe medication practices are embedded in patient care.'. The white paper also suggests 'health community clinical pharmacy teams' to 'oversee and monitor medicines usage and effectiveness' (para 3.64). These teams would be expected to work on the interface issues between primary and secondary care.

The person providing leadership must understand systems and processes to know how to improve performance. It could be argued that the current system has not been able to adapt to the increase in the number of medicines prescribed, and the increasing monitoring recommendations; this needs to be rectified. Within this there would be roles for each sector to improve their systems and communication, and we provide a 'diagnostic' in section 8.5 and some other suggestions later in this section. Each sector (home, GP, pharmacy, PCT) needs to have ownership and understanding of the issues in their own section and those they interact with.

The pharmacist who oversees the whole process may or may not also review individual patients' medications. Ideally the pharmacist who reviews medication in a home should have independent prescriber status in order for them to make medication changes (communicated to the GP records), rather than just making recommendations which may or may not be properly communicated and acted on. Should they be trained as a phlebotomist they would be even more effective. GP practices have the potential to commission such a service through practice based commissioning. We know that pharmacists can improve prescribing in care homes through reviewing patients and their medications, and that this can, for example, significantly reduce falls.²⁶ In the USA it is mandatory to have pharmacists to conduct regular reviews of medication in care homes, although effectiveness is variable.^{106,142} However, this input is usually limited to reviewing the prescription without seeing the patient, and is much more limited than the whole system approach that we are suggesting.

8.4.2 Calming the sea of information

Often there is not a point of certainty in the whole system. The 'truth' of a resident's medicines bobs about like a cork on a storm tossed sea of conflicting information from GP records, pharmacy records, care home records, hospital records, the MAR chart, the physical evidence of medicines and the personal accounts of many people, including the patient. With so many sources of potentially erroneous evidence, it took our researchers (experienced pharmacists) a great deal of time to arrive at some form of "truth". The chance of other individuals having the time and resources to do so is, in many cases, minimal.

Clearly some unified method of access to a single reference point, and simple communication between all the players is required. There could be an argument that the prescription should be the reference point, however there were cases when a GP had changed the prescription but the practice patient record had not been updated, and the MAR chart was more accurate. There were some examples of good practice, including one GP who had a terminal to his practice in the home, and a pharmacist who had access to the GP's computer system, and would always check the patient record, resolving any discrepancies before dispensing.

The ergonomics study identified a cluster of medication errors where the MAR chart was a contributory factor. This particularly related to the number of discontinued items recorded on the chart. The ergonomics study also identified a cluster of medication errors where a contributory factor was the communication between the care home and the pharmacy. This includes administration instructions for individual medicines (on medicine labels and on MAR charts), medication no longer to be given and changes in medication during the 28 day cycle.

There is substantial potential for the NHS Connecting for Health programme to deliver improvements. Here we refer to the English programmes, but other nations have similar programmes. The Electronic Prescribing Service, Release 2 (EPS) will allow transfer of the prescription electronically between prescriber and dispenser, and will also allow repeat dispensing for up to a year. This is a substantial improvement on the current repeat dispensing service as it can be updated in real time, so changes in prescribing are reflected before the next dispensing. This should help ensure dispensing is from the prescription, particularly if the GP can prescribe electronically while in the home. A second point of concern was the long time to transfer records when changing GPs (in one case 4 months), which should be addressed by GP2GP, which will transfer the records electronically when the patient registers with another GP. The GP Systems of Choice (GPSoC) programme should ensure that GPs have systems of sufficient complexity and robustness to deliver these benefits.

Information following hospital discharge or outpatient appointment may improve when the Clinical Records Systems (CRS) are introduced into hospitals, however the timescale is

unclear and effectiveness will depend on how the system is implemented. The Summary Care Record (SCR) and Personal Demographics Service should ensure accurate information on the patient is available remotely. Finally, HealthSpace will become important. This is a 'secure online personal health organiser' which allows residents to log preferences etc, and which can also allow viewing of the SCR. It may be useful if homes could use this on behalf of their clients, whose preferences they often know. All the above (with the exception of some key functions in CRS) are, at the time of writing, scheduled to be available by the start of 2009.

For pharmacists to be effective they need access to relevant patient information, however the access of community pharmacists to the patient record is being contested by some patient groups. Work is needed to find a solution that allows pharmacists appropriate levels of access. Another potential barrier is that some PCTs may choose to delay implementation of some systems on cost grounds.

PCTs need to establish how care homes can be linked into the NHS IT programme to provide patient benefit. Care homes should consider the extent of advanced IT provision of GP practices and pharmacies that they interact with. We recognise that just being enabled to perform an IT function does not mean that benefits will be delivered. Sometimes IT use creates new errors. However there are evaluations being carried out of many IT services which should provide guidance on how to get the best out of them. We revisit technology in a section on error reduction below.

The need for good communication is reduced if there are fewer people involved in care. When patients move into a care home they may choose to have their GP, who they know and trust, continue to provide care. For this reason homes may work with many GPs (the maximum in our study was 14). We think there is a strong case for a home to have a preferred GP, who should be the GP of choice if the patient is in equipoise. In this case it is easier for a terminal from the practice computer system to be in the home, and there may be sufficient patients for regular visits from the GP, or practice nurse, and pharmacist. The GP should also review the effectiveness of their systems if flagging those patients who require monitoring because of their medicines, and how effectively the flags are acted upon.

8.4.3 *The home-bound resident*

The third 'latent failure' that needed to be addressed was that the dominant model of healthcare is predicated on residents being expected to move to points of care (surgeries, clinics, hospitals etc). Most care home residents can be considered as functionally immobile. While a few leave the home alone, most remain within the home, unless taken somewhere. This means that, for example, for one patient to have a blood test at a hospital, or an X-ray, takes a lot of time, effort and resource. An ambulance or taxi needs to be called. A carer has to accompany the patient to the hospital, wait for the test, and then find transport home. It can easily take the best part of half a day of staff time. In contrast, one care home manager explained what a major difference a visiting phlebotomist had made to his managing a home. He phoned them when needed, and when they arrived they were in and out of the home in 10 minutes.

These services are usually resourced (or not) from the PCT, and there needs to be a review of the extent and effectiveness of these services. In some cases, as above, the GP can do more, with the home, to bring the resources of the surgery into the home. The first three issues in this section on the 'whole system' emerged from the study of latent failures; there follow two related issues which also emerged – the way medicines are dispensed and administered in homes.

8.4.4 Medicine dispensing systems

Our work has brought out for the first time the interconnectedness, possibly a reciprocal ratio, between dispensing and administration errors when comparing normal dispensing (predominantly labelling an original container) with various forms of dispensing technologies – Monitored Dosage Systems (MDS). We particularly bring out their role as a technology as we think the problem is usefully informed by the literature on the use and effectiveness of technology, particularly as several computerised secure ‘dispensing’ cabinets are now available.

MDS seems to divide people into those who like or dislike it. We have already described it and its attributes in detail, however the findings of the research are, frustratingly not yet clear enough to make firm recommendations. Is MDS safer than non-MDS? We cannot clearly say, because MDS is limited to regularly prescribed solid dosage forms and non-MDS can include those and everything else. Hence a comparison of the associated prevalence of errors, particularly administration errors, can be misleading as it is not comparing like with like. Our harm scale suggests that dispensing and administration errors are associated with producing similar extents or harm, so both types of error need to be taken equally seriously. There is the suggestion that MDS may be associated with a higher dispensing error rate. As their practices are so varied, pharmacies need to review their error rate with their home and if there is a problem, the pharmacists should be asked to find a solution.

One thing is clear about MDS, the large amount of resource associated with it. Not only is there the large, unfunded repackaging that pharmacies undertake, but there is also an effect on the homes. Several care home managers estimated that 40-50% of staff time was spent on medicines related activities (ordering, storing, administering, recording etc). This suggests that there is considerable potential, and motivation, to find an alternative solution.

Some UK hospitals are now using automated dispensing machines, which can be used to permit access only to prescribed medication for the individual patient, as well as bar code checking systems. Robotic dispensing of original packs of medicines exists in several hospitals and is associated with reduced content errors.¹⁴⁴

There are a number of electronic ‘cupboards’ of various complexity that can store medicines and allow access only for the right medicine for each patient. These systems need a database of all the residents and their medicines, and the boxes need to be refilled; most can send a message to the pharmacy to do this. A third area of technology that can be applied is the use of bar codes. Original packs are increasingly bar coded, and bar codes could be generated for other packaging, and can be used to match the drug to the patient. An advantage of all these systems is that they automatically provide an electronic audit trail, and can be monitored in real time if need be. We have shown that an automated combination of electronically controlled access to medicines, combined with bar coded identity checking, significantly reduced medication administration errors in a UK hospital ward.^{55,96}

We have taken a socio-technical approach to technologies (explained more fully in Chapter 6). The effectiveness of technologies is only found by use, and it is the interaction of what people do to the machines, and what the machines do to people, that produces the end result. The effects of technologies can therefore differ between places, and they need to be well managed to achieve full effectiveness. We are not expecting technology to necessarily provide a solution, but it needs to be explored and, given the rapid rate of change, needs to be constantly reviewed and evaluated.

One final point about MDS (and the other technologies listed above). Like many safety technologies they are ‘structuring’ – they structure the work that people do, making them do a series of ordered acts with little or no discretion. This is commonly seen as a way to improve safety, as people are forced to do the ‘right’ thing. This structuring often takes resource, and can lead to the mechanisation and deskilling of tasks. One care home manager said giving medicines had become a large task of work instead of an act of care. It also means the systems find it hard to cope with anything other than the regular supply of the same tablets: changes of dose, newly prescribed medicines, liquids, creams, inhalers etc all can either not be accommodated by the system, or require a lot of work to accommodate them. These other tasks are not within the main safety system so can be more prone to error, and yet these are also consequences of the system. It is perhaps significant that when comparing all medication administration errors in homes that use MDS, compared to

homes that do not, there was no significant difference. The true effect of the technology is its effect not only of the doses it can control, but also of those it can not control, which people deal with in different ways.

The trend to a higher rate of medication administration error in residential rather than nursing care residents is of particular concern, as these residents are often in the same home so location, systems of work etc are the same. This places the focus on the knowledge, skills and abilities of staff giving the medicines and the support they are given. They need to be observed giving medicines and be seen to show sufficient skills.

8.4.5 Drug round issues

The ergonomics study identified drug administration during the drug round as a critical task, and that interruptions to the care home staff when undertaking drug rounds were common (up to 12 interruptions per hour). The fact that most of these interruptions came from other staff suggest that understanding these interruptions with a view to designing them out should be possible with changes to care home processes and training. A number of potential interventions might be tested including: planned breaks during the round, changing drug administration times and engaging more trained staff. In addition, the drug trolley used during the drug round may be contributing to errors. Re-designing of drug trolleys or use of other forms of storage might be considered, such as a small drugs room.

At a more fundamental level, our research has raised the question of whether the “hospital model” trolley-based drug round is most appropriate for homes providing “personal care” and where many of the staff do not have appropriate knowledge or training in medication administration.

8.5 Appetite for change

We have been very impressed by the interest of the care home managers. There is considerable concern about medication errors and, we think, an appetite for change. There are some homes where they manage medicines very well. However as practices vary so much it is difficult to be too prescriptive about change – there are many ways of creating safe systems and we saw good practices which were sometimes a function of context and

not always transferable to other settings. For this reason our recommendations above are fairly general.

8.5.1 Diagnostic questions

However working from the factors that we found to contribute to errors it is possible to build up a 'diagnostic' list of risk factors which one could look for and work to eliminate. This can be used by anyone involved in the system, or anyone taking a whole systems view. Not all the issues on the list can be resolved easily at present, however that does not mean they disappear as risk factors. The list is below:

Diagnostic risk factors

In this section we create a starting point for a diagnostic tool which could be applied to a home to assess whether it is avoiding factors known to contribute to medication errors. It is a reworking of factors which we found to contribute to error. It is not, however, meant to be sufficient as a sole means of change. It needs to be used as a starting point for a process or regular monitoring and reflective review of the local situation. In some cases questions may not be answered satisfactorily, but a good alternative way of achieving the same ends is available.

Prescribing and Monitoring

- Does the prescriber know the patient?
- At the time of prescribing does the prescriber have access to the patient's electronic record and prescribing software?
- Does the surgery have training/sufficient processes/adequate software to ensure that drugs that need monitoring are flagged and that staff know how to identify monitoring when it is needed, and know how to act on this?
- Is there a regular, independent review of prescribing? Does the reviewer check for appropriateness of prescribing?
- Are there processes to improve transmission of information to and from secondary care, and between GPs and pharmacies?

Dispensing

- If MDS is used, is all the relevant information about medicines getting to the home, including instructions for inhalation devices, and all the appropriate warning labels (relating to food etc) and the patient information leaflet?
- Does the dispensing pharmacy have a relationship with the home and know their requirements?
- Is there a system for identifying medicines which are about to run out before the next supply cycle?
- Can 'interims' and out of stock medicines be rapidly supplied?
- Is dispensing referenced to the prescription, or at least to a current, clear and accurate MAR?

Administration

- Are staff trained to administer medicines, particularly inhalers?
- Are prescriptions written to smooth the workload of staff and hence reduce medication errors? Is the prescribing reviewed to reduce the number of medicines prescribed as much as possible, rationalise to once daily dosage where possible, work with the home to reduce the number of medicines given in the morning round (the busiest and most interrupted, hence the most error prone)?
- Is there a mechanism to alert the home as to which drugs have to be taken in a special relationship to meals (before, after etc)? If there is, does the home have a suitable procedure to ensure this information is acted on?
- Are staff regularly observed administering medicines to establish training needs, and to praise good practice? When was each member of staff last observed administering medicines?

General

- Does all documentation seem clear, non-contradictory and up to date?
- What sources of information about medicines are available to staff in homes?

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- Which services are provided locally by the PCT: regular pharmacist visits? Phlebotomist? District nurse? etc. Are these all readily accessible if required?

8.5.2 Implications for practice

Care homes vary and there can be many ways to create a safe systems – we have tried to balance broad goals with practical suggestions, but the main endpoint is a robust, resilient safe system.

We list here some suggestions for reducing errors (categorised around the error type, rather than who is involved). The context of each suggestion has been explored in the previous parts of the chapter.

Reducing prescribing and monitoring error

- Each home has a preferred general practitioner
- GPs at the home can prescribe using their usual computer system i.e have access to the patients notes and other features of the system. This could be achieved through a remote terminal or by computer and remote link software
- Regular visits of the practice nurse or GP and also pharmacist
- Regular visits by pharmacist to review individual residents medication
- Review processes to identify patients needing monitoring and robust ways developed to trigger the process, carry it out, and act on findings.
- PCT to support GPs and homes in taking bloods, for example by providing phlebotomists or funding training for nurses and others.
- Review handling of information about medicines to and from secondary care

Reducing dispensing errors

- Ensure all relevant information goes with the medicine (including information about taking with respect to meals)

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- Dispense from the most accurate information source (always from the prescription, but also using the returned MAR chart if thought reliable)
 - If using cassette MDS systems, find a way of labeling them correctly
 - Review use of pre-packs to reduce the stock that will be out of date before the end of the month they are dispensed to be used in
 - Audit current practice to identify and reduce dispensing errors.

Reducing administration errors

- Work to make fewer distractions for the administering carer
- Review prescriptions with pharmacist or GP to reduce the workload on the morning round, and to reduce the total daily number of administrations for each medicine - when possible to do with no detriment to the patient
- Have a method of flagging and dealing with medicines that need to be taken at a certain time with respect to food.
- Ensure rapid dispensing and receipt of new medicines, or those about to go out of stock. so that the number of missed doses is reduced.
- Regularly review the number of omitted doses and develop and evaluate solutions.
- Pharmacists and homes should meet to ensure they understand each others needs and constraints

System wide issues

- The commissioning of someone to oversee and facilitate a safer medicines system in each home or group of homes.
- Improve communication between all concerned In England several CfH initiatives are important to improve the situation (in particular EPS Release 2 and GP2GP and summary care record).
- Pharmacist access to the patients' notes is a prerequisite to a truly safer system - something which has not yet been agreed. HealthSpace has potential if homes can use it on the residents' behalf.

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- The use of MDS, and possible alternatives to it, requires further research (questions this research was not designed to answer). The large amount of resource associated with MDS, the rigidity of the systems, the number of medicines it can not handle (40% of doses given) and the lack of clarity about the benefits mean it is time to review the system and to compare it to alternatives.
 - The drug trolley and drug round also need more research to reduce their error producing factors
 - The PCT needs to recognize the problems associated with patients that are effectively home bound and ensure appropriate services are resourced.

Chapter 9

Conclusion

Care home residents are amongst the most vulnerable people in society. They have the potential to both benefit most and suffer most harm from medicines. This study has found that they are at high risk of medication errors. Errors associated with all aspects of medicines management (prescribing, dispensing, administration and monitoring) were as high or higher for this group of care home residents than found in studies of people living in their own homes or being treated in hospitals.

We did not see any cases with the potential for severe harm during the study, but this does not prove that this does not occur. However, we have found that seven out of ten were subject to at least one form of medication error and that for each act of prescribing there was a 8-10% chance of an error occurring. This means that action needs to be taken to improve the benefits care home residents obtain from medicines, reduce the potential harm, and improve the quality of life and independence of residents.

Solutions to improve medicines management in care homes are required at the macro and micro level. At the macro level someone needs to take responsibility for safe medication practices in the whole system, a role the Government has recently assigned to chief pharmacists (DoH 2008). There is a need for someone to understand all aspects of the medication system and ensure that all players and sites are co-ordinated. At the micro level there is work for all to engage in. GPs need to review their prescribing and endeavour to prescribe electronically from the home. They may wish to have regular visits by themselves, nurse practitioners or clinical pharmacists. Within their practice they need to review how they identify medicines that require monitoring and ensure it happens. Homes need to look to their staff, especially the training of those giving medicines to patients in residential care. They should work with GPs and may wish to move towards a main provider. They should review the way they order, to reduce 'out of stock' medications, and may wish to reconsider what is the best way for medicines to be dispensed to them. Pharmacists need to dispense from authoritative sources and need to consider, particularly

with the MDS cassette system, how they can reduce dispensing errors. PCTs need to resource carers visiting the patients in homes.

The extent to which dispensing and administration errors relate to the type of system used, whether conventional individual bottles, cassette MDS or blister MDS, is unclear. The view that MDS is clearly safer is not yet proven in our view. This needs further urgent research. However, the fact that millions of doses a week, which have been factory packed into blister packs, are then popped out of these blisters, only to be put into another blister or cassette cannot be ignored. New technologies to control access to medicines and identify medicines and patients should be explored.

Poor communication underpins many of the types of errors seen in this study. The communication between the home, the GP and the pharmacy (or pharmacies) needs to be improved. IT solutions have been proposed, but they cannot be relied upon, particularly in the short to medium term. The relationship between care home healthcare provision and the Connecting for Health programme (including PCT funding of elements of it) needs to be researched and actively managed to ensure that the potential benefits are fully realised.

Our interaction with all the players in practices, homes and pharmacies has convinced us that change is possible.

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References

1. DoH 2001a. Department of Health. Building a safer NHS for patients. 2001. London, Department of Health.
2. DoH 2000. Expert Group on Learning from Adverse Events in the NHS. An organisation with a memory. 200. London, Stationary Office.
3. DoH 2004. Building a safer NHS for patients: improving medication safety. London: Department of Health, 2004.
4. DoH 2001b. National Service Framework for Older People. London: Department of Health, 2001.
5. DoH 2001c. Medicines and Older People: implementing medicine-related aspects of the NSF for older people. London: Department of Health, 2001.
6. Howard et al 2006. Which drugs cause preventable admissions to hospital? A systematic review. British Journal of Clinical Pharmacology. 63; 136-147.
7. Cannon J, Hughes CM. An assessment of the incidence and factors leading to drug-related hospital admissions in the elderly. Eur.J.Hosp.Pharm. 1997;3:14-8.
8. Cunningham G, Dodd TRP, Grant JA, et al. Drug-related problems in elderly patients admitted to Tayside hospitals, methods for prevention and subsequent reassessment. Age and Aging 1997;26:375-82.
9. CSCI 2007. State of social care: facts and figures. Accessed 10.04.08 www.csci.org.uk/about_us/news/state_of_social_care_facts_a.aspx.
10. McGrath AM, Jackson GA. Survey of neuroleptic prescribing in residents of nursing homes in Glasgow. British Medical Journal 1996;312:611-2.
11. Fahey T, Montgomery AA, Barnes J, Protheroe J. Quality of care for elderly residents in nursing homes and elderly people living at home. British Medical Journal 2003;326:580-3.
12. Zermansky A, Alldred DP, Petty D, Raynor DK, Freemantle N, Eastaugh J, Bowie P. Clinical medication review by a pharmacist of elderly people living in care homes – randomised controlled trial Age and Ageing, 35, pp.586-591, 2006.
13. Alldred et al. Antipsychotic prescribing patterns in care homes and relationship with dementia. Psychiatric Bulletin 2007; 31: 329-332.
14. DoH 2002. Care Homes for Older People. National Minimum Standards. <http://www.doh.gov.uk/ncsc.2002>. London, The Stationery Office.

-
15. NCSC 2004a. Health Select Committee Inquiry into Elder Abuse: Evidence from the National Care Standards Commission.
http://www.carestandards.org.uk/press+release/pressitems/elder_abuse.pdf
 16. NCSC 2004b. The management of medication in care services 2002/3. National Care Standards Commission.
 17. CSCI. Handle with care? February 2006. Commission for Social Care Inspection.
 18. Gurwitz JH, Sanchez-Cross MT, Eckler MA, Matulis J. The epidemiology of adverse and unexpected events in the long- term care setting. *Journal of the American Geriatrics Society* 1994;42:33-8.
 19. Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. Medication errors observed in 36 health care facilities. *Archives of Internal Medicine* 2002;162:1897-903.
 20. Gurwitz et al. The incidence of adverse drug events in two large academic long-term care facilities. *American Journal of medicine* 2005; 118: 251-258.
 21. Osborne CA, Hooper R, Swift CG, Jackson SHD. Explicit evidence based criteria to access the quality of prescribing to elderly nursing home residents. *Age & Ageing* 2003;32:102-108.
 22. Barber N, Bradley C., Barry C, Stevenson F, Britten N, Jenkins L. Measuring the appropriateness of prescribing in primary care: Are current measures complete?. Paper undergoing revision with Quality and Safety in Health Care. 2004.
 23. Spinewine A, Schmader KE, Barber N, Hughes C, Lapane KL, Swine C, Hanlon JT. Prescribing in Elderly People 1: Appropriate prescribing in elderly people: how well can it be measured and optimized? *Lancet* 2007 370: 173-84.
 24. Alldred DP, Zermansky A, Petty D, Raynor DK, Freemantle N, Eastaugh J, Bowie P. Clinical medication review by a pharmacist of elderly people living in care homes: pharmacist interventions. *International Journal of Pharmacy Practice*, 15, pp.93-99,2007b.
 25. Lunn J, Chan K, Donahue J, Riley B, Wally T. A study of appropriateness of prescribing in nursing homes. *International Journal of Pharmacy Practice* 1997; 5: 6-10.
 26. Zermansky A, Alldred D, Petty D, Raynor DK, Freemantle N, Eastaugh J, Bowie P. Clinical medication review by a pharmacist of elderly people living in care homes – randomised controlled trial. *Age and Ageing*. 2006; 35: 586-591.

-
27. Rasmussen J, Jensen A. Mental procedures in real life tasks: a case study of electronic trouble-shooting. *Ergonomics* 1974;17:293-307.
 28. Reason J. *Human Error*. Cambridge: University of Cambridge, 1990.
 29. Vincent C, Taylor-Adams SE, Stanhope N. Framework for analysing risk and safety in clinical practice. *British Medical Journal*. 1998;316:1154-7.
 30. Cornford T, Doukidis G I, Forster D. Experience with a structure, process and outcome framework for evaluating an information system. *Omega. Int J Manage Sci* 1994;22:491–504.
 31. DoH 2003. *Design for patient safety*. London Department of Health.
 32. CSCI. *Handled with care: managing medication for residents of care homes*, (2006).
 33. CSCI. *Professional advice: Medicines administration records (MAR) in care homes and domiciliary care* (2007a).
 34. CSCI. *Professional advice: Administration of medicines in care homes* (2007b).
 35. CSCI. *Professional advice: Training care workers to safely administer medicines in care homes* (2007c).
 36. RPSGB. *Practice Guidance: Advisory services to care homes* (2003).
 37. RPSGB. *Practice Guidance for the provision of printed medication administration record charts (MAR) by community pharmacists* (2005).
 38. RPSGB. *The handling of medicines in social care* (2007a).
 39. RPSGB. *Fitness to Practice & Legal Affairs Directorate Fact Sheet 6. Monitored dosage systems and compliance aids* (2007b).
 40. Zermansky AG. Who controls repeats? *Br J Gen Pract* 1996; 46: 643-647.
 41. Sprey L.S. Monitored dosage systems. *Pharm J* 1995; 254: 767-70.
 42. NPCC (National Pharmaceutical Consultative Committee). *Scottish Health Service Planning Council. Pharmaceutical services for the elderly. Report by the National Pharmaceutical Consultative committee*, 1981.
 43. Rivers PH, Poston JW. Evaluation of a controlled medication system. *The Pharmaceutical Journal* 1985;235:787-89.
 44. Anonymous. *Controlled dosage systems for residential homes. The Pharmaceutical Journal* 1990;244:385-386.

-
45. Ashurst A, Deans BJ. Using a monitored dosage system. *British Journal of Nursing* 1992;1:379-82.
 46. Manrex. The Boots Company PCL Nottingham, England. Monitored Dosage System product information, june 2005. <http://www.manrex.com/ltc.html>
 47. Venalink. Medication Management Systems, England. Monitored Dosage System product information 2004. <http://www.venalink.co.uk/products.html>
 48. Gaucher M, Greer M. A Nursing Evaluation of Unit Dose and Computerized Medication Administration Records. *The Canadian Journal of Hospital Pharmacy* 1992;45:145-50.
 49. Franklin BD, Vincent C, Schachter M, Barber N. (2005). The incidence of prescribing errors in hospital inpatients - an overview of the research methods. *Drug Safety*.28: 891-900.
 50. Barker KN, McConnell WE. The problems of detecting medication errors in hospitals. *American Journal of Hospital Pharmacy* 1962;19:360-9.
 51. Barber N, Franklin BD, Cornford T, Klecun E, Savage I. (2006). Safer, faster better? Evaluating electronic prescribing. Report to the Patient Safety Research Programme, Department of Health.
 52. Dean B, Barber N. (2000). The effects of a patients' own drugs scheme on the incidence and severity of medication administration errors. *International Journal of Pharmacy Practice* 8: 209-16.
 53. Beso A, Franklin BD, Barber N. (2005). The frequency and potential causes of dispensing errors in a hospital pharmacy. *Pharmacy World and Science* 27: 182-190.
 54. Franklin BD, O'Grady K, Parr J and Walton I. (2006). Using the internet to deliver education on medication safety. *Quality and Safety in Health Care*, 15:329-333.
 55. Franklin BD, O'Grady K, Donyai PD, Jacklin A, Barber N. (2007). The impact of a closed-loop electronic prescribing and administration system on prescribing errors, administration errors and staff time: a before and after study. *Quality and Safety in Health Care* 16: 279-284.
 56. Dean B, Barber N, Schachter M. What is a prescribing error? *Quality and Safety in Healthcare* 2000; 9: 232-237.
 57. Dean BS, Schachter M, Vincent C, Barber ND. Prescribing errors in hospital inpatients – incidence and clinical significance. *Quality and Safety in Health Care* 2002; 11: 340-4.

-
58. Sagripanti M, Dean B, Barber N. An evaluation of the process-related medication risks for elective surgery patients from pre-operative assessment to discharge. *International Journal of Pharmacy Practice* 2002; 10: 161-70.
 59. Donyai PD, O'Grady K, Jacklin A, Barber N, Franklin BD. (2007). The effects of electronic prescribing on the quality of prescribing. *British Journal of Clinical Pharmacology*. 15: 133-139.
 60. Zermansky A, Petty D, Raynor DK, Freemantle N, Vail A, Lowe CJ. Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice *British Medical Journal*, 323, pp.1340-1343, 2001.
 61. Zermansky A, Alldred D, Petty D, Raynor DK, Freemantle N, Eastaugh J, Bowie P. Clinical medication review by a pharmacist of elderly people living in care homes—randomised controlled trial *Age and Ageing*, 35, pp.586-591, 2006.
 62. BNF. British Medical Association and Royal Pharmaceutical Society of Great Britain. *British National Formulary* 51 March 2006 ed. London.
 63. North West Drug Information Letter. Monitoring drug therapy. North West Drug Information Letter No.120. Sept 2002. Available at <http://www.ukmi.nhs.uk/newmaterial/html/docs/21100201.pdf> Accessed 6th December 2007.
 64. London and South East Medicines Information Service and Croydon PCT. *Suggestions for Drug Monitoring in Adults in Primary Care: A collaboration between London and South East Medicines Information Service and Croydon Primary Care Trust*. June 2006.
 65. Hinchingsbrooke Hospital NHS Trust . *Monitoring of Maintenance Therapy in Primary Care*. October 2005.
 66. Shekelle PG, MacLean CH, Morton SC, Wenger NS. Assessing care of vulnerable elders: methods for developing quality indicators. *Ann Intern Med* 2001; 135: 647-52.
 67. Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, Lee M, White K, LaPrino J, Erramuspe-Mainard J, DeFlorio M, Gavendo L, Auger J, Bates DW. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med*. 2005;118(3):251-8.
 68. Allan EL, Barker KN. Fundamentals of medication error research. *American Journal of Hospital Pharmacy* 1990; 47: 555-571.

-
69. Dean B, Barber N. Validity and reliability of observational methods for studying medication administration errors. *American Journal of Health-System Pharmacy* 2001; 58: 54-9.
 70. Dean B, Barber N, Schachter M. What is a prescribing error? *Quality and Safety in Healthcare* 2000; 9:232-237.
 71. Reason J. *Managing the risks of organisational accidents*. Aldershot: Ashgate, 1997.
 72. Kirk S, Parker D, Claridge T, Esmail A, Marshall M. (2007). Patient safety culture in primary care: developing a theoretical framework for practical use. *Qual Saf Health Care* 16: 313-320.
 73. Naish J, Carter Y H, Gray R W, Stevens T, Tissier J M, Gantley M M. (2002). Brief encounters of aggression and violence in primary care: a team approach to coping strategies. *Fam Pract* 19: 504-510.
 74. Healey AN, Undre S, Vincent CA. (2004). Developing observational measures of performance in surgical teams. *Qual Saf Health Care* 13: i33-i40.
 75. Thompson AM, Stonebridge PA. (2005). Building a framework for trust: critical event analysis of deaths in surgical care. *BMJ* 330: 1139-1142
 76. Tang B, Hanna GB, Joice P, Cuschieri A. (2004). Identification and Categorization of Technical Errors by Observational Clinical Human Reliability Assessment (OCHRA) During Laparoscopic Cholecystectomy. *Arch Surg* 139: 1215-1220.
 77. Tasker RC. (2000). Training and dealing with errors or mistakes in medical practical procedures. *Arch. Dis. Child.* 83: 95-98.
 78. Williams MV. (2007). Improving patient safety in radiotherapy by learning from near misses, incidents and errors. *Br. J. Radiol.* 80:297-301.
 79. Graves K. (2005). Perfusion safety in Europe: managing risks, learning from mistakes. *Perfusion* 20: 209-215.
 80. Liang BA. (2002). A system of medical error disclosure. *Qual Saf Health Care* 11: 64-68
 81. Waring J. (2007). Getting to the 'roots' of patient safety. *Int J Qual Health Care* 19:257-258.
 82. Bell DS, Cretin S, Marken RS, Landman AB. (2004). A Conceptual Framework for Evaluating Outpatient Electronic Prescribing Systems Based on Their Functional Capabilities. *J. Am. Med. Inform. Assoc.* 11: 60-70.

-
83. van der Sijs H, Aarts J, Vulto A, Berg M. (2006). Overriding of Drug Safety Alerts in Computerized Physician Order Entry. *J. Am. Med. Inform. Assoc.* 13: 138-147.
 84. Stebbing C, Wong ICK, Kaushal, R Jaffe A. (2007). The role of communication in paediatric drug safety. *Arch. Dis. Child.* 92: 440-445.
 85. Ghaleb M A, Barber N, Franklin BD, Yeung VW, Khaki Z F, Wong I C. (2006). Systematic Review of Medication Errors in Pediatric Patients. *The Annals of Pharmacotherapy* 40: 1766-1776.
 86. Walsh KE, Kaushal R, Chessare JB. (2005). How to avoid paediatric medication errors: a user's guide to the literature. *Arch. Dis. Child.* 90: 698-702.
 87. Cresswell KM, Fernando B, McKinstry B, Sheikh A. (2007). Adverse drug events in the elderly. *Br Med Bull* 83: 259-274.
 88. Howard RL, Avery AJ, Howard PD, Partridge M. (2003). Investigation into the reasons for preventable drug related admissions to a medical admissions unit: observational study. *Qual Saf Health Care* 12: 280-285.
 89. Rothschild J M, Federico FA, Gandhi TK, Kaushal R, Williams D H, Bates DW. (2002). Analysis of Medication-Related Malpractice Claims: Causes, Preventability, and Costs. *Arch Intern Med* 162: 2414-2420.
 90. Szeinbach S, Seoane-Vazquez E, Parekh A, Herderick M. (2007). Dispensing errors in community pharmacy: perceived influence of sociotechnical factors. *Int J Qual Health Care* 19: 203-209.
 91. Knudsen P, Herborg H, Mortensen A R, Knudsen M, Hellebek A. (2007). Preventing medication errors in community pharmacy: root-cause analysis of transcription errors. *Qual Saf Health Care* 16: 285-290.
 92. Husch M, Sullivan C, Rooney D, Barnard C, Fotis M, Clarke J, Noskin G. (2005). Insights from the sharp end of intravenous medication errors: implications for infusion pump technology. *Qual Saf Health Care* 14: 80-86.
 93. Taxis K, Barber N. (2003). Causes of intravenous medication errors: an ethnographic study. *Qual Saf Health Care* 12: 343-347.
 94. Vincent C, Taylor-Adams SE, Chapman EJ, Hewett D, Prior S, Strange P et al. How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management Protocol. *British Medical Journal* 2000;320:777-81.
 95. Woloshynowych M, Neale G, Vincent C. Case record review of adverse events: a new approach. *Quality and Safety in Healthcare* 2003;12:411-5.

-
96. Dean B, Schachter M, Vincent C, et al. Cause of prescribing errors in hospital inpatients: a prospective study. *Lancet* 2002; 359:1373–8. (b).
 97. Barber N, Cornford T, Kelcun E. Qualitative evaluation of an electronic prescribing and administration system. *Quality and Safety in Health Care* 2007; 16: 271-278.
 98. Berg M. Patient care information systems and health care work: a sociotechnical approach. *Int J Med Inform* 1999; 55: 87-101.
 99. DoH. Project Review: Objective evaluation. Guidance for NHS managers on evaluating information systems projects. Leeds: NHS Executive, Information Management Group; 1996.
 100. Donabedian A. The quality of medical care - methods for assessing and monitoring quality of care for research and for quality assurance programs. *Science, Technology and Human Values* 1978;200:856-864.
 101. Donabedian A. Evaluating the quality of medical care. *Millbank Memorial Fund* 1966;44(3):166-203.
 102. Kibble SL, Kendray JC. Cost analysis of supplying monitored dosage systems to residential homes from a community pharmacy. *Journal of Pharmacy and Pharmacology* 1996; 48 (Suppl 2): 11.
 103. Church C, Smith J. How stable are medicines moved from original packs into compliance aids? *Pharmaceutical Journal* 2006; 276: 75-76.
 104. Annett J, Duncan KD, Stammers R.B, Gary MJ. 1971. Task Analysis. London: HMSO, Training Information Paper No. 6.
 105. Stammers RB, Carey MS, Astley JA. 1990. Task Analysis. In: *Evaluation of Human Work* ED, Wilson JR, Corlett EN. 1990. Taylor & Francis. Chapter 6, 134 – 160.
 106. Pepper GA, Towsley GL. 2007. Medication errors in nursing homes: Incidence and reduction strategies. *J. of Pharm. Finance, Economics & Policy*. Vol. 16(1).
 107. Castle N. & Engberg J. 2007. The Influence of staffing characteristics on Quality of Care in Nursing Homes. *Health Services Research*. 42 (5), pp, 1822-1847.
 108. Christie B , Scane R, Collyer J. Evaluation of human–computer interaction at the user interface to advanced IT systems. In: J.R. Wilson and E.N. Corlett, Editors, *Evaluation of Human Work* (Second ed), Taylor & Francis, London (1995), pp. 310–356.
 109. Embrey DE. 1986. SHERPA: a systematic human error reduction and prediction approach. Paper presented at the International Topical Meeting on Advances in Human Factors in Nuclear Power Systems. Knoxville, TE.

-
110. NHS 2005. A guide to the national programme for information technology. NHS corporate brochure, April 2005.
 111. Humber M. 2004. National programme for information technology. Article in: BMJ, 328; 1145 – 1146.
 112. BMA, 2004. BMA calls for greater involvement in national programme for information technology. Press release, 29th April 2004. www.bma.org.
 113. BMA, 2006. BMA comment on the National Audit Office report - The National Programme for IT in the NHS. Press release, 16th June 2006. www.bma.org.
 114. National Audit Office, 2006. Department of Health: The National Programme for IT in the NHS. 16/06/2006. HC 1173 2005-2006. ISBN: 0102938288.
 115. QinetiQ, 2005. NHS Connecting for Health, Process Capability Appraisal. QinetiQ/D&TS/CS/CR050700, 28th April 2005.
 116. BS ISO/IEC 15288:2002 Systems Engineering – System lifecycle processes.
 117. BS ISO/IEC 15504-2:2003 Information Technology – Process Assessment – Part 2: Performing an Assessment.
 118. BS ISO/IEC 15504-4:2004 Information Technology – Process Assessment – Part 4: Guidance on use for Process Improvement and Process Capability Determination.
 119. Lyndoch Warrnambool Inc. 2005. Wireless Care Management System. Australian Government publication, December 2005. www.health.gov.au
 120. Perkins D, Burns P, Farrelly T. 2005. The introduction of electronic prescribing in residential aged care facilities. Centre for Equity and Primary Health Research in the Illawarra and Shoalhaven (CEPHRIS), University of New South Wales. www.health.gov.au
 121. Ingram D, Beale T, Heard S, Kalra D, Lloyd D, Schloeffel P. 2006. Introducing openEHR. The openEHR Foundation, 2nd Jan 2006.
 122. Health Management Technology, 2006. Electronic Medical Records. Industry Watch. March 2006 Issue, Health Management Technology. Nelson Publishing Inc.
 123. Blair R. 2006. Pleasantly Plastic. Health Management Technology, April 2006. Nelson Publishing Inc.
 124. Shah SDH et al. A survey of prescription errors in general practice Pharmaceutical Journal, 2001; 267: 860 -862.

-
125. Ridge KW, Jenkins DB, Noyce PR, Barber ND. Medication errors during hospital drug rounds. *Qual Health Care.* 4:240-243, 1995..
 126. Dean BS, Allan EL, Barber ND, Barker KN. Comparison of medication errors in an American and a British Hospital. *Am J Health Syst Pharm.* 52:2543-2549, 1995.
 127. Gethins B. Wise up to medication errors. *Pharmacy in Practice* 6:323-328, 1996.
 128. Ho CYW, Dean BS, Barber ND. When do medication administration errors happen to hospital inpatients? *International Journal of Pharmacy Practice.* 5:91-96, 1997.
 129. Cavell GF, Hughes DK. Does computerised prescribing improve the accuracy of drug administration? *Pharmaceutical Journal.* 259:782-784, 1997..
 130. Ogden DA, Kinnear M, McArthur DM. A quantitative and qualitative evaluation of medication errors in hospital inpatients. *Pharmaceutical Journal* 259:R19, 1997.
 131. Taxis K, Dean BS, Barber ND. Hospital drug distribution systems in the UK and Germany – a study of medication errors. *Pharm World Sci.* 21:25-31, 1999.
 132. Horne R, Weinman J, Barber N et al. Concordance, Adherence and Compliance in Medicine Taking – Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation Research and Development.
 133. Clifford S, Barber N, Horne R. Understanding different beliefs held by adherers, unintentional nonadherers, and intentional nonadherers: Application of the Necessity–Concerns Framework . *Journal of Psychosomatic Research* , Vol64 , Issue 1 , Pages 41-46 S.
 134. Morris CJ, Rodgers S, Hammersley VS, Avery AJ, Cantrill JA. Indicators for preventable drug related morbidity: application in preimary care. *Qual.Saf. Health Care.* Jun 2004; 13:181-185.
 135. Primohamed M, James S, Meakin S, Green C, Scott AK, Walley T, J, Farrar K, Park KB, Breckenridge AM. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *BMJ* 2004; 329: 15-19.
 136. Barker KN, Heller WN, Brennan JJ et al. The development of a unit dose dispensing system. *Am J Hosp Pharm* 1964; 21:609-25.
 137. Cina JL, Gandhi TK, Churchill W, Franikos J, McCrea M, Mitton P et al. How many hospital pharmacy medication dispensing errors go undetected? *J Qual Patient Saf.* 2006;32:73-80.
 138. Duggan C, Bates I, Hough J. Discrepancies in prescribing. Where do they occur? *PJ* 1996; 256: 65-67.
-

-
139. Duggan C, Feldman R, Hough J, et al. Reducing adverse prescribing discrepancies following hospital discharge IJPP 1998; 6: 77-82..
 140. Smith L, McGowan L, Moss-Barclay C, et al. An investigation of hospital generated pharmaceutical care when patients are discharged from hospital. Br J Clin Pharmacol 1997;44:163-165.
 141. Pickrell L, Duggan C, Dhillon S. From hospital admission to discharge: an exploratory study to evaluate seamless care. PJ 2001; 267: 650-653.
 142. DoH. The white paper on Pharmacy Building on Strengths – delivering the future. London TSO 2008.
 143. Patterson, S.P., Hughes, C.M., Lapane, K.L., “Assessment of a United States Pharmaceutical Care Model for Nursing Homes in the United Kingdom,” *Pharmacy World and Science* 2007; 29: 517–25.
 144. Franklin BD, O’Grady K, Voncina L, Popoola J and Jacklin A (2008). An evaluation of two automated dispensing machines in a UK hospital pharmacy. *International Journal of Pharmacy Practice*. 16: 47-53.
 145. Franklin BD, O’grady K. Dispensing errors in community pharmacy: frequency, clinical significance and potential impact of authentication at the point of dispensing. *International Journal of Pharmacy Practice*. 2007; 15: 273-281.

Appendix A

Sample Size

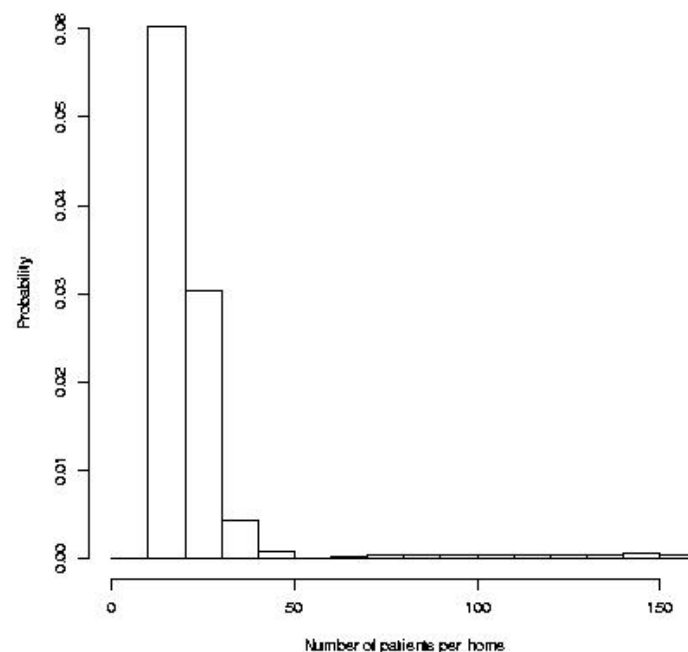
We approached the sample size calculation with the goals of providing sufficient precision to allow a meaningful estimate of the prevalence of medication errors, and allowing future researchers sufficient information (including ICC) to calculate sample sizes for intervention studies. However we did not wish to be over precise, thereby using resources which could be spent on understanding the causes and consequences of errors, and developing solutions. We believe we achieved a suitable balance.

In our experience the major sources of variation in medication error will be the GP and the home, or in other words we would expect clustering of errors because individual GPs or homes will be more likely to create errors. Thus, as the GP is linked to the home, we decided to study a large number of homes to get a realistic estimate of the prevalence of the various types of medication error.

We powered the study on the prevalence of prescribing errors, as they are the commonest cause of harm ¹⁸. We assumed a mean of 7 prescribed items per patient, based on our own experience ¹⁰ and the means of four other UK studies ^{9;17;19;20}. In addition to the clustering effect of GPs/homes, we anticipated a further clustering effect of errors within repeat prescriptions on patients. Ideally, we would have made use of estimates of the ICC at the home level and the patient level in our power calculations. However, the literature does not provide directly relevant ICCs. The closest work, by Osborne et al ²¹, using prescribing indicators, found ICCs ranged from 0.027-0.335, which we bore in mind in choosing parameters in the power calculations below.

We considered the home to be a principal source of variability, followed by GPs used by the home. Given that our previous study showed only 50% of homes and 40% of patients could be recruited, other sources of bias were ignored.

Because of the non-standard nature of the problem, the best way to look at the effect of various options is through simulation. Using the information obtained about the distribution of the number of patients per home in the Leeds study, we set up a model and simulated from the distribution of the number of patients per home. The details of this model are described in the statistical appendix. Using this model, the distribution looks like this:



Using this simulation model for the number of patients/home, we found the mean number of patients per home was 24, range 5 to 160.

At the outset, we did not know the true prevalence of prescribing error in this population, indeed, to find it was a study goal. What is more, although each type of error in this report is calculated on an ‘opportunities for error’ basis, in designing the study we also wished to know the proportion of patients who would suffer at least one error of any type, which we anticipated would be a high proportion of patients. Based on our experience, we decided to assume that about two thirds of patients would suffer a prescribing error. This is roughly equivalent (for a patient taking the mean

value of 7 medicines) to a 10% chance that any one prescribed item contains a prescribing error.

As described in the original application, we decided to sample homes, using the beds/home distribution above, and we sought to have enough homes and patients in our study to estimate an error running at a true rate of 10% per prescription item written, with a 95% confidence interval of (estimated rate) \pm X %. The table below gives the X that we expected to see, given the number of homes and average number of patients consenting to be sampled per home.

The values in the table are estimated using a combination of established formulae for clustered data and simulation, as described in the statistical appendix. We set the variability of error rates between homes to be \pm 6%, and the patient level ICC for the clustering of prescription errors to be 0.17. These were expected to be plausible, but on the conservative side, bearing in mind (i) the tendency for clustered studies to subsequently turn out to be underpowered and (ii) the sensitivity of the calculations to the patient level ICC.

Number of homes	Number of patients per home		
	2 [i.e. if ~10% consent]	3 [i.e. if ~15% consent]	4 [i.e. if ~20% consent]
50	3.1	2.6	2.3
100	2.2	1.9	1.6
150	1.8	1.5	1.4

Number of homes	Number of patients per home	
	6 [i.e. if ~27% consent]	8 [i.e. if ~36% consent]
50	2.04	1.87
80	1.62	1.47
100	1.47	1.33

Thus, to get within $\pm 2\%$ of a prescribing error rate of 10%, when between home variability runs up to a maximum of 6%, we needed 100 homes, and 3 patients per home. Alternatively, we could use fewer homes if we increased the proportion included per home (i.e. chosen to be sampled AND consenting to be included). At the time of the application, recent work by a co-applicant suggested that, at least in larger homes, up to 40% may consent. Given the many unknowns in this process, we sought to have 100 homes, and aimed for a least three patients per home. This would have given us more information on the key component of between home variability. Further, as the principal cost component is for reviewing a patient's medical history, we anticipated relatively little saving in reducing the number of homes included.

Although the numbers above may have seemed large at the outset (in terms of the total number of patients), we believe the sample size calculations were conservative. For example, we did not allow for non-trivial additional sources of variation in prescription error due to factors such as: (i) whether the patient has just arrived from hospital, or is a long term resident, (ii) the GP provision for a home (single, multiple, shared practice, different practices) and (iii) socio-economic differences in patients.

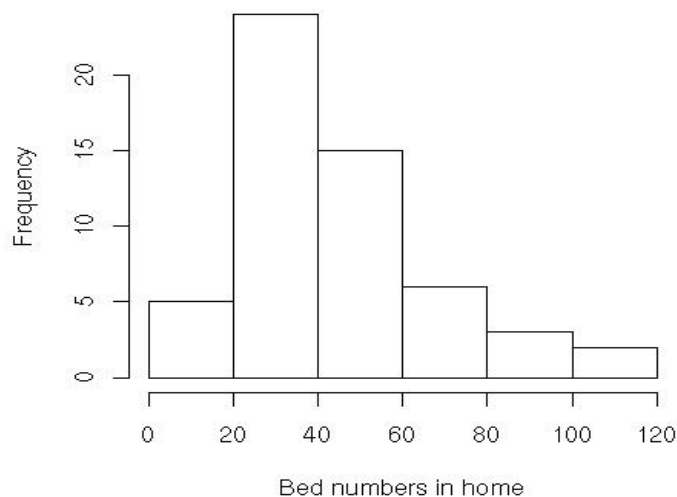
In the original proposal, we planned to stratify the sample of homes, over-sampling larger homes. Based on the simulation of beds/home above, we expected 75% of homes to have less than 30 beds, so using the figure of 100 homes arrived at above, we planned to sample as follows:

Bed numbers in home	Homes sampled
<30	50
30-49	8
50-69	8
70-89	8
90-109	8
110-129	8
130-149	8
>150	2

The rationale for over sampling larger homes was that such homes are likely to be served by more than 1 GP/practice and have more types of patients. Thus this provided more information on the between GP/type of patient effects. This is because small homes are likely to be served by only one GP, so for small homes the GP effect is indistinguishable from the home effect.

In addition, as ~ 10% of primary care prescribing in homes comes from dispensing doctors, we planned that 10 of our sample of 100 homes would be served by dispensing practices, which frequently supply care homes in rural areas. The absence of an independent pharmacist from the system gives these practices a unique structure that we sought to include.

Implementation



In the event, we were able to collect data on 256 patients from 55 homes. The distribution of the number of beds per home in the data is shown in the histogram immediately above. Relative to what we were expecting (see histogram on Appendix, 2 above) we had more smaller homes and fewer very large homes.

This reflects our stratified sampling strategy. However, it is important to note that we were only able to implement this strategy for approximately the first third of the study. This was partly due to the trend towards fewer smaller homes and more larger homes, which continued during the course of this study. Thus we could no longer follow our initial plan. Nevertheless we continued to try and include a variety of home sizes.

In addition, we were pleased that the consent rate was relatively high. Thus we were able to recruit an average of 4.7 (median 5) patients per home. Referring back to the table above, based on our initial assumptions, we would have expected this to give us sampling errors of +/- between 2 and 2.3%. Thus, even though the typical number of beds per home changed substantially during the study, a higher rate of consent within homes than we originally expected meant that our power was only slightly compromised.

Below, for completeness, we reproduce the details of the power calculations from the original proposal.

Appendix: Details of power calculations [reproduced from initial proposal].

James Carpenter, July 7th 2004

1. Distribution of beds within homes

The distribution of homes is suspected of being bimodal, with modes around 20 and 80, and a long right tail. In consultation with co-applicants, I therefore decided to simulate this using a mixture of normal and uniform distributions. The parameters of these distributions were varied until typical datasets from this distribution agreed with co-applicants experience and the limited available literature.

Specifically, for the power calculations, the mixture distribution had three components: I) $N(20,2)$, II) $N(30,8)$, and III) $\text{uniform}(60,160)$, with respective weights 0.85, 0.11 and 0.04.

This generated frequency distribution is shown in the text.

2. Power calculations

Each entry in the table in the main application was based on the average of 20 simulations. Broadly, each simulation drew data from a multilevel structure, with two levels (homes and patients), then reduced the number of patients to allow for those who did not consent. A multilevel logistic model was then fitted to the simulated data, with a component of variance for home and a constant, which estimates the logit (prescription error) probability. The 95% confidence interval for this constant term was back transformed, and its length divided by 2 to give an estimate of the likely variability in rates estimated from real data – i.e. the ‘+/- X %’ in the table in the main application. Twenty such estimates were averaged to get the results presented in the table in the main application.

Details of the simulation are as follows. The number of homes and the probability of a patient in that home consenting were varied as shown in the margins of the table in the main application. The distribution of beds per home was sampled using the model in section 1 above. The underlying prescription error rate was set at 10% and the maximum between home variability was set at ~6%. In other words the linear predictor for the error rate in each home was: $\text{logit}(0.1) + u_j$, where j indexes homes, and $u_j \sim N(0, \sigma^2)$, where $\sigma = [\text{logit}(0.1 + 0.06) - \text{logit}(0.1 - 0.06)]/4$.

Then, each ‘effective individual’ (see next paragraph) in a home had their response (error yes/no) drawn from a binary distribution with home specific probability given by the above (note that individuals correspond to beds in a home).

Using ‘effective individuals’ is a simple way of allowing for repeat prescriptions on individuals without simulating a third level of data. We judge it is an acceptable

approximation given the other unknowns in the power calculation. ‘Effective individuals’ are defined as follows. As, on average each patient would have 7 prescriptions, if the ICC is ρ , then, inverting the standard adjustment for clustering in a randomised trial each patient contributes the equivalent of $7/(1 + (7-1) \rho)$ independent, or ‘effective’ prescriptions. Taking $\rho=0.17$, a rough guide from the literature, we therefore adjust for the intra-patient correlation in prescription error by saying repeat prescriptions mean each patient contributes the equivalent of $7/(1 + 6*0.17) = 3.5$ ‘effective patients’ who each have only one prescription. We thus end up with a simulated data set where instead of three levels, homes, patients, prescriptions, we have two levels, homes and ‘effective’ number of patients per home (adjusted for repeat prescriptions).

Lastly, we reduce the number of ‘effective’ patients per home using the various values of the probability of consent as shown in the table in the application.

We then fit a two level multilevel model with a component of variance for homes to the simulated data and back transform the estimated confidence interval for the error rates. Dividing this by 2 gives an estimate of the ‘+/- X%’ value shown in the table. As discussed in the first paragraph of this section, we repeat the whole simulation/modelling routine above 20 times for each ‘no of patients per home’ / ‘no of homes’ combination and report the average X value in the corresponding cell of the table in the main application.

Appendix B
Care Home Profile

Care Home Use of Medicines Study

CARE HOME PROFILE

Home ref number.....

Date of profile.....

1) Brief description of home location:

Would you classify this as suburban? or rural?

Approx miles from your local research base

2) Your first impressions of this home

AREA

LEEDs

LONDOn

CAMBridge

PCT

Bradford City Bradford North Bradford South Calderdale Craven Harrogate & Rural

Ealing Huntingdon Lambeth Lewisham Southwark

1) Type of care provided

- ☐ Residential (personal) care only
- ☐ Nursing care only
- ☐ Residential care plus nursing

2) Size of home

Type of care	Current n residents	Max places
Residential care		
Nursing care		
Dementia>65		
Short-term respite care		
Residents under 65		

3) Organisation of care within the home

On how many floors is care provided?

Is the type of care provided organised by floor? *(if yes, get details)*

4) Ownership

- ☐ Privately owned
- ☐ Part of a chain.....(*name*)
- ☐ Local authority
- ☐ Not-for-profit.....(*name*)

5) Size of parent organisation

- ☐ N/a- single home
- ☐ 2-5 homes
- ☐ Larger organisation (please specify approx number homes in the group).....

If a large organisation- how often do you have contact with your head office/area managers ?

6. Staffing

Approximately how many staff would be on duty on a typical day?

	Early shift	Late shift	Nights
Team leaders			
Care assistants			
RGNs			
Adaptation (overseas) nurses			
Others (please state)			

7) Staff training

What type of training is there *for new staff* on medicines procedures?
What does training involve and who provides it

What about on-going training (refreshers or updates) for staff ?
What does this involve? Is it ad hoc or on a regular basis?

Does your PCT provide any training support for your home?
If yes, what sort of support, and who provides it.

8) GP visits

How many **GP practices** does the home deal with? (*please circle*)

1 2 3 4 5 more than 5

List names of the practices and ask which doctor(s) usually service the home. The full staff list (including salaried docs and GP registrars) can be completed later

On average, how often do GPs visit residents?

Practice 1 Address		Approx n visits per week	Regular visits	Visits on request
GP1			Y/N	Y/N
GP2			Y/N	Y/N
GP3			Y/N	Y/N
GP4			Y/N	Y/N

Practice 2 Address		Approx n visits per week	Regular visits	Visits on request
GP1			Y/N	Y/N
GP2			Y/N	Y/N
GP3			Y/N	Y/N
GP4			Y/N	Y/N
Practice 3 Address		Approx n visits per week	Regular visits	Visits on request
GP1			Y/N	Y/N
GP2			Y/N	Y/N
GP3			Y/N	Y/N

GP4			Y/N	Y/N
Practice 4 Address		Approx n visits per week	Regular visits	Visits on request
GP1			Y/N	Y/N
GP2			Y/N	Y/N
GP3			Y/N	Y/N
GP4			Y/N	Y/N

8 (cont) **GP visits**

Practice 5 Address		Approx n visits per week	Regular visits	Visits on request
GP1			Y/N	Y/N
GP2			Y/N	Y/N
GP3			Y/N	Y/N
GP4			Y/N	Y/N

Practice 6 Address		Approx n visits per week	Regular visits	Visits on request
GP1			Y/N	Y/N
GP2			Y/N	Y/N
GP3			Y/N	Y/N
GP4			Y/N	Y/N

How would you describe your working relationship with the GP practices?

9) **Clinical and communication records for residents**

a) What type of records are kept in the home?

(NB: Please record the actual terms the home uses- this may vary from place to place)

- ☐ Admissions information
- ☐ Patient/client profiles
- ☐ Care records /nursing notes
- ☐ Shared care records (eg anticoagulant book; Lithium;clozapine)

Hospital discharge info/test results

Does the home usually get copies of lab test results? No ☐ Yes ☐

Does anyone else (eg pharmacy?) No ☐ Yes ☐ *please specify.....*

b) Where are client records kept?

Is this the same for all floors/units in the home? No ☐ Yes ☐
(if no, get details if possible)

Who has access?

If locked, who holds the key?

c) Which types of communication records does the home keep?

- ☐ Doctor's book
- ☐ Multidisciplinary record sheet for all health care professionals
- ☐ Separate district nurse/CPN records

d) Are the GP's clinical records for residents:

- ☐ All kept at the practice
- ☐ All kept in the home
- ☐ Partly kept in the home

Is there a computer link in the home to GP records kept at the practice?

No ☐ Yes ☐

Is there a computer link to the pharmacy? No ☐ Yes ☐

10) Residents medicines

a) How many residents self-medicate?.....

Do they keep their own medicines? No ☐ Yes ☐

b) Are there individual cupboards for medicines in residents' rooms?

☐ No ☐ Yes, for some residents ☐ Yes for all residents

If yes, where is the MAR chart kept?

c) Does your home use a Monitored Dose System (MDS) for residents medicines? No ☐ Yes ☐

IF YES, is this:

☐ a cassette system ☐ a blister sheet system

What is the name of the MDS system do you use?

☐ Nomad ☐ Venalink ☐ Boots ☐ Manrex ☐ Lloyds ☐ Another system.....

How long does it normally take for a new resident to be put onto MDS?

Are there any residents who do NOT routinely get put on MDS (eg short-term respite care?)

10) *continued* Residents medicines

c) Medicine administration records

Does your home use the printed Medicine Administration Record (MAR) charts ☐ No ☐ Yes
supplied by the makers of the MDS system?

If NO, how do you record medication administration?
(*get as much detail as possible*)

How long does one MAR chart last?

Where are old charts stored?

What other records do you keep of medicines administered to residents?
(eg self-administration; district nurse records)

d) GP prescription records

Are *the repeat prescriptions* for all residents produced by the GP practice computer?

☐ Yes ☐ No *which practice(s) don't use a computer?.....*

Where is the repeat medicines list (the RHS of the FP10 form) kept?

☐ In the home

☐ In the pharmacy

☐ Somewhere else (*give details*)

11) For the supply of repeat medication:

a) How are prescriptions for repeat medicines for residents *usually* ordered?

- ☐ Home orders direct from GP practice using repeat slip (RHS of prescription form)
- ☐ Home orders direct from GP practice using the MAR sheets
- ☐ Pharmacy orders from the GP practice after visiting/consulting with the home
- ☐ Pharmacy orders from GP practice without contacting the home
- ☐ Another method (*please describe*)

If repeat medicines are ordered by the home, who usually does this?.....
(*What happens if he or she is on leave?*)

Does the home keep photocopies of residents' prescriptions? No ☐
Yes ☐

Do you have any residents on batch (repeatable) prescriptions? No ☐
Yes ☐

b) How do dispensed medicines usually reach the home?

- ☐ pharmacist delivers personally
- ☐ someone from the pharmacy delivers
- ☐ home staff collect from pharmacy
- ☐ Another arrangement (*please describe*)

c) What time of day are dispensed medicines usually delivered?

How are dispensed medicines checked on delivery?

Who usually does this, and when?

Are records routinely kept of discrepancies? (eg a pharmacy "error book"?)
No ☐ Yes ☐

12) For new or changed medicines

What happens if there is an *urgent change or addition* to a resident's medication? Please tick all that apply

- ☐ Home faxes script to usual pharmacy
- ☐ GP contacts usual pharmacy with script
- ☐ Request telephoned to usual pharmacy
- ☐ Prescription taken to nearest pharmacy
- ☐ Another arrangement (please describe)

What happens if there is an urgent change or addition to a resident's medication *outside normal pharmacy opening hours*?

13) Supplying pharmacy

How many pharmacies does the home *use on a regular basis* to obtain medication for residents?

(List names and complete other details later)

Pharmacy name	Address	Postcode	Approx miles from home

How often do you have telephone or face-to-face contact with the pharmacy about residents' medication?

Who do usually speak to?

How would you describe your working relationship with that person?

How often does the pharmacist visit the home?

- ☐ Most days
- ☐ Once a week
- ☐ Once a month
- ☐ Less often than that
- ☐ Never visits

What does he or she do when they visit?
(check storage etc? or review medication?)

Is there anything else that you would like to tell us?

Thanks and close

Appendix C:

Data sources used

We will be looking at:

1. Records kept within the care home
2. Records kept at the GP surgery
3. Records kept at the community pharmacy.

1 & 2 will be the main sources of our data. It is not intended that the community pharmacy will be routinely included because of time constraints.

Keep a record of all the sources you use in the **Data Sources Used** screen (below).
Make an entry for all the boxes; **do not leave any blanks!**

Data Source	Care home	GP Surgery	Pharmacy	Comments
MAR previous (one cycle)	Yes	Not available	Not available	
MAR records (current) i.e. paper administration records				
MAR previous (one cycle)				
* GP's clinical record				
GP repeat order form (get photocopy if possible)				
GP repeat prescriptions (computer)				
GP communication book				
Care records/ nursing notes				
Hospital discharge info (record date of discharge)				
Other Health Care professionals (specify) communications				
Laboratory reports / investigations				
Anticoagulant clinic book				
Shared care books (Primary/Secondary care sharing e.g. lithium)				
Accident book				
PMR (Patient Medication Records)-from community pharmacy computer				
Other (Give details)				

Medication Administration Records (MARs):

- Remember that the MAR chart is not “the prescription”. MAR charts are purely records of administration and do not act as a medication order as would occur in hospital.
- MARs may be computer generated by the community pharmacy, or can be handwritten at the home by staff (copied from the dispensing label not the previous MAR) or in some cases by the GP.
- MARs come in different formats but essentially the contents are the same.
- MARs most commonly last for 28 days, but can cover one calendar month or can be on-going for up to 3 months or occasionally even longer.
- The MAR often doubles as a medication profile i.e. somewhere where all the medication that the resident is on is recorded. For example, it should include medication that is self-administered or is administered by District Nurse, Community Psychiatric Nurses or GP, but it sometimes doesn't.

- It is worth asking to see the medication profile or asking if they have any other records of medication being administered or taken elsewhere.

Previous MAR:

- It is very important that the previous MAR is looked at and compared with the medications on the current MAR. When changes occur mid-cycle it is on the MAR where it would be recorded, and if medicines are changed close to the end of the cycle, after the request has been put in for the repeats, it is possible that the change may not be carried forward.
- The home must keep MARs for at least 3 years, but sometimes they are not very easy to find. They could be rolled up and put in a box to await sorting with many other previous MARs or kept in with the resident's clinical or care history.
- The old MARs may be stored by resident or by floor/unit or by home.

The GP's clinical record:

- May be computer based, paper based or a combination of both.
 - It may be kept entirely in the home, partly in the home or entirely at the GP practice.
 - Some homes may have a computer link to residents' clinical records at the practice so prescriptions may be generated in the home and signed by the GP during a visit.
 - The pharmacy may have a computer terminal from which all the prescriptions are generated.
- The records in the home may be split in different places- *make a point of asking for all GP records that the doctor may access* e.g. communication book, repeat prescription request slips/book, care plans, clinical records, admission information
 - The clinical records may be locked away in the home and sometimes only the GP has a key, so you need to **ask if anything is locked away**.
- Note that different floors/units in the same care home may have different ways of storing information and can also use different systems for ordering, administering etc.
- Different homes use different terminology for clinical records.
- In the GP surgery records may be entirely on computer or partly in paper. Some GPs may only record repeat prescriptions on the computer, using FP10s for all acute medication and associated medical notes; this may be in Lloyd George envelopes at the surgery or at the care home or both.

Residents' repeat prescriptions:

This refers to the medications that are in the repeat list for that resident on the GP's computer.

- There are many different GP computer systems in use
 - Some will have repeat and acute medications in the same window
 - Some systems have separate windows for repeat and acute medicines
 - GPs vary in how they categorise medicines- some will have all medicines as acutes so only they can reauthorise them, others have all medicines, including antibiotics, authorised for repeats.
- The actual prescription may be available in the home either as the original or as a photocopy.
- If the actual prescription is not available the repeat section of the FP10 might be.
 - Sometimes the repeat section is kept at the pharmacy.
 - Note that some homes may reorder their prescriptions using a copy of the Medication Administration Record (MAR) instead of the computer generated repeat slip.

If possible obtain a photocopy of the prescription/s or repeat slip/s:

- It is possible that some residents have had their medications put on “Repeatable Prescriptions” in line with repeat dispensing guidelines. In this case the batch issues may be either at the care home or at the pharmacy, but the original repeatable prescription will always be kept at the pharmacy. This may become more common as the new Pharmacy Contract becomes fully implemented, and is probably more likely to be used for residential care residents than nursing care residents.

GP communication book:

- It’s usually worth asking if you can see this; most homes have a written method for communication and the doctor will often write comments in it following the visit.
- It should tell you when the resident has last seen the GP and what for.

Care records/nursing notes/client profile:

- Different homes use different terminology for these records and they vary in how much information is stored in them.
- All homes have to keep a daily log of care- this may just refer to personal care but can also include relevant medical information.
- It should include reference to sleep and bowel activity where relevant, and this may be pertinent to the medication review.

Hospital discharge information (record date of discharge):

- These may be found in the surgery in either paper format or on the computer, either scanned in or the data entered from the original.

- In the surgery it may be a doctor or a receptionist entering details of discharge medications.
- The care home may be sent a copy of the results either from the GP or the hospital, but not all hospitals or GPs will do this.
- The pharmacy may also have a system set up so they receive a copy

Other Health Care Professionals' (HCPs) communications:

- Homes vary in how visiting HCPs record their visits. Visiting HCPs can include District Nurses, Community Mental Health Teams, Specialist Nurses, Physiotherapists, Occupational Therapists, Speech and Language Therapists (SALT).
 - Some homes have a record sheet in the care records on which all visiting HCPs record their comments, others will have separate records for each different one
 - District Nurses and Community Psychiatric Nurses will often keep their own records which are not always available in the home, but staff are usually aware of what is being administered, so ask.

Laboratory reports/investigations:

- These may be found in the surgery in either paper format or on the computer, either scanned in or the data entered from the original. Some GPs are also sent lab reports direct to the computer from the hospital, but this does not necessarily include tests initiated by the hospital during inpatient stays.
- The care home may be sent a copy of the results either from the GP or the hospital, but not all hospitals or GPs will do this.
- The pharmacy may also have a system set up so they receive a copy.

Anticoagulant clinic book:

- Often the dose on the GP records and on the dispensing labels and MARs will just have "as directed" as dose changes after INR checks rarely coincide with the issue of new prescriptions, so this book will be the source of up to date information.
- If there is a dose on the MAR it is always worth checking against this book as doses might not get updated on the MAR, which could be a source of error.

Other shared care books:

- This covers all communication means between primary and secondary care where responsibility for care and monitoring is shared e.g. lithium, clozapine, methotrexate, antimentia drugs etc.

Accident book:

- All homes must have an accident book
- Referral to this may be relevant if the resident is at high risk of falls.

Patient Medication Records (PMR):

- These are the records kept by community pharmacists on what has been dispensed for each individual.
 - The repeat medications and acute medications may be kept separately or it may just be a chronological record of everything dispensed.
 - Many systems will generate the dispensing labels and the MAR from the same inputted information, but for some systems they are generated separately and discrepancies between them could be a source of error.

Other:

- Record here anything that doesn't fit into the above. Use the comments boxes in the **Data Sources Used screen** to record anything at all that may be relevant.

Appendix D

Development and validation of criteria to identify medication monitoring errors in care home residents

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Keywords: medication error, monitoring, primary care, care homes

What is already known about this subject?

- Care home residents are particularly susceptible to adverse drug events.
- Failure to adequately monitor drug therapy is associated with significant morbidity.
- A validated definition and criteria for the identification of monitoring errors in the care home setting has not been published.

What this study adds

- A definition and criteria for the identification of monitoring errors in care home residents was validated.
- The definition and criteria are pragmatic and easily operationalised.
- The definition and criteria can be used in future research studies to determine the prevalence and nature of monitoring errors in care homes

Summary

Aim

The identification of medication monitoring errors requires a validated definition. This paper describes the development and validation of a definition which includes criteria for specific drugs to determine whether a monitoring error has occurred in the care home setting.

Setting

Criteria were developed for older people (aged 65 years or older) living in care homes.

Methods

Criteria were developed by two clinical pharmacists using published guidelines. The criteria were divided into those relating to initiation of therapy and maintenance monitoring. The study steering group, made up of clinical pharmacists, a GP and pharmacy academics, then reviewed the criteria and a consensus achieved. The criteria were then reviewed by a sample of general practitioners (21) and clinical pharmacists (11). The threshold for acceptance for each criterion was set at agreement by 70% of all participants.

Results

The definition of a medication monitoring error was accepted as “when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. It includes the absence of tests being carried out at the frequency listed in criteria for each drug, with tolerance of +50%.” Seventy percent agreement was reached on all criteria for the initiation of therapy, except warfarin

(69%), and on all criteria for maintenance monitoring, except penicillamine (63%) and potassium (63%).

Conclusions

To our knowledge, this is the first study to define a medication monitoring error, and to determine and validate specific criteria to identify such errors in older people living in care homes.

Introduction

Older people living in care homes are at a higher risk of medication error, and resultant harm, than most other populations. This is for several reasons. Firstly, older people are more susceptible to adverse drug events due to age-related changes in pharmacokinetics and pharmacodynamics [1]. Secondly, care home residents have a high level of morbidity not only because of their age and frailty, but also because poor health is usually the reason for being in residential care. They therefore receive a greater number of medicines than their counterparts living in their own homes, with a mean number of medicines of 5-7 in the UK [2,3,4]. Thirdly, medicines management in care homes is complex both in terms of the model of care and the sheer numbers of people involved in the process. This further increases the risk of error. The UK Government is committed to reducing medication errors [5,6].

There is a paucity of evidence and often disagreement amongst health care professionals regarding how often, if at all, a particular medicine should be monitored. Several national and local guidelines exist for the monitoring of medication, however, they often differ in their recommendations [7,8,9,10].

Quality indicators for medication monitoring in vulnerable older people have been published [11]. However, specific monitoring criteria were limited to antidepressants, diuretics, angiotensin converting enzyme inhibitors (ACE inhibitors) and warfarin, and other potentially harmful medicines were not included. Gurwitz et al conducted a study of preventable adverse drug events in two US long-term care facilities and identified monitoring errors including inadequate laboratory

monitoring, a delayed response or failure to respond to signs or symptoms or laboratory evidence of drug toxicity [12]. However, criteria to identify monitoring errors for specific medicines were not reported.

There is evidence that medication monitoring in the care home setting is suboptimal. In the study conducted by Gurwitz et al, four fifths of preventable adverse drug events involved a monitoring error with "inadequate monitoring" and "failure to act on monitoring" predominating [12]. In a randomised controlled trial of pharmacist-led clinical medication review in UK care home residents, one fifth of interventions were to conduct monitoring of medication and 14% of these resulted in a medication change [13].

We intended to develop a definition and criteria that were pragmatic, easily operationalised, and owned by practising general practitioners and clinical pharmacists. It was not the intention to produce an exhaustive list of drugs that required monitoring, rather to focus on the drugs most likely to be prescribed with the potential for harm in the care home setting. The aim of this study was, therefore, to define a monitoring error by developing and validating criteria to assess whether a monitoring error had occurred in the care home setting. We intend that such criteria can be utilised in future research studies to determine the prevalence and nature of monitoring errors in the care home population.

Method

Research ethics approval was obtained from the Central Office for Research Ethics Committees. A literature search was conducted using MEDLINE (May 2006) and EMBASE (May 2006) using the search terms “medication error”, “drug monitoring” and “monitoring error” to identify whether criteria for determining medication monitoring errors had previously been published, or whether a monitoring error had previously been defined. No generic definition of a monitoring error was identified.

A definition of a monitoring error was therefore developed and agreed by the study steering group. Criteria were initially developed by two clinical pharmacists (DPA and CS), using local and national guidelines for the monitoring of pharmacotherapy [7,8,9,10]. The criteria developed were designed to reflect routine clinical practice and be applicable to primary care prescribing for care home residents.

Firstly, the list of drugs for which a monitoring error would be included in the definition was determined. This took into account the drugs included in the above guidelines. Sixteen drugs or groups of drugs were deemed to have properties which made monitoring necessary in the primary care setting (Table 1 and Table 2). The criteria were split into two sections:

- (a) monitoring following the initiation of therapy (8 drugs or groups of drugs).
- (b) monitoring of maintenance therapy (all 16 drugs or groups of drugs);

The criteria for each drug were then agreed by experienced practitioners and academics from the study steering group. These comprised four clinical pharmacists (DPA, CS, BJ, BDF), a pharmacist lecturer in patient safety (IS), two professors of

pharmacy practice (NB, DKR) and one practising general practitioner / research fellow (AZ).

To ensure external validity, the criteria were reviewed by a sample of GPs (21) and clinical pharmacists with primary care experience (11) who were selected from the Primary Care Pharmacy Network (5 pharmacists), from GP trainers (9 GPs) and from a convenience sample (6 pharmacists, 12 GPs). The pharmacists and general practitioners were e-mailed the criteria in August 2006 and asked to indicate whether they agreed or disagreed with each specific medication monitoring criterion and to give comments where they disagreed. An overall consensus rate of 70% was deemed sufficient to accept each criterion.

Results

The core definition of a monitoring error was agreed by the study steering group as:

“A monitoring error occurs when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. It includes the absence of tests being carried out at the frequency listed in the criteria, with tolerance of +/-50%. This means, for example, that if a drug requires liver function tests at 3 monthly intervals, we would class as an error if a test has not been conducted within 18 weeks.” If a patient refused to give consent for a test, then this would not constitute an error.

Table 1 shows GP, pharmacist and overall responses for monitoring following the initiation of therapy. An overall agreement of 70% or more was obtained for all drugs except warfarin (69%). One hundred percent of pharmacists agreed with the

suggested warfarin criterion but only 67% of GPs responded, with 52% of all GPs agreeing. Therefore, warfarin was removed from the initiation of therapy criteria.

GP, pharmacist and overall responses for the monitoring of maintenance therapy are shown in Table 2. An overall agreement of 70% or more was obtained for all but two drugs; these were penicillamine and potassium supplements. Ninety one percent of the pharmacists agreed with the suggested penicillamine criterion, but only 67% of GPs gave a response, with only 48% of all GPs agreeing. Although 73% of the pharmacists agreed with the potassium supplements criterion, only 57% of GPs did so. Consequently, penicillamine and potassium supplements were removed from the criteria.

The criterion for the maintenance monitoring of theophylline was to obtain a plasma level when toxicity or lack of efficacy was suspected. It was decided within the study steering group that for the purpose of identifying an error, it was neither reasonable nor practical to include lack of efficacy in the criterion. As such, this part of the criterion was removed.

Although consensus was reached for carbimazole and levothyroxine, it became apparent that the monitoring specified on initiation was a pre-requisite of the drug being prescribed i.e. the test had to be done to establish a diagnosis. Consequently, these three drugs were removed from the monitoring for initiation or dose changes. The final agreed criteria are presented in Table 3.

Discussion

To our knowledge, this is the first study to develop a definition of a medication monitoring error and to develop and validate drug-specific criteria to identify monitoring errors in the care home setting. The 50% tolerance for the frequency of tests conducted was a pragmatic judgement based on what was deemed to be reasonable and practical. Identifying patients who were technically in breach of the criteria because they were, for example, a week late in having their blood test, would not have been a reasonable reflection of routine clinical practice. If a test was not conducted within the 50% leeway, it would be clearly and unequivocally outside the recommendation and represent a significant breach of standards. The 70% agreement level for acceptance of a criterion was also a pragmatic judgement.

Overall agreement was not reached for the monitoring of warfarin on initiation, despite all the pharmacists agreeing. Only two thirds of the GPs responded to this criterion, with just over half agreeing. On analysing the GPs' comments, it would appear that agreement was not reached due to a lack of experience of initiating warfarin as this was usually done in secondary care or by anticoagulant clinics. Overall consensus was not obtained for the maintenance monitoring of penicillamine, although 91% of pharmacists agreed. Only two thirds of GPs responded with just under half agreeing. The reasons for GPs not agreeing were again due to a lack of experience of the drug because it was prescribed infrequently or monitored by a specialist. Overall agreement was not achieved for the maintenance monitoring of potassium supplements, with nearly three quarters of pharmacists agreeing but only 57% of GPs

agreeing. Some disagreed because they felt patients should not be prescribed potassium supplements long-term and some disagreed because they advocated more frequent monitoring. It was clear that the pharmacists were more likely to agree on the criteria than the GPs. This may reflect that the pharmacists had greater familiarity with the monitoring recommendations of drugs. It is also possible that the GPs were less likely to agree due to the potential practical problems of monitoring in this population, for example, difficulties in obtaining samples due to refusal of consent or service restrictions.

Medicines are monitored for two main reasons, to evaluate their effectiveness and to detect or anticipate harm. The majority of the validated criteria developed in this study relate to the detection of medicine-induced harm, for example, the monitoring of full blood counts for azathioprine to identify neutropenia. However, harm can also be caused by a lack of efficacy, for example, an increase risk of thromboembolism due to underdosing with warfarin. A lack of efficacy may also be due to poor adherence and this may be detected by monitoring. Errors in monitoring can occur at several stages: (i) a failure to request a test (ii) a failure to undertake a requested test (including a sample being obtained but no result reported) and (iii) a failure to act upon a deranged result. Morris et al found that 37% of preventable drug-related morbidity was associated with a lack of monitoring of drugs, with over three quarters of the events involving ACE inhibitors [14] It has been found that medicine-related harm accounts for 4.3% of preventable hospital admissions [15]; diuretics account for 16% of these and anticoagulants 8%. Reducing monitoring

errors for these medicines may potentially avoid iatrogenic disease and hospital admissions.

The criteria validated in this study include a wider range of medicines than the ACOVE quality indicators developed by Shekelle et al which were restricted to antidepressants, diuretics, ACE inhibitors and warfarin [11]. Our criteria were designed to reflect common prescribing patterns and clinical practice in the care home setting, and were not designed to be exhaustive. Several potentially harmful medicines, for example, ciclosporin were omitted from the criteria because it was felt that these medicines would not be commonly prescribed in this population and because monitoring is usually conducted in secondary care.

The sample of GPs and clinical pharmacists may not have been representative of the whole population, however, the sample was geographically diverse and consisted of practising experts. Another limitation is the fact that for most drugs there is not an objective scientifically evidence-based criterion for monitoring requirements, and much recommended monitoring may be overcautious extrapolation from what is known about the drug's toxicity.

Such evidence about toxicity is rarely derived from studies of the very elderly or of care home residents. In addition, it is often appropriate to increase monitoring in situations where the patient is clinically unwell and such situations were not considered in the criteria.

In summary, a pragmatic definition and criteria for the identification of monitoring errors in the care home setting was validated and can be used in future to determine

the prevalence and nature of such errors in this setting. It is hoped that intervention studies can then be conducted, and safer systems developed, to reduce the burden of monitoring errors on care home residents and the healthcare system.

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Competing interests

None declared.

References

1. Armour D, Cairns C. (editors). Medicines in the Elderly. London: The Pharmaceutical Press 2002.
2. Furniss L, Burns A, Craig SKL, Scobie S, Cooke J, Faragher B. Effects of a pharmacist's medication review in nursing homes: randomised controlled trial. *Br J Psychiatry* 2000; 176: 563-7.
3. Osborne CA, Hooper R, Swift GC, Jackson SHD. Explicit, evidence-based criteria to assess the quality of prescribing to elderly nursing home residents. *Age Ageing* 2003; 32; 102-8
4. Zermansky AG, Alldred DP, Petty DR, Raynor DK, Freemantle N, Eastaugh J, Bowie P. Clinical medication review by a pharmacist of elderly people living in care homes--randomised controlled trial. *Age Ageing* 2006; 35(6):586-91.

5. Expert Group on Learning from Adverse Events in the NHS. An organisation with a memory. 2000. London, Stationary Office.
6. Department of Health. Building a safer NHS for patients. 2001. London, Department of Health.
7. British Medical Association and Royal Pharmaceutical Society of Great Britain. British National Formulary 51 March 2006 ed. London.
8. Monitoring drug therapy. North West Drug Information Letter No.120. Sept 2002. Available at <http://www.ukmi.nhs.uk/newmaterial/html/docs/21100201.pdf> Accessed 6th December 2007.
9. Suggestions for Drug Monitoring in Adults in Primary Care: A collaboration between London and South East Medicines Information Service and Croydon Primary Care Trust. June 2006
10. Hinchingsbrooke Hospital NHS Trust . Monitoring of Maintenance Therapy in Primary Care. October 2005

11. Shekelle PG, MacLean CH, Morton SC, Wenger NS. Assessing care of vulnerable elders: methods for developing quality indicators. *Ann Intern Med* 2001; 135: 647-52.
12. [Gurwitz JH](#), [Field TS](#), [Judge J](#), [Rochon P](#), [Harrold LR](#), [Cadoret C](#), [Lee M](#), [White K](#), [LaPrino J](#), [Erramuspe-Mainard J](#), [DeFlorio M](#), [Gavendo L](#), [Auger J](#), [Bates DW](#) Gurwitz et al. The incidence of adverse drug events in two large academic long-term care facilities. [Am J Med](#). 2005;118(3):251-8.
13. Alldred DP, Zermansky AG, Petty DR, Raynor DK, Freemantle N, Eastaugh J, Bowie P. Clinical medication review by a pharmacist of elderly people living in care homes: pharmacist interventions. *Int J Pharm Pract* 2007; 13:93-9.
14. Morris CJ, Rodgers S, Hammersley VS, Avery AJ and Cantrill JA. Indicators for preventable drug-related morbidity: applications in primary care. *Qual Saf Health Care* 2004;13:181-5
15. Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P, Pirmohamed M. Which drugs cause preventable admissions to hospital? A systematic review. *Br J Clin Pharmacol* 2006

Appendix E

DATA COLLECTION FORM FOR DISPENSED ITEMS

PATIENT IDENTIFIER: **DATE**.....

CARE HOME IDENTIFIER:

Drug (write each container as separate line)	Strength	Instructions	Date of Disp.	Qty on Label	Qty. Prescribed	Type of MDS or non-MDS	For MDS- number of doses left in pack	For non-MDS – number of packs	Packaged for right time of day? Y/N	Comments	Stable in MDS? (use PJ article 2006for comments)

Table 1: General Practitioners' and pharmacists' responses to criteria for monitoring drugs on initiation

Drug	Criteria	General Practitioners (n=21)			Pharmacists (n=11)			Overall (n=32)		
		No. of responders (%)	No. of responders agreeing (%)	No. of responders disagreeing (%)	No. of responders (%)	No. of responders agreeing (%)	No. of responders disagreeing (%)	No. of responders (%)	No. of responders agreeing (%)	No. of responders disagreeing (%)
ACE inhibitors	Pre U&E; U&E 2/52 after	21 (100.0)	17 (81.0)	4 (19.0)	11 (100.0)	10 (90.9)	1 (9.1)	32 (100.0)	27 (84.4)	5 (15.6)
Carbimazole	Pre TFT	16 (76.2)	16 (76.2)	0 (0.0)	11 (100.0)	11 (100.0)	0 (0.0)	27 (84.4)	27 (84.4)	0 (0.0)
Digoxin	Pre U&E	19 (90.5)	16 (76.2)	3 (14.3)	11 (100.0)	11 (100.0)	0 (0.0)	31 (96.9)	27 (84.4)	3 (9.4)
Diuretics	Pre U&E; 1m after	18 (85.7)	13 (61.9)	5 (23.8)	11 (100.0)	11 (100.0)	0 (0.0)	29 (90.6)	24 (75.0)	5 (15.6)
Glitazones	Pre LFT	17 (81.0)	12 (57.1)	5 (23.8)	11 (100.0)	11 (100.0)	0 (0.0)	28 (87.5)	23 (71.9)	5 (15.6)
Levothyroxine	Pre TFT	20 (95.2)	17 (81.0)	3 (14.3)	11 (100.0)	11 (100.0)	0 (0.0)	32 (100.0)	28 (87.5)	3 (9.4)
Potassium	Pre K ⁺	20 (95.2)	17 (81.0)	3 (14.3)	11 (100.0)	11 (100.0)	0 (0.0)	32 (100.0)	28 (87.5)	3 (9.4)
Warfarin	Pre PT, APTT, platelets, LFT	14 (66.7)	11 (52.4)	3 (14.3)	11 (100.0)	11 (100.0)	0 (0.0)	25 (78.1)	22 (68.8)	3 (9.4)

m = monthly

U&E = urea and electrolytes

TFT = thyroid function tests

LFT = liver function tests

K⁺ = serum potassium level

PT = prothrombin time

APTT = Activated Partial Thromboplastin Time

Table 2: General Practitioners' and pharmacists' responses to criteria for the maintenance monitoring of drugs

Drug	Criteria	General Practitioners (n=21)			Pharmacists (n=11)			Overall (n=32)		
		No. of responders (%)	No. of responders agreeing (% of all GPs)	No. of responders disagreeing (% of all GPs)	No. of responders (%)	No. of responders agreeing (% of all pharmacists)	No. of responders disagreeing (% of all pharmacists)	No. of responders (%)	No. of responders agreeing (% of all GPs/pharmacists)	No. of responders disagreeing (% of all GPs/pharmacists)
ACE inhibitors	12m U&E	21 (100.0)	18 (85.7)	3 (14.3)	11 (100.0)	11 (100.0)	0 (0.0)	32 (100.0)	29 (90.6)	3 (9.4)
Amiodarone	6m TFT; 6m LFT	20 (95.2)	15 (71.4)	5 (23.8)	11 (100.0)	11 (100.0)	0 (0.0)	31 (96.9)	26 (81.3)	5 (15.6)
Azathioprine	3m FBC	17 (81.0)	15 (71.4)	2 (9.5)	11 (100.0)	10 (90.9)	1 (9.1)	28 (87.5)	25 (78.1)	3 (9.4)
Carbimazole	3m TFT; 6m TFT if stable >1year	20 (95.2)	16 (76.2)	4 (19.0)	11 (100.0)	10 (90.9)	1 (9.1)	31 (96.9)	26 (81.3)	5 (15.6)
Digoxin*	If toxicity or lack of efficacy suspected	21 (100.0)	16 (76.2)	5 (23.8)	11 (100.0)	10 (90.9)	1 (9.1)	32 (100.0)	26 (81.3)	6 (18.8)
Diuretics	12m U&E	21 (100.0)	16 (76.2)	5 (23.8)	11 (100.0)	11 (100.0)	0 (0.0)	32 (100.0)	27 (84.4)	5 (15.6)
Glitazones	12m LFT	19 (90.5)	14 (66.7)	5 (23.8)	11 (100.0)	9 (81.8)	2 (18.2)	30 (93.8)	23 (71.9)	7 (21.9)
Levothyroxine	12m TFT	21 (100.0)	21 (100.0)	0 (0.0)	11 (100.0)	11 (100.0)	0 (0.0)	32 (100.0)	32 (100.0)	0 (0.0)
Lithium	3m lithium level; 12m TFT	20 (95.2)	16 (76.2)	4 (19.0)	11 (100.0)	9 (81.8)	2 (18.2)	31 (96.9)	25 (78.1)	6 (18.8)
Methotrexate	3m FBC; 3m LFT; 6m U&E	20 (95.2)	15 (71.4)	5 (23.8)	11 (100.0)	10 (90.9)	1 (9.1)	31 (96.9)	25 (78.1)	6 (18.8)
Penicillamine	3m FBC; 3m urinalysis	14 (66.7)	10 (47.6)	4 (19.0)	11 (100.0)	10 (90.9)	1 (9.1)	25 (78.1)	20 (62.5)	5 (15.6)
Potassium	12m U&E	18 (85.7)	12 (57.1)	6 (28.6)	9 (81.8)	8 (72.7)	1 (9.1)	27 (84.4)	20 (62.5)	7 (21.9)

Sulfasalazine	Year 1: 3m FBC; 3m LFT. Year 2: 6m FBC; 6m LFT	17 (81.0)	13 (61.9)	4 (19.0)	11 (100.0)	11 (100.0)	0 (0.0)	28 (87.5)	24 (75.0)	4 (12.5)
Theophylline	If toxicity or lack of efficacy suspected	19 (90.5)	17 (81.0)	2 (9.5)	11 (100.0)	10 (90.9)	1 (9.1)	30 (93.8)	27 (84.4)	3 (9.4)
Valproate	3m LFT for 6m	15 (71.4)	14 (66.7)	1 (4.8)	10 (90.9)	9 (81.8)	1 (9.1)	25 (78.1)	23 (71.9)	2 (6.3)
Warfarin	12 weekly INR	17 (81.0)	10 (47.6)	7 (33.3)	11 (100.0)	11 (100.0)	0 (0.0)	28 (87.5)	21 (65.6)	7 (21.9)

m = monthly

U&E = urea and electrolytes

TFT = thyroid function tests

LFT = liver function tests

FBC = full blood count

INR = international normalised ratio

* 50% tolerance not applicable

Table 3

Definition of a Monitoring Error“A monitoring error occurs when a prescribed drug or disease is not monitored in the way which would be considered acceptable in routine general practice.

It will include the absence of tests being carried out at the frequency listed in the table below with tolerance of +50%. This means that if a drug requires LFT's at 3 monthly intervals, we would class as an error if a test has not been conducted within 18 weeks.”

Drug/drug group	Maintenance monitoring
ACE inhibitor	12 monthly U&E
Amiodarone	6 monthly TFT 6 monthly LFT
Azathioprine	3 monthly FBC
Carbimazole	3 monthly TFT (6 monthly if patient been stabilised for over 1 year)
Digoxin	Digoxin level if toxicity or lack of efficacy suspected.
Diuretics	12 monthly U&E
Glitazones	12 monthly LFT
Levothyroxine	12 monthly TFT
Lithium	3 monthly lithium levels 12 monthly TFT
Methotrexate	3 monthly FBC 3 monthly LFT 6 monthly U&E
Sulfasalazine	FBC 3 monthly in 1st year LFT 3 monthly in 1st year FBC 6 monthly in 2nd year LFT 6 monthly in 2nd year No further monitoring if stable
Theophylline	Theophylline level if toxicity suspected
Valproate	3 monthly LFT for first 6 months
Warfarin	12 Weekly INR

Medication monitoring for initiation of therapy

Drug/drug group	Monitoring on initiation
ACE inhibitor	On initiation: Pre U&E and 2 week after

Digoxin	Pre U&E
Diuretics	Pre U&E and 1 month after starting
Glitazones	Pre LFT

Appendix F

Medications for which timing is considered clinically significant:

Bisphosphonates – if given less than 30 minutes before breakfast or other medications, or after food or other medications.

Nitrates – if timing is such that there is no nitrate free period.

Antibacterials – only note these if you consider the timing is such so that it is possible that the drug would not be clinically effective e.g. those antibiotics which should be taken on an empty stomach but have been given at mealtimes, or there is a significant gap between doses which has not been due to the resident refusing a dose.

NSAIDs – given on an empty stomach

Antidiabetic medication e.g. sulphonylureas or short acting insulin given late at night when no food will be consumed until breakfast thus increasing the risk of hypoglycaemia

Nateglinide/ repaglinide – have short duration of action and should therefore be given shortly before each main meal. Timing error should be considered if either drug is given more than one hour before food.

Anti-Parkinsonism drugs – where medication has been prescribed to be given at specified times in order to control symptoms adequately, but is being given more than 1 hour before or after.

Opioids – If given in such a way that there is a risk of overdose or clinical ineffectiveness.
e.g. MST Continus given 8 hours apart thus potentially resulting in breakthrough pain.

Paracetamol – doses of 1gm given less than 4 hours apart.

Statins, except atorvastatin, which are given in the morning rather than in the evening

Warfarin – if not given at the regular time for that resident, usually 5-6pm

Antacids – if given at a time so that the absorption of other drugs is adversely effected e.g. lansoprazole, tetracyclines, bisphosphonates, ciprofloxacin.

Appendix G

Observation of medication administration

The morning and teatime drug rounds are to be observed, as residents are most likely to have medicines given at these times.

Have everything you need with you i.e. data collection forms-administration, identification, clipboard, monitoring forms, pens (2 x different colours), spare paper, BNF, digital recorder, consent forms, Guide, EPC.

5.1 Before the drug round

You may decide that you would like to check through the drug trolley before observing the drug round; this would give you the opportunity to note what is dispensed in MDS and what type i.e. single or multi-dose units, and to check for duplications and check labels against the MAR. You may also wish to calculate the dispensing denominator at this time. This would be best done on the same day as the observation but if this is not possible, it can be done the preceding day.

Do take the time to familiarise yourself with the system which is in use. Also you need to be aware of the codes used to record non-administration; these will usually be printed along the bottom or side of the MAR, but the home may also use their own coding system.

Be prepared for the observation before the earliest time that the drug round is likely to begin, and ensure you have introduced yourself to the nurse /care staff.

If consent has not already been obtained, get this NOW. Even if the staff involved have already consented, it is important to ensure they understand what you intend to do.

Explain that you are a researcher, and explain what you would like to do.

Remind them that the purpose is to help design better systems for use in care homes and that consent has been given by the GP and resident to see the medical records as well as to observe the drugs round. Ask if they would mind if you accompanied them on this drug round.

If the nurse/carer is happy to be observed, explain what you will do. For example:

“I will need to record details of all drugs that are administered, so please don’t let it put you off if I am scribbling on the clipboard. I will try to keep out of your way so please try and ignore me”. You may need to explain that only a few residents’ medications are being observed and so you will not be writing all the time.

You should add that all results will be anonymous, and it will not be possible to identify the home, individual residents or individual members of care staff from the results.

Even though you may only be observing one resident's medication, do ensure you are there from the start of the drug round, so the nurse/carer becomes used to you observing. You can leave after you have observed the drug administration to the resident/s who are in the study.

5.2 During the drug round

Accompany the nurse/carer administering medication during the drug round. If the nurse/carer is called away from the drug trolley we would recommend staying with the drug trolley as you should be able to collect all of the relevant data from this point.

Try to be friendly and put the nurses/carers at ease. However, if you are asked for advice about drug administration, we would recommend explaining that you are there in your capacity as a researcher rather than as a pharmacist, so you cannot assist with patient care. Obviously if you feel it would be in the patient's best interests to give advice, and that they may suffer harm if you do not, then you should go ahead and give whatever advice is necessary.

Use the data collection form- administration.

You may wish to make a few notes after the observation and to distinguish between what you write at the time of observation and what you write subsequently- use different coloured pens.

So what do I have to record?

Record every dose that you observe to be given during the drug round using the data collection form provided, plus any doses that should have been given but were not.

Every dose that you observe for which you can definitely say what has been given is recorded on the data collection form-administration as an "Opportunity for Error" (OE) - you put a tick in the column marked OE.

Experienced nurses administer medication very quickly, so you may need to use some form of short-hand during the drug round and then clarify these afterwards. For example, aspirin 75mg can be shortened to 'asp 75' and enteric coated prednisolone 30mg as 'pred EC 30'. The main thing is to use something that is practical for you, and then clarify this afterwards so that it can be entered correctly into the database. Ideally you will need to see both what is written on the medication administration record (MAR) and what is actually given. If for some reason you cannot see both the MAR and the medication administered at the same time, record details of the drugs administered as you can check the MAR at a later stage (you may have been able to note this before the drug round). Record if tablets are crushed etc.

You will also be recording whether or not the dose was in an MDS or not by writing Y or N in the appropriate column.

If you identify an MAE, document this also. Again, use shorthand if you wish and then clarify the details afterwards. If an MAE is prevented by a patient or by yourself, record these details. If in doubt, record anything that happens as we can sort out how to classify it afterwards!

When a dose is omitted during the drug round but the drug chart is signed to indicate that it has been administered, count this as an omission as we will assume that the dose is never given. However if a dose is omitted and the drug chart left blank, you should ask the nurse or carer at the end of the round whether the drug was intentionally omitted. If the omission was unintentional, again, this should be included as an OE and an omission error.

5.3 What is an opportunity for error (OE)?

An opportunity for error is any dose of medication that the researcher observes being administered (or omitted) and can classify as being either correct or incorrect. Drugs prescribed to be given “when required” ie *prn*) should be included as opportunities for error if they are administered while you are observing. Doses given between the observed drug rounds are not considered opportunities for error as they cannot be observed.

Controlled drugs as well as many rectal, topical and intramuscular doses may need to be excluded, as observation of the administration of these may not be appropriate. PEG feeds and other nutritional supplements are excluded as they are not medicines.

Doses left for patient

Please make a note on the data collection form if the nurse/carer does not observe the patient taking the dose, but leaves it at their bedside for them to self-administer. This is not considered an error, but should be noted separately in the field notes.

5.4 After the drug round

Once the drug round is finished, thank the nurse/carer. If there is anything you need to check on the MARs of the residents observed, go back and check these now. You will need to check that the MAR and dispensing label agree and you can fill in whether or not the medicines have been signed for by ticking in the appropriate column. This may also be the best time to check for expiry dates on medicines. Note that medicines in heat sealed MDS are usually considered to have an expiry date of 8 weeks from dispensing.

Record any other ‘field notes’ as soon as possible after the round. Use a different colour pen, or a separate sheet of paper, so that we can tell what was recorded during the drug round and what was recorded afterwards from memory. Explain any abbreviations you have used that may be ambiguous to another pharmacist, and add any other comments about the round, why things happened, and anything else you think may be relevant.

If there is anything that will need checking at a later drug round, or later in the day (such as whether an omitted dose was subsequently given), document this clearly on a separate sheet of paper so you can check it later.

5.5 What can be expected?

In previous studies of this type in secondary care, the majority of MAEs have been drugs omitted because they are not available on the ward. The next most common groups are doses omitted because nursing staff cannot find the medication, or cannot find the drug chart.

Experience to date in care homes is that the majority of MAEs are also omissions. This can be because medicines have not been re-prescribed (ordered) or have not been delivered, or because carers cannot see the medicine in the trolley. We have observed one case of a dose omitted because the tablet was stuck in the MDS. Medicines are also omitted because staff miss the order on the MAR chart.

Other types of administration error encountered so far include dose duplication when the same drug was prescribed generically and by brand name, and inappropriate administration methods eg crushing tablets intended to be swallowed whole.

6. When and how should interventions be made?

6.1 Errors observed during medication administration

The issue of whether or not to intervene is a difficult one. If we intervene for every MAE, however minor, it could affect the study's results. However, most health care professionals would be uncomfortable with the idea of not intervening in a situation that could result in patient harm. You should therefore intervene if you are in a position to prevent patient harm.

For example, it would not be necessary to intervene in the majority of omission errors, because the omission of one dose is unlikely to result in patient harm, or in the administration of two Calcichew tablets instead of one, or the administration of vitamin B compound strong instead of vitamins BPC.

However intervention would be appropriate to prevent the omission of certain medication such as a dose of phenytoin, or the administration of a clinically significant overdose, or the administration of a drug to the wrong patient. At the end of the day however, it is up to your clinical judgement and there are no right or wrong answers.

There will be some situations where you cannot intervene to prevent patient harm, for example because you only realise there has been an error after the drug has been administered, or because the drug is not available in the home. In this case there is no need to intervene.

If you decide to intervene, this should be done in as tactful and non-judgemental a manner as possible, to prevent the patient from receiving the dose. For example:

“Are you sure it’s 250 microgram? I thought that said 125 micrograms”

“Oh, I interpreted that as 70mg once a week, not every day”

Avoid use of judgmental terms like ‘wrong’ and ‘error’. For example do not say ‘Oh, you’ve made an error’ or ‘you’ve got that wrong!’

We have never had problems in previous work in secondary care, and staff have always been grateful for the intervention and not particularly concerned by it.

6.2 Other types of unintentional error

If an error occurs we will be providing feedback to the person who has made the error. We will also be interviewing the person who made the error to gain an understanding of the error in order to prevent further errors.

GP prescribing errors will be communicated to him/her via the medication review form (and if necessary via the telephone), and explored further in interview. If serious dispensing errors are identified, the same will be done for pharmacists.

6.3 What if there is a serious risk of recurrence?

If after providing feedback, we are concerned that the patient may continue to suffer significant harm, or future patients could suffer significant harm, then we would consult the ethics committee as to whether we should break confidentiality in order to protect the patient(s). We would seek to do this urgently. However, it must be stressed that we will be breaking our ethical principles as we have informed consent from participants on the understanding that anonymity and confidentiality will be assured.

If we are in such a situation and the ethics committee recommends breaking confidentiality, then the clinical governance lead for the PCT would be notified if the person of concern is a GP or pharmacist. If harm, or potential harm, is being caused by a care home or a particular member of care home staff, then the local CSCI office would be alerted. If we suspect an individual is harming patients intentionally, then we will notify the appropriate authorities immediately. This would include the clinical governance lead for the PCT.

Appendix H

Medication administration

Data collection form for CHUMs study

Date:	Observer:	Care home identifier:
Time of day:	Day of week:	Page __ of __

Time	Case identifier	Drug details	MDS Y/N	OE?	MAE ?	Signed?

Appendix I

A review of medication administration relating to care homes

1.0 Outline and Aims of the review

To open this review, evidence of the approaches previously or currently being adopted to study the problem of medication errors has been gathered, leading to parallels being drawn with methods of study in other industries. The outcome of some of these earlier studies gives an insight into the prevailing attitudes to medication errors in the existing system. This section therefore aimed to help guide the CHUMS project in the best method to adopt, as well as creating a picture of the current system and attitudes.

The review then progresses to look at current and recent initiatives already adopted to tackle the problem of patient safety in relation to care of the elderly.

The final section of the review of current and recent initiatives looks at the role of the pharmacy, as this has been identified as significant by a number of authors (Ashcroft et al 2005, Hawksworth et al 1999).

In order to tackle the issue of medication errors in an existing system such as the health service, or more specifically on this occasion, the Care Home, there was a need to study and document the current structure and follow this with recommendations for system improvements. To this end, a review of the available methodologies to achieve this goal was included.

2.0 Existing approaches and attitudes towards medication errors

The field of ergonomics promotes the systems approach to error reduction, and in particular the ergonomics systems approach based on user-centred design (*Buckle et al., 2006*). A useful discussion on the shortcomings of punitive approaches to reducing medication errors, and the value of a systems approach can be found in *Anderson and Webster (2001)*. Their study takes medication errors on a hospital ward as a focal point.

It is all too common for nurses to be blamed for medication errors on the grounds of 'carelessness'. Anderson and Webster point out that by focusing on the individual, the "complete set of contributing factors cannot be known". They cite other high-risk industries such as aviation and nuclear power as examples of the successful application of a systems approach to reducing errors/accidents. Although the nurse, and in the case of care homes, possibly the care worker, is the final 'cog' in the safe administration of medication (i.e. they physically deliver the drug to the patient/resident), it should not be assumed that they are responsible for all, or indeed any, errors.

Anderson and Webster (2001) go on to describe the categorization of components of a system. These being Design, Equipment, Procedures,

Operators, Supplies and Environment (DEPOSE). Taking the safety of a new medication as an example, the elements of the system would consist of the following. Testing of the medication before introduction (Design), manufacture and packaging (Equipment), development of the prescription criteria (Procedure), mechanism for giving to patients effectively (Operator), reliability and consistency of supplies (Supply), and finally, whether the situation within the care setting permits or facilitates proper administration (Environment). All of these categories need to be considered to fully understand how errors occur. The commonly found 'person-centred' approach to blame, only examines the 'operator' category of the DEPOSE description of a system.

Further support for the systems approach can be found in *Allard et al (2002)*. They believe that counting and categorizing errors is of limited value. They suggest that more useful information can be obtained by tracing errors through the system. They go on to cite evidence suggesting that 'situational factors', or in other words 'the wider system' can be the root cause of errors. Workload in the form of number of patients and prescriptions may lead to errors, which is in line with findings in other industries such as aviation and nuclear power plants. Evidence has indicated that pilot or operator workload and shift patterns are associated with error rates. In an aircraft simulator study, it was found that cockpit task management (CTM) performance was inversely related to workload (*Chou et al 1996*). In a review of literature relating to medication errors *O'Shea (1999)* found many references to shift patterns and workload influencing error rate. Other factors identified by *O'Shea* included medication delivery systems and policy and procedures, both forming part of the wider 'system' rather than the individual. *Allard et al (2002)* state that "Medication errors can only be prevented and reduced by focusing on the system as a whole, not on the individual clinician or nurse". This may seem obvious to readers within the ergonomics community, but it is not a widespread culture within the health care sector.

3.0 The role of the pharmacy in relation to care homes

Without intentionally singling out one particular aspect of the medication delivery system, it came to the attention of the ergonomist that over the preceding ten years or so, a number of papers/articles have identified the role of the pharmacy as a significant factor in the successful performance of the overall system. *Ashcroft et al (2005)*, as a result of identifying a lack of documented investigations into the performance of community pharmacies, undertook a study to measure their performance in relation to dispensing errors. They point out that, at the time of publication, around 600 million prescription items were dispensed each year through community pharmacies in England and Wales. Their study found that on average, for every 10000 items dispensed there were in the region of 22 'near misses' and four dispensing errors. *Ashcroft* suggested that these figures may be conservative, as their method may have been vulnerable to under reporting of incidents, and only the errors that pharmacists became aware of were recorded.

As will become apparent in later sections of this review, what is particularly interesting is that Ashcroft noted that pharmacists themselves reported that the situations commonly associated with increased errors included occasions when the pharmacy was busier than normal, and when there were telephone interruptions.

3.1 A pharmacy initiative in the UK

While searching for general information associated with medication errors, a regional initiative was identified with the aim of improving the quality of service offered specifically to care homes, by the local community pharmacy. Pharmacy Plus (www.pharmacyplus.co.uk) is a commercial venture centred on the Bristol area of the UK. They have departed from the traditional approach to pharmacy, by separating the day to day service offered to members of the general public, from that offered to care homes. They operate a dedicated dispensing centre whose sole purpose is to cater for care homes. Each care home has a designated area within the complex. Their service integrates aspects such as training for care home staff, medication reviews, re-designed MDS systems, and interim MAR charts. In light of the observations recorded by Ashcroft et al (2005) citing increased errors associated with interruptions within the pharmacy, this dedicated service would seem to have potential for improved medication safety through reduced errors. No independent review into the effectiveness of Pharmacy Plus was found, but an objective study would be valuable in assessing some aspects of their operations for wider application within the UK.

The contribution that community pharmacists can, and often do, make to the quality and not simply the quantity of medication administration, was illustrated in a study by Hawksworth et al (1999). They studied fourteen pharmacists over a one year period. The pharmacists recorded occurrences of 'clinical pharmacy interventions' for one week of each month. 1503 clinical pharmacy interventions were made out of 210 000 items dispensed. The broad finding was that a panel of expert judges determined that 748 (0.37%) interventions "improved the clinical outcome and could have saved a visit to or by the general practitioner".

4.0 Analysing the existing system and seeking improvements

In order to study the issue of medication errors in the Care Home, there was a need to study and document the current structure of the whole medication system and follow this with recommendations for system improvements. What follows is a review of available methodologies to achieve this goal.

As the intention was to adopt task analysis to produce a 'description' of the existing care home medication system; a review of methods was undertaken. Many task analysis methods use a hierarchical structure to some degree, and after a short appraisal of other available methods, Hierarchical Task Analysis

(HTA) (*Annett et al., 1971*) was selected as the preferred method. The selection criteria included the following logic.

HTA permits a scaleable level of complexity depending on the characteristics of the system being studied. The nature of the current study into medication within care homes was such that the complexity and level of analysis required was predominantly unknown; therefore HTA would adapt to match the needs of the project as the investigation progressed. The investigator would have the facility to choose the point at which tasks had been broken down to the component level required.

Secondly, as identified by *Stammers et al., (1990)*, the most appropriate and valuable use of task analysis in general, is in the updating or modification of an existing system, as is the case for care homes. They point out that as long as most elements of the system are likely to remain largely unaltered after any re-design, particularly those that are directly associated with the user, the majority of the task information obtained will be relevant to the new system.

Finally, in line with the goal to reduce errors in medication, HTA (and other task analysis methods), lent themselves well to further analysis of the results using error prediction models.

Lane et al., (2006), clearly demonstrate the application of HTA in a closely related domain to that of interest in this review. Their paper looks at its application specifically to medication administration in the hospital setting, but it was felt by the author that many tasks would be similar in the care home. They proceed to demonstrate how an error prediction and reduction technique could be applied to the lower level tasks obtained from the HTA. The method they selected was SHERPA (The systematic human error reduction and prediction approach), developed by *Embrey (1986)*. This was originally developed for use in industries such as power generation, petrochemical processing and oil and gas extraction. It predicts human error and its probability in a structured way. It is based on a human error taxonomy. Errors are divided into five behaviour categories, these being; action, checking, retrieval, communication and selection. Each error 'type' then has an error 'code' with a number of error modes associated with it. These are shown in Table 1.

Error type	Code	Error mode
Action errors	A1	Operation too long/short
	A2	Operation mistimed
	A3	Operation in wrong direction
	A4	Operation too little/much
	A5	Misalign
	A6	Right operation on wrong object
	A7	Wrong operation on right object
	A8	Operation omitted
	A9	Operation incomplete
	A10	Wrong operation on wrong object
Checking errors	C1	Check omitted
	C2	Check incomplete

	C3	Right check on wrong object
	C4	Wrong check on right object
	C5	Check mistimed
	C6	Wrong check on wrong object
Retrieval errors	R1	Information not obtained
	R2	Wrong information obtained
	R3	Information retrieval incomplete
Communication errors	I1	Information not communicated
	I2	Wrong information communicated
	I3	Information communication incomplete
Selection errors	S1	Selection omitted
	S2	Wrong selection made

Table 1 – SHERPA error modes

Although Lane et al present a case study looking at the actions of an individual nurse; they acknowledge that errors can occur from wider issues, such as organisational and working environment. They identify this as a shortcoming in the SHERPA methodology, as it doesn't cover all of these influences on errors. However, the author believed that with careful consideration of the wider socio-technical system associated with medication in care homes, the HTA could be broadened to encompass these factors, and hence ensure their inclusion in the final results of the SHERPA analysis.

5.0 Conclusions

What was apparent from this review was that much work was still needed to improve the quality of medication administration. To achieve improvements in the future, we have looked at the value of a 'systems approach' to both describe and study the existing procedures, and ultimately to guide the way to future solutions.

The information gathered on the role of the pharmacy in the care home medication system, and the work already underway to enhance the service offered, was a useful resource as the CHUMS field study identified a need for improvements or enhancements in this area.

The field of ergonomics has much to offer this particular application area, through its traditional user-centred approach to systems design, and a departure from the existing culture of individual 'blame'.

References

Ergonomics appendix references

Allard, J., Carthey, J., Cope, J., Pitt M., Woodward S. 2002. Medication errors: Causes, prevention and reduction. British J. of Haematology (116) 255 – 265.

Anderson, D.J., Webster, C.S., 2001. A systems approach to the reduction of medication error on the hospital ward. *J. Adv. Nurs.* 35(1) 34 – 41.

Annett, J., Duncan, K.D., Stammers, R.B., Gary, M.J. 1971. *Task Analysis*. London: HMSO, Training Information Paper No. 6

Ashcroft, D.M., Quinlan, P., Blenkinsopp, A., 2005. Prospective study of the incidence, nature and causes of dispensing errors in community pharmacies. *Pharmacoepidemiology and Drug Safety*. 14: 327 – 332. John Wiley & Sons.

Buckle, P., Clarkson, P.J., Coleman, R., Ward, J., Anderson, J., 2006. Patient safety, systems design and ergonomics. *App. Ergonomics* (37) 491 – 500.

Chou Chung-Di., Madhavan D., Funk K. 1996. Studies of cockpit task management errors. *The Int., J. of Aviation Psychology* 6(4) 307 – 320.

Hawksworth, G.M., Corlett, A.J., Wright, D.J., Chrystyn, H., 1999. Clinical pharmacy interventions by community pharmacists during the dispensing process. *J. of Clinical Pharmacology*, 47, 695 – 700.

Lane, R., Stanton, N.A., Harrison, D., 2006. Applying hierarchical task analysis to medication administration errors. *Applied Ergonomics* 37(2006), 669 - 679

O'Shea, E. 1999. Factors contributing to medication errors: a literature review. *J. of Clinical Nursing* (8) 496 – 504.

Stammers, R.B., Carey, M.S., Astley, J.A., 1990. *Task Analysis*. In: *Evaluation of Human Work*. Ed., Wilson J.R, Corlett, E.N., 1990. Taylor & Francis. Chapter 6, 134 – 160.

Appendix J

Factors used in ergonomics analysis of CHUMS error reports

1 = MAR (General)	15 = Medical records incorrect
2 = MAR (Discontinued drugs)	16 = Medical records unavailable
3 = MAR (General clarity)	17 = Medication records incorrect
4 = MAR (Drug instructions)	18 = Medication records unavailable
5 = MAR (General inaccuracy)	19 = Existing computer hardware
6 = Drug round (General)	20 = Existing computer software
7 = Drug round (interruptions)	21 = Management issues
8 = Drug round (resident availability/reminder)	22 = Use of trade & generic drug names
9 = Drug round (staff procedure)	23 = MDS design or MDS limitation
10 = Drug trolley design	24 = Environment in care home
11 = Staffing levels	25 = Environment in Pharmacy
12 = Staff knowledge/training	26 = Computer System warnings/reminders
13 = Staff motivation	27 = Medication packaging design
14 = Budget	28 = Procedures in Pharmacy

Appendix K

Initial Questionnaire for focus group

The theme for the workshop is 'The MAR chart, its role in the medication system and the issue of discontinued items'. I would like to thank in advance all those that have agreed to take part. The aim of the workshop is to reach agreement amongst the participants, as to the role and use of the MAR chart in the whole medication system. This will allow the CHUMS project team to consider ways in which the design and role of this document may or may not be improved. We will be paying particular attention to the issue of discontinued items on the MAR chart, which has appeared as a contributing factor in a number of the recorded errors during the current project.

At the outset of this workshop/focus group, could I please ask you to write down your responses to the following questions relating to the MAR chart?

1. What is the primary purpose of the MAR chart?

2. What type of information is recorded on the MAR chart?

3. Who makes use of the MAR chart?

4. Who enters/makes changes to, information on the MAR chart?

5. In your opinion, does the MAR chart fulfil its primary purpose, stated in 1?

6. What do you think is the main reason for discontinued items on the MAR chart?

7. What are the priorities when using a MAR chart (e.g. accuracy, efficiency etc)

8. What are the purposes of using a MAR chart (e.g. as a means of recording, auditing etc.)

APPENDIX L Coding framework for analysis of MAR focus group transcript

Code	Category	Sub-code	Sub-category	Description
1	Purpose of MAR chart	A	Primary	Primary purpose of the MAR chart
		B	Additional	Any additional purposes
		C	Fulfil primary purpose?	Does it fulfil its primary purpose
		D	Fulfil additional purpose?	Does it fulfil its secondary purpose
2	Information on MAR Chart	A	Current	Information now on chart
		B	New required	Any new information required in the future
		C	Old not required	Any information not required
		D	Accuracy of information	Is the information correct
3	Physical Presentation of information	A	Layout	Layout of forms (e.g. columns and rows, colour)
		B	Print quality	Clarity (e.g. use of technology)
4	Who makes use of the MAR chart	A	Currently	Current people who access the information on the MAR chart
		B	Suggested	Suggested changes to access
5	Who enters/makes changes	A	Existing	Current situation
		B	Future	Future changes
6	Discontinued items	A	Reasons for	Reasons for discontinued items. Who can make a difference
		B	Suggested changes to reduce items	Improvements that could be made to reduce such items
7	Pharmacy operations	A	Accuracy of MAR	Actions taken that affect the accuracy of the MAR chart
		B	Clarity	Actions taken that affect clarity of information on the MAR chart
8	Care home operations	A	Accuracy of MAR	Actions that affect the accuracy of

				the MAR chart
		B	Clarity	Actions taken that affect clarity of information on the MAR chart
9	Communication/operations	A	Problems	
		B	Suggested improvements	
10	Priorities for MAR charts	A	Clarity	
		B	Accuracy	

Appendix M

Sample of focus group transcript

MAR Focus Group

We'll do two stages. Further on in the meeting we'll go on to look at the organizational chart, but first of all we'll look at this. The primary terms of the MAR chart is the first question that I've posed on there and maybe we can start a heated discussion on the purpose of the MAR chart. So, if I pop that up there ... there we go. Who wants to start the ball rolling? What's at the top of the list?

(1A) D: I've got to ensure safe administration of medicines i.e. to provide the right medicines to the right patient at the right time, which is what I tell my students.

A: I think administration is a matter of patch, ?fine rights? The safe administration of medicines implies, one, that the medicines are the right ones and secondly that you actually administer them appropriately.

So for you to split that down ...

M: Yes, it seems to me that there is a split in it.

(1A) K: I've split it down and I've put it to indicate the drug that's being prescribed, the dose and the time of when that medication should be given, so it gives you an indicator of when it should be administered and what dose, to whichever patient, which is probably slightly more hands-on practical rather than ??? point, what it should be ideally. But I look at it more that it's sort of components that make up what should be administered to that patient, because there's a practical element between it coming out of the bottle and going to the patient, and that's dependent on the human giving it ... human errors and that.

(1A, 1C) D: And I think, like you were saying, the assumption that the medicines are correct. That's in an ideal world, it would be nice, but from the administrators' point of view, everything before and everything that is on there should be entirely 100% correct, and then it's your job to follow those instructions.

A: I'm beginning to doubt your definition then, because I don't think there's a MAR chart ... I guess there's a MAR chart was invented by some pharmacist somewhere who just wanted to provide a list of what he was sending to the Care Home and that the bells and whistles on it, like the tick boxes from the administration were probably things that happened afterwards.

(1A) C: You see, I don't agree with that. I think the MAR chart purpose is purely what it says. You've got a prescription, and then the pharmacist dispenses it and you've got a label and they've done their job. The MAR chart is surplus to that, which is pure ???

Sorry, can I ask you start again. I was just talking to Dave. I'm sorry. I missed that very good point.

(1A, 1B) C: My understanding of a MAR chart is that it's a medicine's administration record. So it's purely a record of what you've administered to the patient. The fact that it helps to give safety and a list of the ??? that the patient's taking is a bonus, if you like. But for me, the purpose of the document is to provide a record. It's an historical record and it's for legal, so nurses know what they've been given. So it's a sort of legal document.

(1C) A: So when something seems to have gone wrong and you go back over it, you can say "Ah. They didn't get it, or they did get it, or they refused it, or whatever."

(1A, 1B) C: So that's the sole purpose of the MAR chart. That's what I've written on my piece of paper, but then it fuels the other things.

(1B) A: That fits the name of the actual document, doesn't it, but what it in effect gets used for is the very opposite of that, not a historical document, but a contemporaneous document of what the patient's having. Part of the issue is that those two things are inherently incompatible.

(1A, 4A, 7A, 7B) M: The other thing is to look at it from a perspective ... I was looking at it in terms of if you look at it from a care homes perspective, what a MAR chart's for, is very different from a pharmacist's perspective. I can do these things all the time, and I'm ??? and the thing with it was, the MAR chart was the least important thing from the pharmacists, the way they were preparing them. What was important was the label and the prescription and everything else; and this was completely incidental because we never really used it, which is why I think you find all the errors, because a lot of the software wasn't designed to integrate the MAR chart or the labeling. I mean, now it's getting better and better, but in a lot of places this is what happens ... the label, they prepare the product but because the pharmacist doesn't use the MAR chart it's no value to them and legally they're not required to make one, it's completely incidental. So it's something that happens at the end of the periphery of what they do. They prepare, supply the medicines and they give that out, because that's what the home wants. More often than not the pharmacy never sees them and in a lot of places, you look at the error and ??? check it. The important thing for them is the medicines and the labels and ?dossit? boxes, that's the legal thing and this is completely incidental, this is additional; and because of that it gets pushed aside and I think the focus then for the pharmacist is the medicines, not the MAR charts; and you can see that come through in how critical they are, how much attention they pay to their MAR charts.

(2D, 7A) C: And the fact that there's paracetamol, like three times, or cocodomal. There's just not the same care when you're checking it. It's not given at all to the MAR chart.

A: Sorry. When who's checking it?

(2D, 7A) C: The pharmacist. Are not checking it.

A: Sorry, you mean the man or the woman in the pharmacy who is dispensing the medicine, checking it, or do you mean the pharmacist who actually goes into the home and and makes sure that things ...

C: The person who's in the chemist.

A: The chemist shop, right.

(2D, 7A, 9B) M: What they should be doing is, they should have an audit trail in the pharmacy for who checked the prescriptions when they came in, who prepared the products, who dispensed them, who checked the ?dossit? boxes, who checked the labels, who checked the PRNs which are done separately, but then most places you go, it's not reckoned ??? just the MAR chart. In some cases it's the same person, but in other cases it's not. If you've got two pharmacists working, where they pre-prepare things, and then this is where the errors sneak in.

A: When you say checking them, they're checking them against ...?

(2D, 7A) M: The prescription. Making sure that it's an accurate record of what the person should be on.

(7A) A: Right. So, in effect, what you're saying is the pharmacist sees his role as ensuring that what goes out of the pharmacy matches what the prescription is, but not part of the role to decide what the prescription says is what the patient ought to be having.

(7A, 9A, 9B) M: No, no. I think the pharmacist has that responsibility, not just to supply it but also more than that; but too often what happens is that, and the problems that I've had in Leeds in some of the pharmacies when we've found errors in care homes, is that the pharmacist thinks it's ??? prescription hasn't had that drug and if there isn't a prescription, you don't need to follow it up. For example, something starts last month and they haven't got another prescription for him, if he hasn't had a repeat after discharge or something like that, and they don't bother ... they don't challenge any omissions or additions on the prescriptions. They just think "Oh, the legal prescription act ..." but what you're saying is actually right, what they should be doing is looking at are they entitled to supply legally and is it something the patient needs? Or is something missing that the patient needs

(8A, 9B) K: Well, the care home, whoever does the repeat order at the care home, has a responsibility to say "The script's come back and actually they were put on something in hospital and that isn't on this, and therefore it needs to go back to the GP to say in fact you need to do me a script for the ??? because it's not on this prescription."

D: That's right.

