A Qualitative Exploration of the Underlying Causes of Preventable Drug-Related Morbidity in Primary Care, Resulting in Hospitalisation

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Summary

This study has explored the underlying causes of preventable drug-related admissions to hospital, from primary care through semi-structured interviews and review of patients' medical records. Analysis of the data has revealed that communication failures between different groups of healthcare professionals and between healthcare professionals and patients contribute to preventable drug-related admissions, as do knowledge gaps about medication in both healthcare professionals and patients. In addition, working conditions for community pharmacists severely limit their ability to effectively act as a safety barrier to patients receiving inappropriate medication. Limitations include heavy workloads, lack of access to patients' clinical information, poor relationships with general practitioners and time restrictions. The results of this study represent an important addition to our understanding of the contribution of human error as an underlying cause of preventable drug-related morbidity, and the factors which contribute to errors occurring in the primary healthcare setting.
Acknowledgements

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Foreword

This report makes a valuable contribution to the knowledge base on patient safety and more specifically on preventable medication errors. It explores underlying causes of preventable drug related admissions to hospital and therefore is notable for its setting in primary care, an area that is under researched in terms of medication error.

It is known that the vast majority of medication incidents reported to the National Patient Safety Agency’s NRLS (National Reporting and Learning System) are from acute, general and community hospitals. When one considers that most patients receive care in the community, the low percentage of errors reported from primary and community care is surprising. This does not mean, however, that practice is better in these settings. It may be a reflection of inadequate reporting or that medication errors are not picked up so easily in a community setting with patients taking a greater unsupervised role in care and disease management. In addition, problems may arise from health professionals in the care pathway working for different organisations.

The study employs the principles of root cause analysis and uses human factor analysis and error cascade as tools to seek the cause of errors. The inclusion of patients as participants in the research is therefore vital, as the study of human factors in this area of research must include all those involved at each stage of the medication use process. The strength of this study lies in the inclusion of not only patients but general practitioners and pharmacists and the examination of behaviour and decision-making and the role these play in eventual identified errors.

The study covers a sensitive area of research investigating both potential and actual harm and identifies contributory factors unique to community settings. These include access (or lack of) to patient records and medical histories, interprofessional and individual working practices and communication between professions and with patients. In addition, the report highlights potential knowledge gaps. It must, however, be noted that most error incidents are not single acts but a chain of events and the report goes some way to linking multiple factors leading to these.

The report also identifies those at higher risk of experiencing an error, namely older people, those with co morbidities and those taking multiple medications. This is in contrast with the findings of errors reported to the NRLS (mostly hospital) which identifies two groups of patients particularly vulnerable to medication error as those with known allergies and children aged 0 to 4. These differences in findings from the two settings serve to emphasise the need for a greater degree of research to be undertaken in community settings. This is of particular importance given the government’s driving policy of bringing care closer to home and the shift from secondary care to primary care.

From a pharmacy practice perspective, communication issues between pharmacists and patients are important to note in their contribution towards errors. The study found that pharmacists routinely counseled patients only on new prescriptions, in addition, they questioned their role in counseling patients about other medication. Subsequent implementation of the Contractual Framework for Community Pharmacy and the introduction of structured services such as Medicines Use Reviews may well have influenced these factors. Research to follow the impact of these new services on medication error particularly those arising from factors related to patients or pharmacists should now be considered. Furthermore, the identification of high risk patient groups in this research together with the risk factors should be brought to the attention of all community based healthcare practitioners and service commissioners. Although the study includes a relatively small number of incidents – there are lessons to be learnt.

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Executive Director, Association of Litigation and Risk Management
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Section 1 - Introduction

In 2000 the Department of Health published ‘An organisation with a memory’\(^1\) which highlighted the problem of drug related morbidity and the paucity of data relating to this subject in the UK. This report followed ‘Saving lives: our healthier nation’\(^2\) which targeted areas under the broad heading of accidents such as adverse outcomes of treatment due to adverse effects of medications and failure of treatment. Since the publication of these reports there has been increasing emphasis on the investigation of ‘system failures’ as a method for understanding why errors occur in the NHS and how they might be prevented.

The word system relates to the many and varied processes involved in medicines management and the word failure to a problem with these, leading to the potential or actual injury to a patient. A system failure relates to a problem in the medicines management process which has led to a drug-related morbidity. A system failure in this context could range from overriding a drug interaction alert on a computer system leading to bleeding with Warfarin secondary to raised INR, to the unnoticed under-usage of medication in a poorly adherent patient leading to an exacerbation of congestive cardiac failure.

Medication errors are responsible for a median of 4.3% of all hospital admissions world-wide\(^3\). These admissions should be eminently preventable and the department of Health in the UK is committed to reducing the number of serious errors involving drugs. The most common type of medication errors in primary care that result in hospital admission involve the prescribing and monitoring of medication\(^4\). Little is known, however about the underlying causes of these medication errors.

The majority of studies exploring the factors that contribute to medication errors have either been observational\(^5-7\) or reviews of incident reports\(^8-10\). There are however limitations to both these methodologies. Observation of practice is time consuming, and usually identifies only errors not adverse events. In addition, in primary care, where prescribing errors are relatively infrequent and can be hard to detect, an observational study would not be very useful\(^11\). Also, the quality of data in studies based on incident reports is limited by the quality of the data recorded in the reports which can be old and lacking in detail.

A small number of studies of medication errors have interviewed participants in order to identify factors that contribute to errors\(^12-14\). Only one of these has interviewed participants about specific errors that have recently occurred\(^12\).

This report describes a qualitative interview study, exploring the factors contributing to preventable drug related admissions to hospital from primary care.
The aim of this study was:

1. To identify the underlying causes of medication-related admissions to hospital, from primary care.
Section 3 - Methodology

It is recognised that this is a potentially sensitive area of research, especially when errors have resulted in hospital admission, patient injury may have occurred, and patients and professionals may be traumatised. Recruitment of participants was identified as a key area that could be affected. The researchers liaised with appropriate regulatory and support bodies across the participatory professions. Ethics consent was granted in early 2004.

Root cause analysis has been shown to be a useful tool in many organisations, including secondary care, however its usefulness in primary care has not been confirmed. One of the prerequisites of root cause analysis is that it is carried out promptly so that events are fresh in people’s minds. The original proposal put forward for this project planned to investigate the feasibility of a root cause analysis tool to be performed in practices where GPs and practice managers gave consent. In the study, formal group sessions of brainstorming (a part of root cause analysis) were not felt to be necessary or appropriate. However, the principles of root cause analysis i.e. interviewing participants, examining relevant paper and computer records, producing time lines of events etc. were undertaken in the study15.

This study involved two-phases of recruitment. The first phase gauged healthcare professional acceptance of involvement in the study16. The second phase recruited patients who had been admitted to hospital with a preventable drug-related morbidity, and the healthcare professionals involved in their care17.

3.1 Phase-one recruitment

Letters were sent to general practitioners (GPs) and hospital consultants asking if they were willing for their patients to be approached as part of the study. Letters were sent to superintendent pharmacists asking whether they were willing for their pharmacists to be approached in the event of one of their patients being admitted as a result of a preventable-drug related morbidity. The letters sent to GPs and community pharmacists also asked if they would be willing to be interviewed in the event of one of their patients being admitted with a preventable drug-related morbidity. A repeat mailing was sent to all GPs and community pharmacists who had not responded within four weeks.

A number of other strategies were used to enhance healthcare professional participation in this study:

1. Local support was obtained from pharmaceutical prescribing advisors from each primary care trust and a respected member of the local general practice community.

2. The study was advertised locally through a meeting of GPs and community pharmacists, local publications sent to all GPs and community pharmacists, and letters to general practice managers and senior PCT managers.

3. National support was obtained from the Medical Defence Union and the Medical Protection Society.

4. Recompense was offered in recognition of time given (GPs £50 for interviews and access to medical records, and pharmacists £25 for interviews)
Phase 1 recruitment is described in more detail in:  

### 3.2 Phase-two recruitment

Clinical pharmacists identified patients admitted to medical and neurology wards with purposively selected potentially preventable medication-related morbidities (based on the most common causes of PDRA 4, 18) (see Figure 1). Patients, whose GPs had given consent for their patients to be approached, were asked if they would participate in the study. Where written consent was obtained from patients, their medical notes were summarised and reviewed for causality, contribution of adverse drug event to the admission and preventability of the admission using a previously validated method 4.

#### Figure 1: Sampling framework for patient recruitment

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number Recruited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiepileptic (toxicity or sub-therapeutic)</td>
<td>1 patient recruited</td>
</tr>
<tr>
<td>Aspirin/NSAID induced GI bleed or renal failure</td>
<td>6 patients recruited</td>
</tr>
<tr>
<td>Digoxin (toxicity or sub-therapeutic)</td>
<td>2 patients recruited</td>
</tr>
<tr>
<td>Exacerbation of asthma in patients poorly adherent to preventer therapy</td>
<td>2 patients recruited</td>
</tr>
<tr>
<td>Dehydration or electrolyte imbalance with diuretics</td>
<td>3 patients recruited</td>
</tr>
<tr>
<td>Warfarin with a bleeding event &amp; a raised INR, or a thrombotic event &amp; low INR</td>
<td>3 patients recruited</td>
</tr>
<tr>
<td>Thrombotic event in patient not prescribed aspirin (where aspirin is indicated)</td>
<td>1 patient recruited</td>
</tr>
<tr>
<td>Adverse reaction to initiation or cessation of beta-blocker</td>
<td>1 patient recruited</td>
</tr>
<tr>
<td>Diabetes poorly controlled with insulin or sulphonylureas</td>
<td>3 patients recruited</td>
</tr>
<tr>
<td>Poorly controlled angina on submaximal therapy</td>
<td>0 patients recruited</td>
</tr>
</tbody>
</table>

Total number of cases >18 because 3 hospital admissions fitted more than one box of the sampling framework

### 3.3 Data collection

Where patients were thought to have had preventable medication-related hospital admissions, written informed consent was obtained from GPs, community pharmacists and patients. Once patients were discharged to home, they were interviewed about their involvement in events leading up to their admission, their relationship with healthcare professionals and how they managed their medication at home. GPs and pharmacists were interviewed about their involvement in events leading up to the patients’ admissions and general medicines management issues. Patients’ primary and secondary care medical records were reviewed and interviews were audio-taped and transcribed verbatim.

### 3.4 Data Analysis

Using the principles of constant comparison 19, narrative case synopses 20 were developed from transcripts, field notes, summaries of medical records, and relevant protocols. The case synopses highlighted the main themes arising from each case. Time lines helped to clarify the order of events leading up to patients’ admissions, and error cascade diagrams illustrated the factors contributing to, and safety barriers
overcome in events leading up to, patients’ admissions\textsuperscript{21}. Template analysis,\textsuperscript{22} based on human factors theory,\textsuperscript{23} and error cascades\textsuperscript{21} were used to identify the main underlying causes of each case. Finally, the main themes were derived using between and across case comparison\textsuperscript{24}. These themes were developed into an error cascade which models the main underlying causes of preventable drug-related morbidity in primary care which resulted in hospitalisation (see Figure 3).

Phase 2 recruitment, data collection and analysis are described in more detail in\textsuperscript{17}:

Section 4 - Results

4.1 Phase-one recruitment

Letters were sent to 385 GPs, 149 community pharmacists, 41 hospital consultants, and 34 superintendent pharmacists. Response rates following first and second mailings are shown in Table 1.

**Table 1: Number of replies to letters**

<table>
<thead>
<tr>
<th>Letters sent to:</th>
<th>General Practitioners (n=385)</th>
<th>Community Pharmacists (n=149)</th>
<th>Superintendent Pharmacists (n=34)</th>
<th>Hospital Consultants (n=41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of replies after 1\textsuperscript{st} mailing (%)</td>
<td>235 (61)</td>
<td>66 (44)</td>
<td>21 (62)</td>
<td>38 (93)</td>
</tr>
<tr>
<td>Number of replies after 2\textsuperscript{nd} mailing (%)</td>
<td>310 (85)</td>
<td>93 (62)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of professionals giving provisional consent (%)</td>
<td>274 (71)*</td>
<td>266 (69)**</td>
<td>75 (50)</td>
<td>20 (59)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Permission to approach patients  **Provisional consent to be interviewed

4.2 Phase-two recruitment

Fifteen patients were recruited from 38 potentially eligible patients identified by clinical pharmacists (see Figure 2). Data from three cases recruited during pilot work were also included in the analysis. Characteristics of patients, general practitioners, and pharmacists recruited into the study are shown in Appendix 1 to Appendix 3.

**Figure 2: Patient recruitment flow-chart**

69 patients → 24 patients (GP not consented)

45 patients → 7 patients (unable to give consent)

38 patients → 14 patients (did not wish to consent)

24 patients → 7 patients (did not have PDRA)

17 patients → 2 patients (withdrew due to ongoing ill health)

3 patients recruited in pilot work

Data from 18 patients with potentially preventable medication-related admissions included in analysis
4.3 Qualitative data analysis

Data analysis of the 18 cases revealed problems (underlying causes) arising at every stage in the medication use process (prescribing, dispensing, administering, monitoring and help seeking) in most cases. Combining cascade analysis with Reason’s model of organisation accidents illustrates how underlying causes at each stage in the medication use process contribute to PDRA (see Figure 3). The following sections will describe the underlying causes which commonly arose at each stage of the medication use process. Short summaries of each case are shown in Appendix 5 to Appendix 22. Participant’s identities have been preserved by the use of pseudonyms and removing references to place names and other identifying features.

4.3.1 Prescribing

Problems occurred at the point of prescribing the medication in 17 cases. In each of these cases, the prescribing problem occurred because the prescriber did not recognise the problem themselves, or because the computer did not alert the prescriber to the problem. In eleven cases the prescribing problem involved the provision of a high risk drug or combination of drugs to a patient, in six cases the problem involved not prescribing a drug (or equipment for administering a drug), in three cases the problem involved not giving sufficient information to the patient to allow them to administer the drug as desired by the prescriber, in two cases the patient did not give sufficient information to allow the prescriber to effectively manage the medication, and in twelve cases the problem involved not giving the patient sufficient information to enable them to appropriately manage the side effects of their medication. The underlying causes of these prescribing problems are displayed in Figure 3 and illustrated with examples from cases in the following sections: prescribers’ knowledge gaps about patients medical and medication histories, prescribers’ knowledge gaps about drugs, communication problems between prescribers and patients/carers, and communication problems between secondary and primary care.

Prescribers’ knowledge gaps about patients’ medical and medication histories

Prescribers’ knowledge gaps about patients’ medical and medication histories contributed to hospital admission in six cases. A number of different reasons for these knowledge gaps were identified: complex medical histories, communication problems between patients and GPs, communication problems between secondary care and GPs, incomplete record keeping on the computer system, and not being able to access the computer system.

In the majority of cases, the patients were older, with multiple co-morbidities and taking multiple medications. This made it more difficult to identify when risky prescriptions were written and increased the risk of injury to patients as a result of suboptimal prescribing, because they were frail. The complexity of these patients’ medical histories meant that prescribers were less likely to be aware of a diagnosis which increased the risk of injury to the patient from the prescription. For example, Mr Taylor’s GP (case 27; appendix 22) appeared to be unaware of his diagnosis of renal failure, despite previous test results on the computer system indicating declining renal function.

Incomplete record keeping on the computer system resulted in the accidental discontinuation of medication in case 9 (appendix 11). In this example, Mr Smith’s GP continued a prescription for lansoprazole, which had been initiated by the hospital, on a handwritten prescription during a home visit. When he returned to the surgery he did not add it to Mr Smith’s repeat prescription and the lansoprazole stopped when Mr Smith’s supply ran out. During home visits prescribers were unable
to access patients’ computer records and were unaware of important information when initiating prescriptions. For example, Mrs Harwood’s GP (case 21; appendix 19) was unaware of her last serum potassium result when he prescribed her amiloride, a drug which can increase levels of potassium.

These cases illustrate that prescribers who were unaware of vital pieces of information about a patient’s medication or their medical history were more likely to initiate or continue medication which could cause patient injury. Prescribers could be unaware of these pieces of information because they had no access to the medical record or because the information was perceived to be difficult to access within the record.

**Prescribers’ knowledge gaps about drugs**

Prescribers’ knowledge gaps about drugs contributed to hospital admission in nine cases. Knowledge gaps about drugs could result from prescribers not checking prescribing information before prescribing relatively unfamiliar drugs or from computer alerts not issuing sufficient warnings to alert them to problems. For example, Mrs Harwood’s GP (case 21; appendix 19) was unclear about how much amiloride was contained in co-amilofruse and it is likely that he intended to give her half the dose he did. Mr Taylor’s GP (case 27; appendix 22) was seemingly unaware that rofecoxib should be used with caution in patients with renal failure and that the recommended starting dose in older people was lower than in younger people. Mr Matheson’s GP (case 13; appendix 13) was seemingly unaware that venlafaxine could make INR control more brittle during warfarin therapy, a particular problem in this case as Mr Matheson had a tendency for haemarthrosis to occur when his INR was raised a small amount above the intended therapeutic range. Finally, Mr Jones’s (case 18; appendix 16) and Mrs Davis’s (case 20; appendix 18) GPs were apparently unaware of the increased risk of gastrointestinal bleeding when rofecoxib and aspirin were used in combination, compared to rofecoxib alone.

In seven cases, the GPs could have expected the computer to alert them when a prescription was potentially hazardous. For example, in case 25 Mrs Brown’s GP (case 25; appendix 20) was surprised that the computer had not alerted him to the risks of co-prescribing verapamil and atenolol (the alerts were switched on and the computer system did appear to raise alerts for this interaction) and Mr Taylor’s GP (case 27; appendix 22) thought that the computer might alert him to the fact that a patient had renal failure when he was prescribing a non-steroidal anti-inflammatory drug. The computer systems did not, however, alert to potentially hazardous prescriptions for two reasons: the design of the system (some alerts could be easily ignored or bypassed and this is presumably what happened in case 25), and training in how the system worked (not being aware that warning alerts did not link drugs to blood results or morbidity codes for renal failure as in case 27). Mr Smith’s GP (case 9; appendix 11) demonstrated how the warning alert for a combination of aspirin and warfarin appeared as a long scrollable list in a large box. The alerts were not graded in terms of importance, and were not specific to the pair of drugs prescribed i.e. all the drugs interacting with warfarin were listed. The alert was overridden at the touch of a button, and did not require any explanation of why it had been overridden.

These cases illustrate how prescribers’ knowledge gaps about drug side effects, cautions, contraindications, contents of specific preparations and recommended dosing schedules resulted in the prescription of medications (or combinations of medications) which increased the risk of patient injury. These knowledge gaps arose when prescribers did not check the prescribing information available, or when computer alerts were either insufficient or non-existent.
Figure 3: Cascade diagram depicting the contributing factors, proximal causes, active failures and barriers overcome in events leading up to 18 cases of PDRA

Numbers in [ ] indicate the number of cases where a contributing factor, proximal cause, or active failure was present.
Communication problems between prescribers and patients/carers

Communication problems between the prescriber and patient or carer contributed to hospital admission in fourteen cases. These communication problems resulted in patients not having adequate information about how to manage their medication and arose from asymmetrical relationships between patients and prescribers, impaired hearing, vision, or memory, and inappropriate allocation of tasks.

Mrs Brown’s (case 25; appendix 20) asymmetrical relationship with her GP meant that she was reluctant to question him when he told her she should be taking three antihypertensives, not two, as she had previously understood. Mrs Harwood (case 21; appendix 19) and her daughter found their GP difficult to relate to and felt that they had to “pull information out of him.”

Mr Knox’s (case 15; appendix 15) impaired eyesight meant he was unable to read the faint carbon copy of his prescription, supplied as a medication guide on discharge from hospital, or the labels on his medication. In addition, he was also hard of hearing and did not recall receiving verbal information about his newly started medication. Hence, he did not take the digoxin tablets prescribed to control his heart rate and two weeks later was readmitted to hospital. Miss Weir (case 5; appendix 8) did not recall being told that she should not lie down for half an hour after taking her alendronate (it is unclear whether she was ever told this) as this increased the risk of oesophageal ulceration, a problem that eventually led to her hospital admission. Mr Kemp (case 12; appendix 12) did not recall being told to weigh himself every day to monitor his fluid balance. Hence, he was unlikely to have understood the significance of his GP asking if his weight was stable.

Two patients found their GPs hard to talk to because they could not hear what they said properly. For example, Mr Knox (case 15; appendix 15) found that he had difficulty hearing his GP’s quiet voice. This was especially difficult as she often rang him for telephone consultations. Mr Taylor (case 27; appendix 22) also found he had difficulty hearing his GP’s quiet voice and strong accent.

In one case, inappropriate task allocation meant that members of staff were required to perform tasks where they were unaware of the importance of some elements of their role. For example, Mrs Privett’s (case 14; appendix 14) prescription for phenytoin was altered by the practice receptionist. Mrs Privett was, apparently, not informed of the change to her phenytoin when she next collected her repeat prescription and continued to take three daily of the higher strength phenytoin capsules, when she should only have taken one daily.

These cases illustrate how communication problems between prescriber and patient or carer resulted in patients having insufficient information to enable them to safely manage their medication, and increased the risk of serious injury as a result. Communication problems arose when patients had impaired hearing and could not understand what the prescriber said, had impaired eyesight and could not read instructions supplied by the prescriber, were reluctant to question the prescriber or found the prescriber was reluctant to provide information, or when tasks were allocated to individuals who were not aware of important elements of these tasks.

Communication problems between secondary and primary care

Communication problems occurred when information was not transmitted from secondary care to primary care in a timely fashion. For example, a letter from the hospital informing Mr Taylor’s GP (case 27; appendix 22) of his diagnosis of renal failure and advising caution in prescribing NSAIDs had not arrived at the time...
rofecoxib was prescribed. Had the letter arrived sooner, Mr Taylor’s GP may have prescribed a lower dose of rofecoxib, and monitored Mr Taylor’s response to the medication more carefully.

**Summary of the underlying causes of prescribing problems**

Prescribing problems contributed to 17 of the 18 hospital admissions explored. Problems with prescribing resulted from knowledge gaps about patients’ medical and medication histories, knowledge gaps about the drugs prescribed and communication problems between prescribers and patients or carers. Prescribers who were unaware of vital pieces of information about a patient’s medication or their medical history could initiate or continue medication which could cause patient injury. These knowledge gaps could arise because prescribers had no access to the medical record or because the information was perceived to be difficult to access within the record. Prescriber knowledge gaps about drug side effects, cautions, contraindications, contents of specific preparations and recommended dosing schedules resulted in the prescription of medications (or combinations of medications) which increased the risk of patient injury. These knowledge gaps arose when prescribers did not check the prescribing information available, or when computer alerts were either insufficient or non-existent. Communication problems between prescriber and patient, or carer, resulted in patients having insufficient information to enable them to safely manage their medication, and increased the risk of serious injury as a result. Communication problems arose when patients had impaired hearing and could not understand what the prescriber said, had impaired eyesight and could not read instructions supplied by the prescriber, were reluctant to question the prescriber, found the prescriber was reluctant to provide information, and when tasks were allocated to individuals who were not aware of important elements of the task.

**4.3.2 Dispensing**

Problems occurred at the point of dispensing medication in 13 cases. In each of these cases, the dispensing problem occurred because the pharmacist did not recognise the problem themselves, or the computer system did not alert them to it. In ten cases the problem involved the pharmacist not contacting the GP about a high risk medication, or combination of medications, before supplying these to the patients. In three cases the problem involved not giving the patient sufficient information to take their medication as directed by the prescriber, and in eleven cases the problem involved not giving the patient sufficient information to be able to recognise, and manage, the side effects of their medication. The underlying causes of these dispensing problems are displayed in Figure 3 and illustrated with examples from cases in the following sections: Pharmacists’ knowledge gaps about patients’ medical and medication histories, pharmacists’ knowledge gaps about drugs, communication problems between pharmacists and patients, and communication problems between pharmacists and general practitioners.

**Pharmacists’ knowledge gaps about patients’ medical and medication histories**

Pharmacists' knowledge gaps about patients' medical and medication histories contributed to hospital admission in eight cases. These knowledge gaps resulted from difficulties in accessing patients’ medical records, problems with computer alerts, and problems with communication, and were exacerbated by time and workload pressures.

Community pharmacists rarely had access to patients’ medical histories and therefore were often unaware which conditions they were dispensing medication for, or when a medication was cautioned or contraindicated in a patient. For example, Mr
Taylor’s pharmacist (case 27; appendix 22) was unaware that Mr Taylor had impaired renal function when dispensing a high dose of rofecoxib for him. Mrs Brown’s pharmacist (case 25; appendix 20) was unaware that Mrs Brown had a history of heart disease (although this could have been inferred from her medication history) when dispensing a combination of verapamil and atenolol for her. These knowledge gaps meant that the pharmacists were unable to adequately assess the safety of prescriptions, and contributed to them not contacting GPs to suggest changes to prescriptions.

Community pharmacists also had limited knowledge of what medication a patient had taken in the past if they had not attended that pharmacy before, or only occasionally attended it. This meant that in two cases, pharmacists were unable to identify changes to medication which may have been inappropriate, or to advise patients about changes to their medication. For example, Mrs Harwood’s brother-in-law (case 21; appendix 19) took her prescription for co-amilofruse to a new pharmacy which was unaware that she did not normally take this medication. The pharmacist, therefore, did not contact Mrs Harwood’s GP to clarify the prescription. Mrs Privett (case 14; appendix 14) took her prescription for phenytoin to a new pharmacy which was unaware that she normally took 100mg capsules, so did not advise her of the change in capsule strength.

Even if the pharmacy usually dispensed medication for a patient, they did not always check the patient’s past drugs due to time pressures. This meant that if interacting drugs were presented on different prescriptions at different times, the problem could go unnoticed. For example, Mrs Brown’s prescription (case 25; appendix 20) for atenolol was presented separately to prescriptions for verapamil for the first two dispensings and there was no evidence that the hazardous combination of drugs had been identified by the pharmacist.

These cases illustrate how knowledge gaps about patients’ medical histories and past medication usage resulted in community pharmacists not contacting doctors to clarify prescriptions and not giving patients information on how to manage their medication.

**Pharmacists’ knowledge gaps about drugs**

Community pharmacists’ knowledge gaps about drugs contributed to hospital admission in six cases. Community pharmacists had limited knowledge of the risks associated with some medications, partly due to problems with their training and partly due to time and workload pressures which prevented them from checking the appropriateness of drug combinations. For example, Mr Stewart’s pharmacist (case 6; appendix 9) was unaware that low doses of aspirin could cause gastrointestinal bleeding and Mrs Brown’s pharmacist (case 25; appendix 20) was unaware of the interaction between verapamil and atenolol until she had looked in the BNF. After looking up the interaction, she remained unsure of its significance.

Pharmacists gained information about drug side effects through their experience. They were, however, rarely told if a patient had had a problem with their medication, and this may have contributed to their limited awareness of the risks of some medications. For example, Mr Smith’s pharmacist (case 9; appendix 11) stated that he was not aware of any patients having had a problem whilst taking aspirin and warfarin in combination. He also stated that he usually did not know if patients had been admitted to hospital, this was echoed by Mr Taylor’s pharmacist in case 27 (appendix 22).
The computer systems used by the pharmacists had less sophisticated alert mechanisms than the GP systems and this made it difficult to identify when important drug interactions were present. For example, in case 25 (appendix 20), the computer system printed out a list of interacting drugs on the dispensing labels. This list gave no indication as to the importance of the interaction and could easily be lost. As a result, it is unsurprising that the interaction between verapamil and atenolol went (apparently) unnoticed and the GP was not contacted.

These cases illustrate how knowledge gaps about drugs contributed to community pharmacists not contacting GPs about potentially dangerous drug interactions or doses. These knowledge gaps arose because of problems with pharmacists’ training and problems with the design of their computer systems.

**Communication problems between pharmacists and patients**

Communication problems between pharmacists and patients contributed to hospital admission in nine cases. These communication problems arose because pharmacists did not routinely counsel patients unless they were presenting new prescriptions, the pharmacist and patient were not familiar with each other, or the pharmacists perceived themselves to be too busy. In addition, some pharmacists did not seem to view counselling patients about their medication as their role.

Due to time pressures, community pharmacists did not routinely counsel patients unless they were presenting a prescription for the first time, and did not clarify whether patients knew how to take their medication or whether they had any problems with their medication on subsequent presentations. For example, Miss Weir (case 5; appendix 8) was unaware of the need to remain upright after taking her alendronate, and this had apparently not been identified or communicated by the pharmacist when she collected subsequent prescriptions. Indeed, the pharmacist stated that she thought Miss Weir would have received counselling on how to take her medication from the doctor or the asthma nurse. Furthermore, Mrs Privett (case 14; appendix 14), who took her prescription for a higher strength of phenytoin capsules to a new pharmacy, was unaware that she needed to only take one phenytoin capsule a day, not three as she had previously, and had not been told this by the pharmacist. Finally, Mrs Harwood’s daughter (case 21; appendix 19) commented that she never received any information about her mother’s medication. The pharmacist pointed out that Mrs Harwood’s daughter always collected her mother’s medication at the busiest time of day on a Friday, so they did not have time to speak to her.

Pharmacists did not routinely tell patients about the potential side effects of their medication. For example, Mr Stewart (case 6; appendix 9) was not aware that aspirin could cause gastrointestinal bleeding, Mr Ray (case 7; appendix 10) was not aware that diclofenac could cause gastrointestinal bleeding, and Mr Taylor’s pharmacist (case 27; appendix 22) did not communicate verbal information about side effects because he was aware that Mr Taylor would not remember what he was told.

These cases illustrate how communication problems between pharmacists and patients contributed to patients not knowing enough about how to administer their medication, or how to manage the side effects of their medication. These communication problems arose when patients and pharmacists were not familiar with each other, when pharmacists perceived themselves to be too busy, and when pharmacists perceived patient counselling to be someone else’s role.
Communication problems between pharmacists and general practitioners

Communication problems between pharmacists and GPs contributed to hospital admission in eight cases. Communication problems arose because of asymmetrical relationships between community pharmacists and GPs, pharmacists finding it difficult to contact GPs, and time and workload pressures.

Community pharmacists referred to workload pressures as a barrier to contacting GPs. This was sometimes related to how frequently the pharmacist saw a high risk prescription. Mrs Davis’s pharmacist (case 20; appendix 18) stated that she would “always be on the phone” to the GP if she queried the combination of aspirin and rofecoxib. On other occasions, time pressures were the result of the high workload within the pharmacy itself and low staffing levels. Mrs Davis’s pharmacist (case 20; appendix 18) commented that when trying to throughput 200 to 300 items a day, it was difficult to find the time to contact GPs and this sentiment was echoed by Mr Kemp’s pharmacist (case 12; appendix 12). Mr Brown’s pharmacist (case 25; appendix 20) highlighted the pressure which results from patients waiting in the shop for their prescription. She believed that some patients viewed her as a supply route for their medication, rather than perceiving her to have a role to play in the safety of their medication. This view was supported by Mrs Kemp (case 12; appendix 2) who expressed surprise that the pharmacist was anything other than a shop keeper.

Some pharmacists expressed frustration about difficulties in contacting GPs. They felt that practice receptionists posed a barrier to their communication and in some cases pharmacists’ previous negative experience of contacting GPs meant they were less likely to question prescriptions. For example, Mrs Davis’s pharmacist (case 20; appendix 18) said it was obvious that doctors did not like to be contacted about problems with prescriptions all the time, and when they were contacted GPs usually did not change the prescription. The pharmacist did not explain why this happened, but her description of a typical conversation between herself and a GP implied a lack of respect for her input.

There was also evidence that not all pharmacists felt confident about contacting GPs. In some cases, the approach taken by a pharmacist when contacting the GP was unlikely to result in a change to the prescription. For example, Mrs Harwood’s GP (case 21; appendix 19) had intentionally changed Mrs Harwood’s furosemide to co-amilofruse. However, it is likely that he had not intended to prescribe her as much co-amilofruse as he had. The pharmacist in this case suggested that, had she been aware that Mrs Harwood had not taken the co-amilofruse before, she would have contacted the GP to double-check that he really did mean that drug. She did not suggest that she would have discussed the potential risk of the drug at the dose prescribed, although this may also reflect a knowledge gap on the part of the pharmacist.

These cases illustrate how communication problems between pharmacists and GPs contribute to community pharmacists not highlighting important drug-related problems to GPs. These communication problems result from pharmacists’ perceptions of their workload and time available to them, pressures from patients who have limited understanding of the breadth of community pharmacists’ role in medication supply, difficulties contacting GPs, and asymmetrical relationships between community pharmacists and GPs.

Summary of the underlying causes of dispensing problems

Dispensing problems contributed to hospital admission in 13 cases. Problems with dispensing medication arose because of pharmacists’ knowledge gaps about
patients' medication and medical histories, pharmacists' knowledge gaps about drugs, and communication problems between pharmacists and patients and pharmacists and GPs. Knowledge gaps about patients' medical histories and past medication usage contributed to community pharmacists not contacting doctors to clarify prescriptions and not giving patients information on how to manage their medication. These knowledge gaps arose because pharmacists rarely had access to medical records, patients could attend any pharmacy (therefore pharmacists' did not always have an up to date medication record available) and pharmacists' felt too pressured for time to check existing medication records. Knowledge gaps about drugs also contributed to community pharmacists not contacting GPs about potentially dangerous drug interactions or doses. These knowledge gaps arose because of problems with pharmacists' training and problems with the design of their computer systems. Communication problems between pharmacists and patients contributed to patients not knowing enough about how to administer their medication, or how to manage the side effects of their medication. These communication problems arose when patients and pharmacists were not familiar with each other, when pharmacists perceived themselves to be too busy to counsel patients, and when pharmacists perceived patient counselling to be someone else's role. In addition, communication problems between pharmacists and GPs also contributed to community pharmacists not highlighting important drug-related problems to GPs. These communication problems resulted from pharmacists' perceptions of their workloads and time available to them, pressures from patients who had limited understanding of the breadth of the community pharmacists' role in medication supply, difficulties contacting GPs, and asymmetrical relationships between community pharmacists and GPs.

4.3.3 Administering

Problems occurred at the point of administering medication in all 18 cases. In twelve cases these problems arose because patients and carers had not been given sufficient information to assess the appropriateness of their medication. In four cases patients or their carers had not been given sufficient information to allow them to administer their medication appropriately. In two cases the patients did not have the appropriate equipment to administer their medication, and in five cases patients' understanding of their medication and medical conditions were not consistent with regularly administering their medication according to the instructions of the prescriber. The underlying causes of the administration problems are displayed in Figure 3 and illustrated with examples from cases in the following sections: patients' (or carers') knowledge gaps about drugs, practical problems administering medication, and patients' understanding of their medication or medical conditions.

Patients' (or carers') knowledge gaps about drugs

Patients' or carers' knowledge gaps about drugs contributed to administration problems in 13 cases. Knowledge gaps existed for a variety of reasons including patients or carers receiving insufficient information about their medication, information leaflets being difficult to read because they contained complex information and were produced in small print, and patients and carers becoming confused by verbal messages, or forgetting them. These factors contributed to patients being unable to make fully informed decisions about whether or not to take their medication, how to take it, and how the medication would affect them.

Patient information leaflets were presented in a type face that was so small it could be hard to read, resulting in patients being unaware of important side effects about their medication. For example, Mr Stewart (case 6; appendix 9) had been unable to read the information leaflet wrapped around his aspirin bottle and was unaware that
aspirin could cause stomach bleeding. Instructions to patients printed on medication labels could also be in too small a type face. Mr Knox (case 15; appendix 15) had been unable to read the instructions provided by the hospital pharmacy on the medication labels and this contributed to him not knowing that he should be taking digoxin.

Patient information leaflets also contained large amounts of complex information which patients and their carers could find confusing and frightening. Mrs Harwood’s daughter (case 21; appendix 19) was convinced that she had read that furosemide could cause tiredness, and wondered whether she should query this with the doctor as her mother had been very tired since leaving hospital. During the interview with her and her mother, however, she was unable to find where she had read this information. Mrs Brown (case 25; appendix 20) referred to the fact that all her drugs mentioned risk of death as a side effect, but she did not let this stop her taking her medication.

Patients and their carers could also become confused by verbal messages they had received, either forgetting them or mixing them up. For example, Mrs Harwood’s GP (case 21; appendix 19) had originally intended for her to take two tablets daily of co-amilofruse for one week, then to reduce to one daily. Neither she nor her daughter recalled this instruction and she continued to take two tablets daily until she became so unwell that she stopped them.

Patients sometimes were not aware how to take their medication, having either not been told, or forgotten what they should do.

These cases illustrate how patients and carers received insufficient information about their medication to enable them to safely administer it according to the prescriber’s directions. These knowledge gaps could arise as a result of complex information being presented inappropriately or patients having difficulty hearing, reading, or retaining information.

**Practical problems administering medication**

Three patients experienced practical problems with administering their medication. These problems could arise as a result of difficult to open packaging, equipment failure, or not being able to read the instructions provided. For example, Mrs Privett (case 14; appendix 14) had difficulty opening the blister packs in which her phenytoin capsules were supplied. To overcome this difficulty she popped them out into a bottle supplied on a previous hospital discharge and discarded the original packet (the bottle was labelled as Phenytoin 100mg capsules, take three daily). This meant that she did not have the appropriate dosage instructions available when she started to take the higher strength capsules and took three daily instead of one. Mr Knox (case 15; appendix 15) was unable to read the labels on his boxes of medication, or the medication guide provided by the hospital, and was therefore unaware that he should be taking digoxin tablets. Mr Pessall (case 2; appendix 6) had previously used an insulin pen because he had difficulty measuring his insulin in syringes due to his impaired vision. He had broken this pen two years earlier, and had not asked for a replacement. At no point in his medical record was it documented as remarkable that he was obtaining insulin syringes and needles (usually used to administer insulin from a vial) and cartridges for use with a pen. It is possible that his difficulty in accurately measuring his insulin dose contributed to his poor diabetic control.

These cases illustrate how practical problems with administering medication can contribute to loss of disease control or taking inappropriate doses of medication.
Practical problems can result from inappropriate packaging or labelling of medication, or not having the equipment necessary to safely administer medication.

**Patients’ understanding of their medication or medical conditions**

Patients’ understanding of their medication or medical conditions differed from that of the healthcare professionals caring for them in five cases. These differences in understanding presented in different ways. In four cases patients found that tight control of their medical condition was less important to them than other factors in their life and less important than the healthcare professionals perceived it should be. In one case, a patient was more concerned by his symptoms than his GP, and strove to manage them without his GP’s help. These differences in understanding contributed to patients’ disease control, and communication with their healthcare professionals, being less than optimal.

Mr Stott (case 26; appendix 21) had recently lost his job and his disability allowance (following an unfavourable report written by his GP) and was having problems caring for his teenage son. The report written by his GP resulted in a breakdown in their relationship and he no longer trusted this GP, whom he had previously had a great deal of respect for. These factors contributed to a worsening in his depression, an increasing sense of helplessness and loss of control, and eventually contributed to him stopping his insulin.

Mr Pessall (case 2; appendix 6) was ambivalent about the treatment of his diabetes. He believed his diabetes to have started following the shock of his mother dying (although there was a strong history of diabetes in his family) and hated having to inject himself with insulin. He would have been much happier if his diabetes could have been managed with tablets. He did not feel able to maintain his blood sugar below 10mmol/L, preferring instead to maintain a level of 15mmol/L as this enabled him to enjoy alcohol and other treats. In addition, he feared becoming overweight (as he had been in the past) and therefore ate very little food. He also believed that he was able to tell when he needed to take his medication for his blood pressure and raised cholesterol, despite these being asymptomatic problems, and took these tablets only when he felt like it. These factors contributed to his poor diabetic control, which in turn contributed to his recurrent diabetic foot ulcer which caused him to be admitted to hospital.

Mr Twelftree (case 1; appendix 5) had not experienced problems with his asthma for a number of years and therefore did not attend his GP surgery for regular reviews. He had not had any contact with a healthcare professional about his asthma for at least seven years, partly because there were staffing problems within his GP surgery’s asthma clinic which meant that they had not been chasing up non-attenders. Mr Twelftree understood that he could control exacerbations of his asthma by using inhaled steroids when he became unwell. When he began to develop an exacerbation of his asthma however, he did not have sufficient supplies of his inhalers to be able to control the exacerbation and required admission to hospital. Had Mr Twelftree had more frequent contact with the asthma clinic it is likely that he would have had an up to date supply of inhalers at home.

Miss Weir (case 5; appendix 8) was ambivalent about her asthma treatment and admitted to not wanting to take her medication at times, but said her mother usually ensured that she did. When she began to vomit after taking her medication, she did not seek medical help, although it is unclear whether this was ambivalence about her treatment, not recognising the significance of not taking her treatment, or recognition
that if she did contact her GP she was likely to be admitted to hospital (something she did not want to happen).

Mr Bond (case 3; appendix 7) was a retired lecturer with specialist knowledge about haematology and therefore viewed himself (and was viewed by his GP) as having more knowledge about warfarin therapy than his GP or the practice nurse. He had been started on warfarin twenty years earlier by a cardiologist at the hospital but had not been reviewed by a cardiologist about his ongoing need for warfarin therapy for 11 years. He perceived his warfarin to be controlled by the hospital and hence did not view his GP or the practice nurse as having a role in the control of his warfarin. Despite this, he regularly attended the surgery’s anticoagulation clinic to have his blood taken but did not voice his concerns to either the practice nurse or his GP about his slowly increasing INR. This concern was compounded by his two year history of anaemia of unknown cause, which he was more worried about than his GP. As a result, Mr Bond made small adjustments to his warfarin dose to avoid his INR increasing outside of the specified therapeutic range, but did not inform the practice nurse or make a note in his warfarin book. This meant that the anticoagulation clinic were unaware of these dosage adjustments when they subsequently dosed his warfarin. Over time, it could become increasingly difficult for Mr Bond to manage his warfarin dose, although it is unclear whether this was the case. Had he communicated his concerns to his GP adequately, however, his anaemia could have been more vigorously investigated, and his warfarin dose possibly managed more easily.

These cases illustrate how patients’ understandings of their medical conditions and treatment can differ from healthcare professionals’ understandings and how this can contribute to communication problems and ultimately, poor disease control leading to hospital admission.

**Summary of the underlying causes of administration problems**

Administration problems contributed to hospital admissions in all 18 cases. Problems with administration arose as a result of patients’ or carers’ knowledge gaps about drugs, practical administration problems, and patients’ understanding of their medical conditions and medication. Knowledge gaps arose when patients and carers received insufficient information about their medication to enable them to safely administer it according to the prescriber’s directions. These knowledge gaps resulted from complex information being presented inappropriately or patients having difficulty hearing, reading or retaining information. In addition, practical problems with administering medication contributed to loss of disease control or patients taking inappropriate doses of medication. Practical problems resulted from inappropriate packaging or labelling of medication, and not having the equipment necessary to safely and accurately administer medication. Finally, some patients’ understandings of their medical conditions and treatment differed from healthcare professionals’ understandings and this contributed to communication problems, and ultimately poor disease control, leading to hospital admission.

**4.3.4 Monitoring**

Problems occurred at the point of monitoring medication in 14 cases. In each of these cases the monitoring problem occurred because the doctor, nurse, pharmacist, or patient did not appropriately monitor the medication. In five cases the healthcare professionals did not monitor the efficacy of the medication. In two cases the monitoring of efficacy was not frequent enough. In six cases the healthcare professionals did not monitor for side effects of medication. In two cases the healthcare professionals did not respond appropriately to abnormal blood results. In
one case the patient did not monitor the efficacy of the medication. In two cases patients did not respond appropriately to loss of disease control and in another two cases the ongoing need for the medication was not monitored. The underlying causes of these monitoring problems are displayed in Figure 3 and illustrated with examples from the cases in the following sections: patients’ knowledge gaps about drugs, nurses’ knowledge gaps about drugs, doctor’s knowledge gaps about drugs, time and workload pressures, and blurred responsibilities.

**Patients’ knowledge gaps about drugs**

In three cases monitoring problems occurred because patients did not know their medication needed to be monitored, or how to respond to the results of monitoring. These knowledge gaps resulted from communication problems between doctors and patients. For example, Mr Kemp (case 12; appendix 12) was discharged from hospital with instructions to monitor his weight, but forgot that he had been told this. Furthermore, he had not received any written guidance and his wife had not been present when he was asked to do this, despite Mr Kemp being known to have problems with his short term memory. Also, Mrs Turner (case 19; appendix 17) was not aware of the importance of having blood tests to assess the efficacy of her carbimazole, and therefore did not attend the hospital appointment sent to her. This lack of monitoring extended the time it took to identify the fact that she was being treated with carbimazole unnecessarily, and the length of time she was unwell. In addition, Mr Taylor (case 27; appendix 22) recognised that he had hypoglycaemia from his symptoms and his blood test results, but continued to take his insulin at the same dose. Instead of reducing the amount of insulin and seeking help, he took sugar to try and maintain his glucose levels, extending the time it took to identify how unwell he was.

These cases illustrate how patients’ knowledge gaps about the need to monitor their medication, and how to respond to the results, contributed to patients becoming increasingly unwell as a result of their medication. Knowledge gaps could be the result of patients not recalling information given to them about how to monitor their medication, or not being given this information.

**Nurses’ knowledge gaps about drugs**

In case 25 (appendix 20), the monitoring of a patient’s diabetic and blood pressure medication was largely the responsibility of the practice nurse. Mrs Brown had seen the practice nurse four weeks before her admission to hospital for a diabetic check. The practice nurse had recorded an unusually low blood pressure for Mrs Brown in her medical record, but not recognised the significance of the result. Hence, the blood pressure result had not been communicated to the GP and the practice nurse made Mrs Brown an appointment to see the GP eight weeks later. The nurse said that she knew little about drugs and could not be expected to recognise problems with them. It could be argued, however, that she would be expected to recognise an abnormally low blood pressure result and to respond appropriately. Had Mrs Brown been seen more swiftly by the GP it is possible that her drug-related problems could have been recognised before they resulted in hospital admission.

**Doctors’ knowledge gaps about drugs**

In seven cases GPs had insufficient knowledge about how to monitor drugs and how to respond to abnormal test results. These knowledge gaps contributed to patients becoming increasingly unwell. Knowledge gaps existed because of insufficient training, insufficient instructions about monitoring (either as a guideline or from the
professional initiating a medication) and because GP computer systems were not always designed to remind GPs to monitor drugs.

Case 12 (appendix 12) illustrates what can happen when the professional initiating a medication does not provide adequate instructions to the professional who is responsible for the long term monitoring of the medication. Mr Kemp was discharged home from hospital on a potent combination of diuretics before he was fully stabilised. Mr Kemp’s GP was asked to “closely monitor” his urea and electrolytes by the hospital doctor, but Mr Kemp’s GP was not familiar with the drug combination used and interpreted “closely” to mean weekly. Whilst in hospital, however, Mr Kemp’s urea and electrolytes had been monitored every day. When Mr Kemp’s GP did review his test results he did not recognise the significance of the changes in Mr Kemp’s urea and electrolytes. The GP had not been given instructions on how to respond to any changes in the test results or any accurate baseline test results to compare subsequent results to. These factors contributed to Mr Kemp’s dehydration not being recognised at a stage early enough to avoid hospital admission.

In two cases the GPs were familiar with the drug being monitored, but assumed that the hospital was monitoring it. For example, Mrs Turner’s GP (case 19; appendix 17) had not been told whether he should monitor her carbimazole or whether the hospital would monitor it. As carbimazole was normally monitored by the hospital he assumed that this was the case and did not follow it up. He was not copied into correspondence with Mrs Turner, where the hospital had asked her to attend an appointment to monitor the carbimazole which she did not attend, and was therefore unaware that her medication was not being monitored. Likewise, Mr Pessall’s GP (case 2; appendix 6) had assumed that the hospital consultants were performing Mr Pessall’s annual diabetic checks. The lack of monitoring of Mr Pessall’s diabetes came to light only when Mr Pessall requested that his care be transferred to another hospital because he was unhappy with the standard of care he was currently receiving.

In four cases GPs exhibited knowledge gaps about monitoring medication they had initiated. For example, the GP in case 20 (appendix 18) did not recognise the need to monitor Mrs Davis’s renal function when he started rofecoxib, hence the decline in her renal function caused by the rofecoxib was not identified until she was admitted to hospital. There was no guideline in place to recommend checking a patient’s renal function following initiating this drug, despite it being known to cause renal failure in high risk patients such as Mrs Davis. Mrs Harwood’s GP (case 21; appendix 19) checked her urea and electrolytes but did not recognise the significance of the results which were the early signs of the hyperkalaemia which caused her hospital admission. When he viewed the results on the computer screen he would not have had easy access to a previous test result as a comparison, or to her current medication, although this information was available if he had time to look for it and knew where to find it. In two cases GPs started drugs which interacted with other drugs already being taken by the patients. In neither case did they recognise the need for monitoring these combinations. For example, Mr Matheson (case 13; appendix 13) was started on venlafaxine, a drug which could upset the control of his warfarin. His GP did not increase the frequency with which he monitored Mr Matheson’s warfarin, despite it being known that Mr Matheson had a tendency to bleed into his knee if his INR increased a small amount above the desired therapeutic range. Mr Bond’s GP (case 3; appendix 7) did not recognise the significance of anaemia in a patient taking warfarin and it is likely that this contributed to the GP not investigating the cause of the anaemia sufficiently rigorously. In neither case did the computer system alert to a need for increased monitoring or further investigation.
These cases illustrate how GPs’ knowledge gaps about how to monitor medication contribute to delays in identifying drug-related problems. These delays can result in patients becoming increasingly unwell and requiring hospital admission. The knowledge gaps can result from communication problems between primary and secondary care, lack of guidelines on how to monitor medication, and problems with the design of computer systems which mean they don’t alert to the need to monitor some medications, or to the presence of abnormal test results.

**Time and workload pressures**

Some of the GPs felt that it was difficult to frequently monitor patients in primary care because it was time consuming and difficult to get access to the patients, especially if the patient’s mobility meant they had to be visited at home. For example, Mr Kemp’s GP (case 12; appendix 12) felt that it was not feasible to check a patient’s blood more than once a week. In other cases, patients were not followed up quickly enough after monitoring had taken place. This is illustrated in case 25 (appendix 20), where Mrs Brown’s practice had a system for diabetic review where the practice nurse reviewed the patient and monitored their disease control. According to the practice’s procedure, the patient should see the GP two weeks later to have their results reviewed. However, the diabetic nurse saw twice as many patients in her clinic as the GP did in his. This meant that half the patients had to be slotted into routine appointment times in order to receive follow up. Mrs Brown was not due to be seen for 8 weeks after the practice nurse had recorded an unusually low blood pressure during her diabetic review.

These cases illustrate how time and workload pressures can contribute to patients not being monitored or not being followed up sufficiently quickly after test results are received.

**Blurred responsibilities**

In three cases, GPs were not clear whose responsibility it was to monitor a patient’s medication, especially where the medication had been started in hospital. This, combined with time and workload pressures, resulted in patients’ medication either not being monitored, or not being monitored frequently enough. For example, Mrs Turner’s GP (case 19; appendix 17) assumed that the hospital had checked her baseline blood results when starting carbimazole and that the hospital would also be responsible for her long term monitoring. This was not, however, confirmed with either the hospital doctors or Mrs Turner. Mrs Turner was unaware of the need for long term monitoring, and did not attend her appointment at the hospital. Also, Mr Kemp’s GP (case 12; appendix 12) assumed that Mr Kemp was weighing himself at home and therefore did not weigh him in the surgery. Instead, he accepted Mr Kemp’s statement that his weight was stable. This contributed to a delay in recognising Mr Kemp’s dehydration. Finally, Mr Pessall (case 2; appendix 6) had not had a diabetic review at the hospital for a number of years. Mr Pessall’s GP and his consultant at the foot clinic had both assumed that Mr Pessall was under the care of another diabetic consultant but had not verified this until Mr Pessall highlighted the problem. This lack of care may have contributed to Mr Pessall’s ambivalence about the treatment for his diabetes, and hence, his poor diabetic control.

These cases illustrate that, where more than one professional was responsible for monitoring a patient’s medication, individuals assumed that other people were doing the monitoring. Where time and workload pressures were present, the individuals were less likely to check that this monitoring was being done.
Summary of the underlying causes of monitoring problems

Monitoring problems contributed to 14 hospital admissions. Problems with monitoring arose because of knowledge gaps about drugs, blurred responsibilities for monitoring, and time and workload pressures. Patients’ knowledge gaps about the need to monitor their medication and how to respond to the results contributed to patients becoming increasingly unwell as a result of their medication. Knowledge gaps resulted from patients not recalling information given to them about how to monitor their medication, or not being given this information. In addition, GPs’ knowledge gaps about how to monitor medication contributed to delays in identifying drug-related problems. These delays also resulted in patients becoming increasingly unwell and requiring hospital admission. Knowledge gaps resulted from communication problems between primary and secondary care, lack of guidelines on how to monitor medication, and problems with the design of computer systems which meant they did not alert to the need to monitor some medications or to the presence of abnormal test results. Where more than one professional was responsible for monitoring a patient’s medication, one could assume that another was doing the monitoring. This was more likely where professionals were working in pressured conditions.

4.3.5 Help seeking

Problems occurred at the point of seeking help for symptoms in fifteen cases. In nine cases patients did not recognise the significance of their symptoms and therefore did not seek timely help from a healthcare professional, in three cases patients did not seek timely help, and in six cases patients did not seek help from a healthcare professional. In two cases patients consulted healthcare professionals with mild symptoms, but the significance of their symptoms was not recognised soon enough. Problems occurred at the point of seeking help for medication problems in five cases, in two cases patients did not voice their concerns about the potential side effects of their medication, in another two cases patients’ concerns about side effects were dismissed, in one case a patient did not ask for further clarification about how to take his medication, and in another case a patient did not ask for new equipment when his own had broken. The underlying causes of these problems are displayed in Figure 3 and illustrated with examples from cases in the following sections: Patients’ knowledge gaps about drugs, Communication problems and Prescribers’ knowledge gaps about drugs.

Patients’ knowledge gaps about drugs

Patients’ knowledge gaps about drugs meant that they did not seek timely assistance for drug-related problems. In five cases, had help been sought earlier, the patients’ admissions could have been avoided, whilst in three cases the severity of their illness could have been reduced. Patients were often unaware of the potential side effects of their medication, or why they should take their medication. Therefore, when symptoms manifested, patients were unable to recognise their significance and did not seek timely help. For example, Mrs Privett (case 14; appendix 14) began to feel dizzy and lose her appetite a week before she was admitted to hospital. Medical help was not sought until she told her daughter she had never felt so unwell a week later. On admission to hospital she was found to have taken too much phenytoin and this had contributed to her dizziness. In this case, the identification of dizziness as a side effect of phenytoin is made more difficult because it is a non-specific symptom. Mr Knox (case 15; appendix 15) was discharged home from hospital without being given sufficient information to manage his medication. When he unpacked his tablets, he did not recognise the digoxin tablets which had been supplied in a plain white box (the print on the label was too small for him to read) and, instead of seeking help from his GP about whether he should take them, he placed them in a drawer and
forgot about them. Two weeks later he was readmitted to hospital with a fast heart rate and shortness of breath because he had not taken the digoxin. In both cases, had the patients sought help earlier, their admissions could have been avoided.

Similarly, Mr Ray (case 7; appendix 10) began to vomit up “black-stuff” and collapsed four days prior to his hospital admission. He was not aware of the significance of the vomiting and instead feared that it might be “cancer.” Medical attention was not sought until his daughter found him unconscious in his chair and called an ambulance. On admission to hospital he was found to be very anaemic. Although seeking medical attention four days earlier would not have avoided his hospital admission, it would have reduced the severity of his illness and possibly the duration of the admission. In addition, Mrs Brown (case 25; appendix 20) did not take appropriate action when she developed chest pain. Instead of calling for an ambulance, she asked her husband to call the surgery and see if someone could come and check her blood sugar. This was partly because she did not want to worry her husband and partly because she did not want to be seen as troublesome by the GP. This delayed her admission by seven hours. Although this delay did not contribute to the severity of her admission, it meant that she remained in pain for longer than necessary.

These cases illustrate that patients’ lack of knowledge about their medication can lead to delays in seeking help for symptoms of illness or more practical problems with medication administration. In these cases, had help been sought sooner, hospital admission could have been avoided or the duration and severity of illness reduced.

Communication problems and prescribers’ knowledge gaps about drugs

Sometimes patients did try to seek help, but were put off by the response of the healthcare professional they contacted. Mr Smith’s wife (case 9; appendix 11) contacted the surgery when he first felt unwell, but the receptionist told her to ring back later. Subsequently, Mr Smith played down his symptoms and his wife contacted the surgery again only when he collapsed later that day. Although a more rapid consultation would not have prevented his admission, it may have made the admission less traumatic, and the consequences less severe; Mr Smith began to vomit blood in the back of the emergency service car on the way to the hospital.

On other occasions, patients consulted a GP but their symptoms were not recognised as side effects of their medication. Patients usually presented with non-specific symptoms such as tiredness and lethargy, which were attributed to other causes. The GPs did not seem to be aware that these patients were taking medication which put them at a high risk of injury and that increased vigilance was required. For example, Mr Jones (case 18; appendix 16) consulted his GP about stomach upsets a week prior to his admission. The GP thought the stomach upsets were secondary to constipation and no further investigation was made. In retrospect, it is more likely that the stomach upset was an early sign of peptic ulceration. Similarly, Mrs Harwood (case 21; appendix 19) was seen by two different doctors, neither of whom recognised the significance of her falls or that a recent change in her medication had caused them. In both cases, had the symptoms and their causes been recognised and treated sooner, hospital admission could have been avoided.

Mr Bond (case 3; appendix 7) had a two-year history of anaemia, prior to his hospital admission. His GP had not rigorously investigated the source of his bleeding, because Mr Bond appeared to be well with it. Mr Bond’s GP had not shared his view that bleeding, and not knowing where from, whilst taking warfarin was a cause for concern. Although it is not known whether Mr Bond’s longstanding anaemia was due
to bleeding from the stomach, this source of bleeding had not been adequately investigated prior to his admission.

Mr Matheson’s haemarthrosis (case 13; appendix 13) was dismissed as trivial by the orthopaedic doctors, when they were contacted by his GP. The accident and emergency doctors misdiagnosed the cause of his swollen knee and sent him back home. In the following week, Mr Matheson had a downstairs existence and became increasingly unwell, finally requiring admission to hospital with sepsis. Although the connection between the haemarthrosis and the sepsis is unknown, it is probable that the delay in treatment increased the severity of his illness and the duration of his admission.

In some cases patients had concerns about their medication at an early stage, but these concerns had either not been raised with a healthcare professional, or their concerns had been dismissed. For example, Mr Smith (case 9; appendix 11) had questioned the combination of aspirin and warfarin, because he had been told not to take the two medications together. Mr Smith said that he was told “that was what the consultant had asked for and that was what he should take.” Also, in case 25 Mrs Brown recalled a consultation with her GP where he had added in another antihypertensive medication. She had said to him that she was now taking two antihypertensives, but her GP corrected her saying she should now be taking three. She did not question his statement.

These cases illustrate how prescribers’ knowledge gaps and communication problems can contribute to delays in patients receiving medical attention for their symptoms. Asymmetrical relationships between healthcare professionals and patients and time and workload pressures can contribute to professionals being dismissive of patients’ concerns about drug-related problems. This can lead to a delay in identifying high risk combinations of medication.

**Summary of the underlying causes of problems in seeking help for illness or other problems with medication**

Problems in seeking help for medication problems and symptoms contributed to hospital admission in 15 cases. Problems with help seeking arose because of knowledge gaps about drugs and communication problems. Patients’ lack of knowledge about their medication led to delays in seeking help for symptoms of illness or help with practical problems with medication administration. Had help been sought sooner, hospital admission could have been avoided or the duration and severity of illness reduced. Prescribers’ knowledge gaps and communication problems contributed to delays in patients receiving medical attention for their symptoms. In addition, asymmetrical relationships between healthcare professionals and patients, and time and workload pressures, contributed to professionals being dismissive of patients’ concerns about drug-related problems. This led to delays in identifying high risk combinations of medication.
Section 5 - Discussion

5.1 Main findings
This study has found that the underlying causes of preventable drug-related morbidities resulting in hospital admission are multifaceted and complex. In the majority of cases, problems arose at multiple stages in the medication use process. The most important contributory factors are communication problems between patients and healthcare professionals and between different groups of healthcare professionals, and knowledge gaps about medication on the part of patients and healthcare professionals. All these are underpinned by time and workload pressures.

5.2 Strengths and weaknesses of the study
Previous studies have concentrated on the incidence of preventable drug-related admissions, or on statistical analysis of associated factors. This study is one of the first to examine, in detail, the underlying causes of preventable drug-related morbidity in primary care resulting in hospital admission, from the perspective of the prescriber, the patient and the pharmacist. Previous studies have examined the proximal causes of preventable adverse events or have undertaken detailed studies of the underlying causes of adverse events in other areas.

This study has successfully identified some of the factors which contribute to preventable adverse drug events in primary care through the use of detailed case studies, involving triangulation of different data sources, which has increased the robustness of the results.

The retrospective nature of the data collection (interviews with patients and professionals, sometimes months after the initial event) means that some of the underlying causes may have been lost over time. Specifically, there is no way of knowing what happened during consultations between GPs and patients and pharmacists and patients at the time the drugs were prescribed or dispensed. However, triangulation of data between medical records, interviews with GPs, patients and pharmacists, and review of protocols and guidelines means that a number of important issues around medicines management have been highlighted. In addition, there is already a large body of work which has looked at the interactions between patients and professionals during consultations, and this work supports the findings of this study i.e. communication problems contribute to poorer care.

One of the main strengths of this study is the participation of patients in identifying the underlying causes of their hospital admissions. Few studies have involved the patients in this process, and will have therefore missed the important contributions of patient-specific factors such as lack of understanding of their medication and disease, poor relationships with healthcare professionals and their perspectives on taking their medication. Although it was not felt appropriate to examine the issues underlying these admissions in a group setting with patients, GPs and pharmacists all present in a room together, the methodology used allowed each party to contribute their understanding of the underlying causes and, as all interviews were carried out in the workplace (for GPs and pharmacists) or the home (for patients), also allowed useful observation of day to day practice.

Although the study has explored comparatively small numbers of cases, there was some evidence of data saturation, with the same themes appearing recurrently. In addition, the small numbers of cases explored allowed an in-depth exploration of the underlying causes of these admissions. Previous studies which have explored larger
numbers of cases have been unable to explore the causes of problems with medical care in such depth\textsuperscript{21}.

5.3 Implications for healthcare provision

This study has important implications for clinicians, patients and policy makers. The results highlight the importance of good communication between patients and clinicians, and the importance of knowing about the medication that is being prescribed or supplied. It also helps to raise the profile of the time and workload pressures which can lead to these tasks being performed poorly.

The study also highlights the importance of patients knowing about their medication, when and how to take it and which symptoms mean they should be seeking urgent medical attention. In order for patients to obtain this information, they may need to be more assertive with healthcare professionals, asking for the information where it is not volunteered.

In addition, the study highlights the difficulties experienced by community pharmacists with respect to intervening on prescriptions with a high risk of causing adverse events. These difficulties stem from pharmacists' knowledge gaps about the drugs they are supplying, poor relationships with GPs, and time pressures. The new community pharmacy contract may help to relieve some of the time pressures by providing funding for pharmacist interventions. Individual pharmacists, however, need to do more to improve relationships with local GP surgeries. There is some evidence that this can be achieved through increased face-to-face contact between pharmacists and GPs\textsuperscript{37-39}.

For policy makers it raises important issues around the set up of healthcare in the NHS. Poor access to patient information during home visits and pharmacy consultations clearly contributes to preventable adverse drug events in primary care. Hopefully the National Programme for IT will resolve some of these issues. To enable this, it is vitally important that community pharmacists are allowed good access to both medication and medical histories, as well as blood test results and other criteria associated with monitoring medication e.g. blood pressure and pulse rates. Only with this information can pharmacists begin to decide whether a medication is appropriate for a specific patient. In addition, it is important that the National Programme for IT also provides GPs with access to this information when they visit patients outside the surgery. Also, improved clinical decision support for both prescribers and pharmacists should help to overcome some of the problems associated with healthcare professionals' knowledge gaps about drugs.

5.4 Unanswered questions and future research

Although this study has highlighted some important underlying causes of preventable drug related morbidities in primary care, it has not answered the question of why these problems result in injury in some patients, and not in others. This avoidance of injury may be luck, or it may be that there are characteristics specific to service provision for these patients, or to the patients themselves, which protect against preventable adverse drug events.

Having identified the underlying causes of preventable adverse drug events, it would be useful to compare these to aspects of care in patients who have not suffered adverse drug events. Is their knowledge of their medication much greater? Are they willing to seek help about symptoms sooner? Do they have better relationships with healthcare professionals? In addition, it would be useful to know how commonly the underlying causes identified in this study occur in day to day practice. Are these
common problems which affect multiple patients and healthcare professionals? Or are they rare events?

This study has once again highlighted problems around the communication between primary and secondary care, and it would be useful to look at ways of improving this communication in a way that is likely to be widely implemented. Previous studies have used strategies that appear to require high inputs of time, and are therefore unlikely to be widely implemented in the NHS, where time is at a premium.

Another problem highlighted in this study is the inadequate guidance given to GPs around the monitoring of medication. This largely stems from an inadequate evidence base on which to base guidelines. For high-risk medications e.g. non-steroidal anti-inflammatory drugs, diuretics etc. it would be very useful to be able to develop evidence based guidelines on what monitoring is useful, and when it should be done.

Finally, the role of community pharmacists as a safety barrier to prevent adverse drug events in primary care is currently limited. It would be useful to look at ways of improving their contribution to patient care in this area. The provision of extra patient information through the National Programme for IT will hopefully facilitate this role, and it would be useful to assess the impact of this on community pharmacist practice and patient outcomes.
Section 6 - Conclusions

The underlying causes of preventable drug-related admissions to hospital, from primary care, are multifaceted and complex. Interventions to prevent future admissions will have to take account of their impact on time and workload for the professionals implementing them, as this is the most common reason for tasks not being performed. The current trend to devolve tasks away from professionals will only help to improve the level of care if it results in real increases in the time that professionals spend with patients, not just in time to see more patients.
8.1 Changes to objectives

The secondary objectives of the study changed following further analysis of pilot data, and after discussion with the ethics committee. The original secondary objectives were:

- How effective is root cause analysis in identifying system failures leading to drug-related morbidity in primary care?

- How important do primary healthcare professionals perceive adverse drug events to be in terms of preventability, impact on patients and impact on themselves?

These were changed to a single secondary objective:

- To explore the views of GPs, pharmacists and patients on a range of issues concerning medication-related morbidity in primary care.

The primary objective of the study remained unchanged.

8.2 Changes to methodology

1. The original protocol stated that five cycles of patient identification, equivalent to 10 weeks, would be performed over a period of one year. In the study four cycles of patient identification, equating to 12 weeks, were performed over one year.

2. The original protocol aimed to recruit 20 patients. The study recruited 15 patients, and supplemented this with data from three patients recruited during pilot work. The decision was made to stop recruitment as data saturation had largely been achieved.

3. The original proposal stated that NVivo would be used to manage data analysis. Once the data had been collected, this was felt to be inappropriate, and the decision was made to develop narrative case synopses instead, to maintain the richness of the data.

4. The original protocol stated that James Reason’s theory of human error would be used as a framework to analyse the data. In the study, this has been supplemented by human factors theory, from The London Protocol20.

5. The original protocol stated that summaries of interviews would be sent to interviewees to facilitate respondent validation26. However, due to delays in obtaining transcripts, this was no longer feasible. The time delay between the interview and summarising the transcripts was greater than one month in most cases, and it was felt that most participants would not have a good recollection of the interview after this time period.
### Appendix 1: Characteristics of patients interviewed

<table>
<thead>
<tr>
<th>Case number</th>
<th>Patients’ name (fictional)</th>
<th>Patients’ age (years)</th>
<th>Gender</th>
<th>Townsend score</th>
<th>Self-reported ethnicity</th>
<th>Cause of admission</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Mr Twelftree</td>
<td>25</td>
<td>Male</td>
<td>3.99</td>
<td>Asian</td>
<td>Asthma exacerbation following not using regular corticosteroid, and no access to function reliever therapy</td>
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<tr>
<td>2</td>
<td>Mr Pessall</td>
<td>48</td>
<td>Male</td>
<td>0.43</td>
<td>White British</td>
<td>Foot ulcer associated with long term problems with diabetic control</td>
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<td>3</td>
<td>Mr Bond</td>
<td>73</td>
<td>Male</td>
<td>-3.92</td>
<td>White British</td>
<td>Gastrointestinal bleed associated with warfarin following self adjustment of dose, and long term anaemia of unknown cause</td>
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<tr>
<td>5</td>
<td>Miss Weir</td>
<td>19</td>
<td>Female</td>
<td>7.28</td>
<td>White British</td>
<td>Asthma exacerbation following cessation of oral preventer therapy following oesophageal irritation from alendronate which had been taken whilst lying down</td>
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<tr>
<td>6</td>
<td>Mr Stewart</td>
<td>86</td>
<td>Male</td>
<td>-2.73</td>
<td>White British</td>
<td>Gastrointestinal bleed associated with aspirin</td>
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<td>7</td>
<td>Mr Ray</td>
<td>56</td>
<td>Male</td>
<td>0.70</td>
<td>White British</td>
<td>Gastrointestinal bleed associated with alcohol and diclofenac</td>
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<td>9</td>
<td>Mr Smith</td>
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<td>Male</td>
<td>-1.91</td>
<td>White British</td>
<td>Gastrointestinal bleed associated with aspirin and warfarin</td>
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<td>12</td>
<td>Mr Kemp</td>
<td>68</td>
<td>Male</td>
<td>-2.69</td>
<td>White British</td>
<td>Collapse associated with dehydration and electrolyte imbalances following increase in diuretic dosages</td>
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<td>Mr Matheson</td>
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<tr>
<td>14</td>
<td>Mrs Privett</td>
<td>90</td>
<td>Female</td>
<td>1.84</td>
<td>White British</td>
<td>Collapse secondary to phenytoin toxicity following accidental increase in phenytoin dose</td>
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<tr>
<td>15</td>
<td>Mr Knox</td>
<td>91</td>
<td>Male</td>
<td>6.78</td>
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<td>Collapse secondary to fast atrial fibrillation following accidental cessation of digoxin</td>
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<td>18</td>
<td>Mr Jones</td>
<td>83</td>
<td>Male</td>
<td>-0.21</td>
<td>White British</td>
<td>Gastrointestinal bleed associated with aspirin, rofecoxib and alendronate</td>
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<td>19</td>
<td>Mrs Turner</td>
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<td>20</td>
<td>Mrs Davis</td>
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<td>Female</td>
<td>2.52</td>
<td>White British</td>
<td>Gastrointestinal bleed and renal failure associated with aspirin and rofecoxib</td>
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<td>21</td>
<td>Mrs Harwood</td>
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<td>-0.20</td>
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<td>Hyperkalaemia following initiation of high dose of amiloride</td>
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<td>25</td>
<td>Mrs Brown</td>
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<td>Female</td>
<td>4.74</td>
<td>White British</td>
<td>Bradycardia with verapamil and atenolol</td>
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<td>26</td>
<td>Mr Stott</td>
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<td>Male</td>
<td>7.34</td>
<td>White British</td>
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<td>27</td>
<td>Mr Taylor</td>
<td>82</td>
<td>Male</td>
<td>-2.73</td>
<td>White British</td>
<td>Collapse associated with hypoglycaemia, following the development of rofecoxib induced renal failure</td>
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32
<table>
<thead>
<tr>
<th>Case number</th>
<th>Gender</th>
<th>Self-reported Ethnicity</th>
<th>Number of years qualified</th>
<th>Role in general practice</th>
<th>Previous experience</th>
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<td>Single handed GP</td>
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</tr>
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<td>Male</td>
<td>White British</td>
<td>17</td>
<td>Partner in small practice</td>
<td>General practice</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>White British</td>
<td>23</td>
<td>Partner in large practice</td>
<td>General practice, VTS trainer</td>
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<tr>
<td>5</td>
<td>Male</td>
<td>White British</td>
<td>15</td>
<td>Senior partner in small practice</td>
<td>General practice, previous clinical governance lead for PCT</td>
</tr>
<tr>
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<td>24</td>
<td>Partner in large practice</td>
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</tr>
<tr>
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<td>Male</td>
<td>White British</td>
<td>20</td>
<td>Partner in large practice</td>
<td>General practice</td>
</tr>
<tr>
<td>12</td>
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<td>Partner in medium sized dispensing practice</td>
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</tr>
<tr>
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<td>Asian</td>
<td>Unknown</td>
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<td>Unknown</td>
</tr>
<tr>
<td>15</td>
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<td>Indian</td>
<td>34 as doctor, 23 as general practitioner</td>
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<td>Obstetrics &amp; gynaecology (MRCOG) &amp; general practice (working towards MRCGP)</td>
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<td>18</td>
<td>Male</td>
<td>White British</td>
<td>22 (17 as general practitioner)</td>
<td>Partner in large group practice</td>
<td>General practice</td>
</tr>
<tr>
<td>19</td>
<td>Male</td>
<td>White British</td>
<td>12 (7 as general practitioner)</td>
<td>Partner in medium sized practice</td>
<td>Obstetrics &amp; gynaecology &amp; general practice</td>
</tr>
<tr>
<td>20</td>
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<td>Partner</td>
<td>General practice (MRCGP)</td>
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<td>General practice</td>
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<td>General practice</td>
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<td>Case number</td>
<td>Gender</td>
<td>Self-reported ethnicity</td>
<td>Number of years qualified</td>
<td>Role in community pharmacy</td>
<td>Previous experience</td>
</tr>
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<td>---------------------------</td>
<td>-----------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>2</td>
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<td>Community pharmacy</td>
</tr>
<tr>
<td>6</td>
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<td>Asian</td>
<td>4</td>
<td>Full time employee for a large multiple</td>
<td>Community pharmacy</td>
</tr>
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<td>7</td>
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<td>1</td>
<td>Full time employee for a small chain</td>
<td>Community pharmacy</td>
</tr>
<tr>
<td>9</td>
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<td>Full time employee for small chain</td>
<td>Community pharmacy (small and large chains)</td>
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<td>Pre-registration pharmacist tutor, Masters in Primary Health Care</td>
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<td>Owner of two pharmacies</td>
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<tr>
<td>19</td>
<td>Female</td>
<td>White British</td>
<td>27</td>
<td>Co-owner of independent pharmacy for 15 years</td>
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<td>27</td>
<td>Male</td>
<td>White Other</td>
<td>21</td>
<td>Independent pharmacy owner for 13 years</td>
<td>Hospital pharmacy, clinical trials pharmacist in pharmaceutical industry, community pharmacy</td>
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Appendix 4 – Data sources and duration of interviews for each case

<table>
<thead>
<tr>
<th>Case number</th>
<th>Duration of interviews (in minutes) with:</th>
<th>Medical records reviewed:</th>
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<tr>
<td></td>
<td>Patient</td>
<td>GP</td>
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<tr>
<td>1</td>
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<td>27</td>
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</tr>
</tbody>
</table>

PN = Practice nurse  PM = Practice Manager
HP = Hospital Pharmacists  SR = Senior Receptionist
CP = Community Pharmacist  * = Main carer contributed to interview
✓ = Record reviewed  x = Patient died before interview took place
Mr Twelftree was admitted to hospital with a mild exacerbation of his asthma. He had not received a supply of inhalers since his last asthma assessment three and a half years ago, and had therefore not been using regular asthma therapy since then. When his asthma did become worse, he did not have a supply of reliever therapy to control it with.

Two months before his admission Mr Twelftree had a chest infection with a productive cough. When this resolved he continued to have a dry cough which may have been symptomatic of his worsening asthma symptoms.

During the week before his admission he became increasingly unwell, and said he had used his salbutamol inhaler 3 or 4 times a day. He said that he only used his beclomethasone inhaler when he became unwell, and had been using it twice a day for a few days before his admission. He had also been using an old salbutamol inhaler during this period which ran out on the day of admission.

Mr Twelftree had not seen his GP for two and half years. He only saw him when he was very unwell. He was not sure why, but thought it might be because it took 2 or 3 days to get an appointment.

Patients with asthma should have been seen by the asthma nurses. The GP stated that it was the patient’s responsibility to see the nurse. There were, however, long term staffing problems with the practice nurses who ran the asthma clinic. This meant that patients had not been recalled for routine asthma reviews.
Appendix 6: Case 2 - Mr Pessall

Mr Pessall was admitted to hospital in January 2004 with cellulitis from an infected mixed diabetic foot ulcer. He had long term poor diabetic control, which may have contributed to the severity of his infection. He was partially sighted and had a complex medical history including poorly controlled type-2 diabetes, depression, congenital cataracts, intractable glaucoma, Charcot’s foot and recurrent foot ulcers. Mr Pessall also drank 3 to 5 cans of lager a day to relieve his boredom. He was poorly compliant with his oral medication (aspirin, simvastatin and blood pressure tablets) and maintained his blood sugar between 12 and 15. Mr Pessall felt he would have to give up too many of the pleasures in life to maintain his blood sugar at 7 to 8.

A few weeks before his hospital admission, Mr Pessall was admitted to a psychiatric unit following the death of an ex-girlfriend. Following this he had a 3-week history of worsening pain from an infected foot ulcer. He had ignored the pain because he did not want to be admitted to hospital. When he finally saw his GP, an ambulance was called and he was admitted straight away. He had fever and rigors and his blood sugar was running at 15 to 16. It remained erratic throughout his admission.

Mr Pessall had both social and practical issues with his diabetes which contributed to his poor control. He hated having diabetes, believing it had started as a result of the shock of his mother dying in his arms. He hated injecting himself with insulin, and would readily have taken an alternative had it been available. Two years prior to his admission, his insulin pen had broken and he had subsequently drawn up his insulin using needles and syringes from the pen-cartridges (his poor eyesight made this particularly difficult). He had not thought to ask his GP for a replacement pen. He had not had a diabetic check up (at the hospital) for 2 years; his GP had recently taken over his annual checks.
Appendix 7: Case 3 (Mr Bond)

Mr Bond was admitted with gastrointestinal bleeding, associated with a raised INR which caused anaemia and subsequently led to a myocardial infarction. He was found to have gastrointestinal ulceration with no obvious cause. He had taken warfarin for 20 years for mitral regurgitation and paroxysmal atrial fibrillation (AF), and this indication had not been reviewed for over ten years. He had had low grade anaemia of unknown cause for three years prior to his admission. He had not been referred to a gastroenterologist in this time period, but also had no symptoms to suggest that he had gastrointestinal bleeding. His INR had been stable for a number of months and his monitoring interval was being slowly increased. However, Mr Bond had been concerned that his INR had been slowly increasing and had been reducing his warfarin dose without informing the anticoagulation clinic. Therefore, this had not been taken into account when dosing his warfarin.

Life-long warfarin started by cardiologist for mitral regurgitation and paroxysmal atrial fibrillation
Mr Bond discharged from cardiology follow-up after two years
Inheritance for warfarin never assessed

Persistent low grade anaemia found during hospital admission
Inheritance for anaemia not investigated

GP thought anaemia related to haemorrhage and referred to urology clinic

Mr Bond concerned about anaemia and INR

Mr Bond arrived at the clinic for his follow-up appointment

Mr Bond discussed his concerns with his GP

Mr Bond was a retired lecturer with expertise in haematology. He had a good understanding of why he took his medication and his GP thought Mr Bond probably had a better understanding than he did. Mr Bond understood his warfarin to be controlled by the anticoagulation clinic at the hospital (because they dosed his warfarin). However, he had no direct contact with them, because his blood was taken by the practice nurse. He did not seem to perceive the practice nurse to have any involvement in the management of his anticoagulation.

Mr Bond was concerned by his longstanding anaemia and had been investigated at a urology clinic following some painless haematuria; no cause for the bleeding was found. His GP did not organise any further investigation for the cause of his anaemia because he was otherwise well.

Following his hospital admission, Mr Bond felt that there had been insufficient justification for taking warfarin. He believed that, had he received more follow up from a cardiologist, then it would have been stopped. His GP disagreed with this view, believing that Mr Bond had a similar risk from his paroxysmal atrial fibrillation to that of another patient who had recently been started on warfarin.
Appendix 8: Case 5 (Miss Weir)

Miss Weir was admitted to hospital with an exacerbation of her asthma. She had stopped taking her preventative medication four days prior to the hospital admission because of vomiting. It seems likely that her sickness was due to oesophageal irritation from alendronate (it was relieved by Gaviscon®). Alendronate is known to cause this problem, and patients should remain sitting or standing upright for 30 minutes after taking. However, Miss Weir was unaware of this and sometimes lay down after taking it.

Miss Weir had severe asthma which was poorly controlled (she was admitted to hospital every one to two months and became short of breath after walking fast). Her GP and pharmacist both assumed that Miss Weir had a good understanding of her medication and how to take it. However, Miss Weir was confused by why some of her medication was stopped and started when she came in and out of hospital. Despite this, she believed she knew all she needed to about her medication. Miss Weir's GP did feel that she had a poor understanding of the severity of her asthma.

Miss Weir displayed some ambivalence about her asthma and the impact it had on her life, at times saying it was OK, and at others expressing frustration and annoyance. This meant that there were times when she did not want to take her medication, but said her mum always made sure she did.

Miss Weir’s local pharmacy was staffed by two part-time pharmacists. She reported having a good relationship with the first, but not the second. The second pharmacist said she rarely had contact with Miss Weir because a representative usually collected her prescriptions. This pharmacist believed that Miss Weir should have received counselling about her medication from the hospital, GP or asthma nurse. She appeared reluctant to provide counselling to patients herself because she could spend up to 10 minutes talking to patients if she did so.

When Miss Weir began vomiting, 4 days before her hospital admission, she did not seek medical help until her asthma had deteriorated (despite using her nebuliser). She explained that this was because she was reluctant to be admitted to hospital again.
Mr Stewart was admitted to hospital with gastrointestinal bleeding thought to be due to aspirin. Six weeks earlier he had been advised to take aspirin by the practice nurse as primary prophylaxis against stroke following a diagnosis of type-2 diabetes. He was not immediately aware that stomach bleeding could be caused by aspirin and had not been told this by the nurse who advised him to take it, or the pharmacy assistant who sold it to him.

Mr Stewart had a poor understanding of his type-2 diabetes (he did not believe he had diabetes); in contrast, the practice nurse believed he had a very good understanding. When informing Mr Stewart of his diagnosis, the practice nurse told him he may need to take aspirin. At this point she normally advised patients to make an appointment with the GP. Instead, Mr Stewart decided to buy the aspirin from his local pharmacy. Five weeks later, Mr Stewart’s GP added aspirin to his repeat prescription.

Mr Bond said that the sale of aspirin was not checked with a pharmacist and he was not told about the potential for gastrointestinal bleeding by either the nurse or the pharmacy assistant. In addition, he had not seen the PIL wrapped around the aspirin bottle. If he had, the print size would have been too small for him to read.

According to the pharmacist, if a patient had been advised to take aspirin by the GP surgery no further questions were asked (it was assumed that the GP would have assessed the appropriateness of aspirin for the patient). The pharmacist believed that the counter staff normally gave two pieces of information to patients when they sold medicines (such as the dose and a common side effect), but was not sure exactly what information was provided with the sale of aspirin. She did not believe that the patient would be told about gastrointestinal bleeding because she was not aware that low dose aspirin could cause that.

Mr Stewart did not have a close relationship with any of the healthcare professionals looking after him. He reported multiple instances where his care had been inadequate (but his wife corrected him, explaining he had received good care on most of these occasions). This probably contributed to his decision to buy the aspirin over the counter.
Appendix 10: Case 7 (Mr Ray)

Mr Ray was admitted to hospital with peptic ulceration and anaemia caused by a combination of increased alcohol intake and diclofenac. He had drunk approximately 11 pints of lager a day since separating from his wife 18 months earlier. He had also been taking diclofenac 50mg twice daily for 5 months for chronic back pain. Mr Ray had previously taken aspirin following a stroke, but had stopped this when he read about the risk of gastrointestinal bleeding in the newspaper.

Mr Ray was aware why he took his medication, but was not aware of the potential side effects of his treatment. He got most of his information about medication from family, friends and the media; he did not read patient information leaflets. In contrast, his GP believed Mr Ray had a good understanding of his medication and the potential side effects.

Mr Ray started taking diclofenac when a friend gave him some to try (prior to this he was taking ibuprofen and co-proxamol). Having found the diclofenac helpful, he asked his GP to prescribe them. Mr Ray’s GP prescribed diclofenac 50mg three times daily; because Mr Ray only took them twice a day, his GP assumed that his use was intermittent. When asked about alcohol intake, Mr Ray told his GP that he drank around 9 units of alcohol a day (less than half of his actual intake) and was advised to try and halve his alcohol intake. Although his increased alcohol intake was recorded on the computer, it would not have been easily accessible during a consultation and would not have triggered a computer alert when diclofenac was prescribed. The combination of these two factors meant that Mr Ray’s increased risk of bleeding with diclofenac was not recognised.

Mr Ray did not have a strong relationship with any healthcare professionals, partly due to the difficulty of seeing the same person at each appointment.

Four days before his admission Mr Ray began to vomit altered blood. He did not recognise the significance of the symptom, instead believing it to be a sign of cancer. As a result he did not seek medical help. He was admitted to hospital four days later when his daughter found him unconscious in his armchair. On admission, he was found to be very anaemic, having bled from large gastric and duodenal ulcers.
Mr Smith was admitted to hospital with a bleeding gastric ulcer due to a combination of aspirin and warfarin. He had been prescribed warfarin following a metallic aortic valve and root replacement five years earlier. Five months prior to admission, aspirin and pravastatin had been added to the warfarin following a transient ischaemic attack associated with a low INR.

Mr Smith did not recall being told about an increased risk of bleeding on the combination of aspirin and warfarin (although the letter from the hospital to the GP stated that he had been informed). When aspirin was started Mr Smith queried it with the cardiology registrar because he had previously been told not to take it. He said that the registrar told him that the consultant had said he had to have the aspirin.

The cardiology consultant believed that there was good evidence from the APRICOT and WARIS studies to justify prescribing aspirin and warfarin in combination for Mr Smith. He did not believe there was sufficient evidence to warrant co-prescribing gastroduodenal prophylaxis. Mr Smith’s GP had previously queried the use of aspirin and warfarin in combination, but had been told not to worry about it because it was something the cardiologists did quite often. He felt that it was difficult to assess a patient’s medication in the middle of a consultation and pointed out that the computer system did not warn him about prescribing aspirin and warfarin in combination. He also said that, if a guideline were in place recommending the prescription of gastroduodenal prophylaxis with aspirin and warfarin, he would prescribe it.

Mr Smith’s pharmacist did not recall seeing any patients who had had a problem with the aspirin:warfarin combination, therefore he did not believe that gastroduodenal prophylaxis was necessary and was not sure if he routinely counselled patients about the increased risk. He also said that he did not know when patients had been admitted to hospital (therefore he was unlikely to know that a patient had had a problem).

The day before admission, Mr Smith had begun to feel unwell. When his wife rang the surgery for advice she was advised to ring back later. Mr Smith thought he would feel better the next day, so they did not ring back. Later that evening, Mr Smith began to pass blood and his wife rang the on call GP service.
Appendix 12: Case 12 (Mr Kemp)

Mr Kemp was admitted to hospital with dehydration, hypokalaemia, and renal failure, thought to be due to an increased dose of diuretic when he was discharged from hospital. He had been admitted to hospital with an exacerbation of congestive cardiac failure which was treated by changing his furosemide 80mg daily to bumetanide 2mg twice daily (at a higher equivalent dose) and adding in metolazone 5mg daily (a potent thiazide-type diuretic used in resistant oedema). In the four days prior to his discharge from hospital, Mr Kemp lost 8kg in weight. Despite this rapid weight loss, his diuretics were not reduced prior to his discharge home.

Mr Kemp had poor short term memory and found it difficult to recall verbal instructions. He remembered being told to take his tablets as directed on the labels, but did not remember that he should weigh himself (the hospital notes documented that he had been told this). Normally, his wife remembered verbal instructions for him, but she was not present when he received his instructions.

The information sent to Mr Kemp’s GP on his discharge from hospital instructed him to “monitor U&Es closely”. Mr Kemp’s GP was not familiar with using metolazone and interpreted this instruction to mean weekly monitoring (Mr Kemp’s U&Es and weight had been monitored daily during his hospital admission). Following discharge, Mr Kemp’s U&Es were only monitored once, one week after discharge; they showed a slight decline in renal function (from creatinine 192micromol/L to 218micromol/L) and a mild hypokalaemia (potassium 3.2mmol/L). No alteration was made to Mr Kemp’s treatment.

Mr Kemp’s medical hospital notes contained an instruction to reduce his diuretics once his weight was stable; this was not communicated to Mr Kemp’s GP. Instead, when the GP saw Mr Kemp two weeks after his discharge he assumed that Mr Kemp was weighing himself. When Mr Kemp said his weight was stable the GP told him to reduce the metolazone to alternate days (an instruction which Mr Kemp did not remember). During this appointment, Mr Kemp complained of nausea which was treated with domperidone. Mr Kemp became increasingly unwell. When he saw the hospital consultant the following week, he was advised to stop his diuretics. Blood test results received the following day showed hypokalaemia and acute on chronic renal failure (potassium 3.0mmol/L, urea 50mmol/L, creatinine 347 micromol/L). Mr Kemp was contacted at home and admitted to hospital.
Mr Matheson was admitted to hospital with a haemarthrosis associated with a raised INR whilst on warfarin and sepsis of unknown source. Mr Kemp had a complicated medical history, including hypertension, congestive cardiac failure, glaucoma, depression, permanent pacemaker, a metallic aortic valve replacement, and a history of haemarthrosis on three previous occasions. He took seven different medications including warfarin and venlafaxine.

Two weeks prior to admission, Mr Matheson developed a painful, swollen knee which had not resolved five days later, at which time Mr Matheson requested a home visit from his GP. She contacted the orthopaedic doctors, explaining that she thought he had a haemarthrosis, who refused to admit him. Instead the GP sent him to A&E where he was diagnosed with a suprapatellar bursitis and discharged back to home without checking his INR. The GP reviewed Mr Matheson the following day and found him in severe pain with a raised INR (5.36). She prescribed regular paracetamol and dihydrocodeine. Mr Matheson’s warfarin dose was reduced by the anticoagulation clinic but, because they only reduced the dose to be taken on a Monday and Friday, he continued to take 6mg of warfarin daily for a further four days. Mr Matheson was seen by another GP after four days who aspirated his knee. Following this, he became increasingly confused and unwell; he was admitted via A&E three days later with sepsis of unknown cause, INR 11.6, and a haemarthrosis.
Appendix 14: Case 14 (Mrs Privett)

Mrs Privett was admitted to hospital with symptoms of phenytoin toxicity following accidentally tripling her phenytoin dose for up to two and a half weeks before admission. Mrs Privett had a complex medical history including nocturnal seizures, hypothyroidism, anaemia, cervical carcinoma, arthritis and nocturnal leg cramps.

Nine weeks prior to her hospital admission with phenytoin toxicity, she had been admitted to hospital with a chest infection. She was discharged back to home with all her usual medication (including phenytoin 3x100mg capsules daily). When the GP surgery received a copy of her discharge prescription, her phenytoin prescription was changed from 3x100mg daily to 1x300mg daily. This was changed by the repeat prescription clerk who assumed that the hospital had supplied 300mg phenytoin capsules (the prescription documented that 100mg capsules had been supplied in very small handwriting). Mrs Privett was not informed of the change to her prescription.

When Mrs Privett next collected a prescription for her phenytoin, she took it to a pharmacy who had not dispensed phenytoin for her before. Therefore, the pharmacist did not identify the change in capsule strength and Mrs Privett was not told of the change to her prescription. Mrs Privett found the blister strips difficult to open and popped the capsules out into the bottle from the hospital, labelled “phenytoin 100mg capsules: take three daily”, and then threw the box away. She did not realise that the new capsules were a higher strength and, when the supply from the hospital ran out, she continued to take three capsules daily (equivalent to 900mg daily) for up to two weeks. During this time, she became increasingly unwell with dizziness and loss of appetite. Her GP admitted her to hospital via ambulance where she had signs of phenytoin toxicity (nystagmus, and lower limb incoordination) and an adjusted total phenytoin level of 30.9mmol/L. She was diagnosed with phenytoin toxicity exacerbated by vertigo caused by an ear infection. One month prior to her hospital admission, a routine phenytoin level had shown a level of 2.7mmol/L. Her GP had recommended that she continue on the same dose if she remained fit free.

Mrs Privett had a poor relationship with both her GP and pharmacist, describing them as “foreigners”. She felt that her GP did not have time for her. Mrs Privett also believed that her daughter was keen for her to move into a residential home and was therefore reluctant to contact her for help when she felt unwell (in case this was viewed as her being unable to cope). As a rule, she was able to manage her tablets, but had limited awareness of what they were for or which potential adverse effect to monitor for.
Appendix 15: Case 15 (Mr Knox)

Mr Knox was admitted to hospital with shortness of breath associated with fast atrial fibrillation (AF) and chronic obstructive pulmonary disease (COPD). Two weeks earlier, he had been discharged from hospital following new onset atrial fibrillation, which had been treated with digoxin and diltiazem (changed from felodipine).

Mr Knox had a complex medical history including hypertension, glaucoma, COPD, arthritis, bilateral hip replacements, registered blind and deaf. He was admitted to hospital with a new diagnosis of AF which was successfully controlled with digoxin. On admission, his blindness was documented in his medical record. After he had been in hospital for two weeks he was transferred to an intermediate care ward where he was seen by a pharmacy ward technician. The technician documented that he was able to read the labels on his medication and to open child resistant closures on bottles (despite having arthritis and being registered blind). This was a new role for the technician and it was not common practice for them to read the medical notes as part of their review.

During his two day stay on the intermediate care ward Mr Knox only self medicated his eye drops, not his new medication. The changes made to his medication during the admission meant that his medication regimen was more complicated, requiring him to take four tablets each morning and one in the evening (previously he only took two tablets each morning). When he was discharged to home he was not offered large labels or other compliance aids. Because he did not self-medicate, there was no opportunity to identify any potential problems with adherence. On discharge to home, Mr Knox’s nursing notes documented that he had been provided with a list of his medication. On return to home, however, Mr Knox did not know his medication had been changed. He did not know what the digoxin tablets were and therefore did not take them.

Mr Knox’s GP visited him at home and asked him about the medication he was currently taking, but did not compare this to a list of medication he should be taking, therefore she did not identify that he was not taking digoxin. Two weeks after his discharge to home, he was readmitted to hospital in fast AF (digoxin level <0.3 micrograms/L).
Appendix 16: Case 18 (Mr Jones)

Mr Jones was admitted to hospital with a duodenal ulcer secondary to aspirin 75mg daily, rofecoxib 25mg daily, and alendronate 10mg daily. He had been treated with this combination of drugs, known to cause peptic ulceration, for two years without gastroduodenal prophylaxis.

Mr Jones had a complex medical history including benign prostatic hyperplasia, left renal carcinoma (surgically removed), right renal thrombosis (following removal of left kidney) causing renal failure, transient ischaemic attacks, polymyalgia rheumatica, osteoporotic collapse of the spine, pain from adhesions following removal of kidney, chronic constipation, chronic obstructive pulmonary disease, indigestion and chronic stable renal failure.

Mr Jones was started on lansoprazole for gastroduodenal prophylaxis during a previous hospital admission. Following a home visit, this was not entered on the GP computer system as a repeat prescription and was therefore accidentally stopped following discharge to home.

Two weeks prior to admission, Mr Jones was seen at home by his GP. He was complaining of stomach pain. The GP did not find any blood on rectal examination and reiterated to Mr Jones that he should take his laxatives regularly. Two weeks later Mr Jones passed black blood and was found to have a duodenal ulcer.

Mr Jones admitted to confusion about his tablets. He was not aware of the side effects of his medications, but his wife was (she chose not to tell him all the potential side effects in case he stopped taking his tablets). Mr Jones, his wife and his GP all agreed that Mr Jones was a worrier.

Mr Jones’ GP was aware that rofecoxib was associated with an increased risk of peptic ulceration and that this risk was increased further with aspirin. He believed that Mr Jones should have received gastroduodenal prophylaxis but felt a number of factors meant this had not happened, including: large volumes of repeat prescriptions, reviewing medication started by someone else, short consultation times, overload from multiple computer alerts, and trying to address multiple issues in a single consultation.
Mrs Turner was admitted to hospital after she collapsed when standing up. She was thought to have multiple drug reasons for her collapse, including hypotension associated with enalapril, carbimazole-induced hypothyroidism, digoxin toxicity, dehydration associated with furosemide, and a possible infection. She had a complex medical history including cancer of the cervix (surgically removed), hypertension, two previous CVAs, a post-operative MI, and paroxysmal atrial fibrillation (AF).

Mrs Turner was admitted to hospital four months earlier with AF, presumed to be persistent (there was no record in her notes of paroxysmal AF). Digoxin was initiated to control her heart rate, and furosemide for fluid overload. Thyroid function tests showed a low TSH, but normal fT4. She was diagnosed with hyperthyroidism and started on carbimazole 20mg daily. Enalapril and warfarin were continued for hypertension and thromboprophylaxis. When she was discharged home a copy of her discharge prescription was faxed to her GP but he did not receive a full discharge letter. In addition, the GP was not copied into a letter inviting Mrs Turner to an appointment to have her carbimazole reviewed (which she did not attend).

Twelve days following her discharge, Mrs Turner was reviewed by a GP from her practice. She was still in AF and digoxin and furosemide were added to her repeat prescription; carbimazole was not added to the repeat prescription because the surgery had not received a management plan. Instead, Mrs Turner requested it by telephone (the same way she requested her other repeat prescriptions). This was designed to act as an alarm system to the GPs not to issue it as a routine prescription. Despite the GP not receiving a copy of Mrs Turner’s FBC and TFTs from her admission, it was assumed they had been done during her admission.

Mrs Turner was not well supported at home; she and her husband had a strained relationship and he was also unwell, requiring kidney dialysis twice a week. Mrs Turner was unable to visit her GP surgery because it was on the first floor and the lift was not usually working (her poor mobility meant she could not climb the stairs). Her GP wondered if this contributed to less mobile patients receiving less frequent monitoring; Mrs Turner had not had her U&Es checked for 6 years.

Mrs Turner was admitted to hospital following a collapse at home, she was found to be dehydrated (furosemide was stopped), hypotensive (enalapril stopped), digoxin toxic (changed to sotalol), and hypothyroid (carbamazole stopped).
Mrs Davis was admitted to hospital with shortness of breath. On admission she was found to have acute renal failure (associated with rofecoxib, furosemide, and ramipril), and gastrointestinal bleeding (associated with aspirin and rofecoxib). Mrs Davis died the day after discharge from hospital from bronchopneumonia. Although her death was not a direct result of her drug-related morbidity, it is possible that the immobility associated with her hospital admission contributed to her death.

Mrs Davis had a complex medical history including COPD with cor pulmonale (treated with furosemide and ramipril), type-2 diabetes, paroxysmal atrial flutter, glaucoma, arthritis and a tendency to constipation.

Six weeks before admission Mrs Davis was visited at home by her GP for increased shortness of breath and swollen ankles. Her furosemide was increased and her renal function checked (urea 6.6mmol/L, creatinine 87micromol/L). Two weeks later Mrs Davis was again visited by her GP for severe hip pain. Due to her problems with constipation and previous intolerance to Arthrotec®, her GP was unwilling to prescribe opioids or a traditional NSAID. Instead he initially prescribed paracetamol. When he reviewed Mrs Davis 10 days later, her hip pain was worse. He chose to prescribe rofecoxib 25mg. During the home visit he did not have access to her medical record and was not aware she was taking aspirin. Had he reviewed Mrs Davis 10 days later, her hip pain was worse. He chose to prescribe rofecoxib 25mg. During the home visit he did not have access to her medical record and was not aware she was taking aspirin. Had he seen her in the surgery, he did not think he would have checked her repeat prescription. He was not sure if he would have been aware of the increase in risk of gastrointestinal bleeding with aspirin and rofecoxib at the time he wrote the prescription.

Mrs Davis’s pharmacist dispensed the rofecoxib without question because she frequently saw it prescribed with aspirin. She did not feel there was time to query this combination every time she saw it and, based on past experience, she would not expect a positive response from a GP if she did. Mrs Davis’s GP was not keen to tell patients about side effects of medicines because he felt this would give unbalanced information (he did not give extensive information about benefits of medicines). Instead, he preferred to check for side-effects at follow-up visits.

Two weeks later Mrs Davis began to feel exhausted and lethargic with increasingly swollen ankles, worsening shortness of breath, and reduced urine output. She did not consult her GP during this time. On admission she was found to have acute renal failure and gastrointestinal bleeding.
Mrs Harwood was admitted to hospital with a life-threatening hyperkalaemia caused by a combination of rofecoxib and co-amilofruse which had been recently started by her GP. Mrs Harwood had a complex medical history including probable uterine carcinoma, hyperthyroidism (no longer active), osteoarthritis (treated with rofecoxib 12.5mg daily), pernicious anaemia, hypertension and a hip replacement. Mrs Harwood lived with her daughter (her main carer).

Twelve days before her admission, Mrs Harwood was visited at home by her GP for shortness of breath. Because she was elderly, prone to falling and had mild renal failure the GP was reluctant to start an ACE Inhibitor. Instead, he chose to add amiloride (a potassium-sparing diuretic) to increase the diuretic effect. He changed her furosemide 40mg twice daily to co-amilofruse 5/40, one twice daily. He did not seem to be aware how much amiloride was contained in one tablet and it seems likely that he thought he was starting 5mg/day not 10mg/day. When he returned to the surgery, the GP documented the prescribing decision on the computer, but did not enter the co-amilofruse on the electronic prescription record.

Mrs Harwood’s prescription was taken to a new pharmacy by Mrs Harwood’s brother. The pharmacy was unaware that co-amilofruse was a new prescription and it appears to have been dispensed without question. After Mrs Harwood had taken 2 or 3 doses of co-amilofruse, her U&Es were checked (Potassium 5.3mmol/L, Creatinine 143). The GP checked the results and documented them as “abnormal but satisfactory”; he did not compare them to results from 15 months earlier (potassium 4.0mmol/L, creatinine 123mmol/L).

Mrs Harwood was seen at home by a locum GP four days later following a fall. Mrs Harwood’s daughter was advised to observe her overnight. The locum was unlikely to be aware of the recent medication change because it was not on the electronic prescription record. At this time, Mrs Harwood and her daughter stopped administering the co-amilofruse because they were concerned it was making her unwell. Mrs Harwood was seen at home by her GP two days later for shortness of breath. He recommended restarting the co-amilofruse. Both Mrs Harwood and her daughter found the GP difficult to talk to and felt he did not give them enough information. The GP felt that Mrs Harwood’s daughter tended to be very involved and could become anxious.

Two days later Mrs Harwood’s daughter called the out of hours GP service and Mrs Harwood was seen by an on-call doctor who recommended hospital admission. On admission she was found to have hyperkalaemia (potassium 8.6mmol/L) and acute chronic renal failure (urea 23.7mmol/L, creatinine 279micromol/L).
Appendix 20: Case 25 (Mrs Brown)

Mrs Brown was admitted to hospital with bradycardia and unstable angina. She was taking a combination of drugs (verapamil and atenolol) to control her hypertension, which are known to cause bradycardia. This combination is only used in special circumstances, such as difficult to control arrhythmias, where patients are known to have good cardiac function. In addition, she was not prescribed aspirin as thromboprophylaxis, despite this being indicated.

Eighteen months before her hospital admission Mrs Brown was started on atenolol to help control her hypertension. This was currently treated with verapamil and irbesartan; a number of other antihypertensives had been tried in the past which Mrs Brown had been unable to tolerate. It is unclear whether the electronic prescribing system would have alerted the GP to the interaction between atenolol and verapamil. The GP placed a lot of faith in the interaction alerts and, despite knowing the risks of the combination, may have relied on the system to alert him to any problems.

Mrs Brown’s pharmacy first dispensed the atenolol as a lone prescription, reducing the chances of the interaction being recognised. Atenolol was not presented on the same prescription as verapamil until five months later. There was no record of an intervention having been attempted by the pharmacy. The pharmacy’s computer system would have alerted to the interaction, but the importance of the interaction would not have been highlighted, no additional information would have been given, and the alert would have been in the middle of a list of alerts printed on dispensing labels. The pharmacist thought time pressures would have contributed to the interaction either not being noted, or not being adequately checked. However, the pharmacist was unconvinced of the significance of the interaction even after she had looked it up.

Mrs Brown’s GP performed 6-monthly medication reviews, but admitted these were unlikely to identify existing drug interactions (although the surgery policy stated that these should be looked for).

Mrs Brown had a diabetic check up every 3 months. One month before her admission, the practice nurse recorded an unusually low blood pressure for her (112/62mmHg). This was not noted as remarkable and an appointment was made with the GP for 8 weeks time. She was admitted to hospital before she was followed up by her GP. On the day of admission, she developed chest pain and hypoglycaemia. When reviewed by a locum GP she was found to be bradycardic and was admitted to hospital with unstable angina.
Mr Stott was admitted to hospital with diabetic ketoacidosis after he did not take his insulin for two days. Mr Stott had a history of type 1 diabetes, hypertension, depression and chronic back pain. He was known to have poor diabetic control and had discussed this with the hospital consultant 6 months before his admission. They had agreed not to try and improve his diabetic control at this time because he had just started his new job as a courier driver and wanted time to settle into this role. He had difficult social circumstances having divorced from his wife, lost custody of his children (for whom he was the main carer during the marriage) and recently been made redundant from his job as a courier driver.

Mr Stott found it difficult to maintain a full-time job due to his diabetes and claimed disability living allowance as a result. Whilst working as a courier driver he had developed hypoglycaemic attacks overnight. He was dependent on his youngest son (who had recently started to live with him) to help him manage these attacks. He did not tell his GP about these attacks because he was worried that he would lose his driving licence (and therefore his job). Mr Stott subsequently lost his disability living allowance following a report written by his GP. Although Mr Stott felt this was in part because he had not told his GP about the hypoglycaemic attacks, this resulted in a complete breakdown in his relationship with his GP. The GP held negative views about Mr Stott, describing many of Mr Stott’s problems as being related to his “personality deficit”.

Mr Stott became increasingly depressed as a result of his financial difficulties (after the loss of his job and disability living allowance) and difficulties with his son. He stopped taking his insulin and became increasingly unwell. He was seen at the surgery by a locum GP and was reluctant to explain his full history to them. Instead, he said he had suffered from diarrhoea (he had had one episode earlier in the week). The GP assumed Mr Stott had diabetic ketoacidosis secondary to diarrhoea and admitted him to hospital.
Mr Taylor was admitted to hospital with hypoglycaemia. On admission he was found to have acute on chronic renal failure, associated with a new prescription of rofecoxib for gout pain. It is likely that his hypoglycaemia was caused by reduced insulin requirements due to his renal failure.

Mr Taylor has a complex medical history including two myocardial infarctions, congestive cardiac failure, angina, type-2 diabetes mellitus, chronic renal failure, osteoarthritis, gout, depression and leg cramps. At the time of his admission, he was taking 12 different medications, including rofecoxib 50mg daily. Rofecoxib is a cyclo-oxygenase 2 inhibitor which is thought to have a lower potential to cause gastrointestinal bleeding than traditional NSAIDs. It should be used with caution in patients with chronic renal failure and/or cardiac failure due to the risk of worsening renal function or cardiac function, and is contraindicated in severe congestive cardiac failure.

Mr Taylor had recurrent flare ups of his gout; 6 months before his admission he had bought naproxen whilst abroad and taken it without problem for a flare-up. Two months before his admission he attended a hospital clinic where he was warned about the potential for stomach bleeding and acute on chronic renal failure with naproxen (his creatinine was 164micromol/L). At this time he was told it would be safe for him to continue with the naproxen as required for gout flare ups.

Two weeks before his admission with hypoglycaemia, he was admitted to hospital with knee pain. He was noted to have mild renal failure (creatinine clearance 40ml/min). The discharge letter sent to Mr Taylor’s GP advised caution with NSAIDs but if he had taken them in the past without an exacerbation of his renal failure then they should be safe to use. This letter was unlikely to have reached Mr Taylor’s GP prior to his consultation 3 days before his admission for hypoglycaemia.

One week before his admission, Mr Taylor developed a flare up of gout. Three days later he consulted his GP who prescribed rofecoxib 50mg daily (28 tablets). Mr Taylor’s GP believed that rofecoxib was generally safer than traditional NSAIDs; in his experience a 25mg dose was insufficient to relieve pain for most patients. He did not seem to be aware of guidance that rofecoxib should be initiated at a dose of 12.5mg in elderly patients. Mr Taylor’s GP believed that the computer system would normally warn him if a prescription was potentially dangerous, however, clinical decision support on electronic prescribing systems does not currently link to patient age, test results, or current diagnoses. Therefore, the computer system would have been unable to warn the GP of the risks associated with rofecoxib in Mr Taylor’s case.

Mr Taylor’s pharmacist dispensed the rofecoxib without question (even though the 50mg dose was only licensed for short-term use in acute pain); he had seen this dose prescribed many times by the same GP and was not aware of any patients experiencing problems.

Mr Taylor took 3 doses of rofecoxib 50mg. During this time he became hypoglycaemic. Following advice from the diabetic nurse, he reduced his insulin dose but remained hypoglycaemic. Subsequently, he was unable to contact the nurse, therefore he continued his insulin and took sugar to try and maintain his blood glucose levels. He was admitted to
hospital when a neighbour rang for an ambulance. On admission he was found to have acute
on chronic renal failure (creatinine 351micromol/L). His rofecoxib, lisinopril and spironolactone
were stopped and his bumetanide increased.