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**General
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Regulating doctors
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Investigating the prevalence and causes of prescribing errors in general practice:

The PRACTICE Study

**(PREvalence And Causes of prescribing errors
in general practiCe)**

A report for the GMC

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Abstract

Aim: To determine the prevalence and nature of prescribing errors in general practice; to explore the causes, and to identify defences against error.

Methods: 1) Systematic reviews; 2) Retrospective review of unique medication items prescribed over a 12 month period to a 2% sample of patients from 15 general practices in England; 3) Interviews with 34 prescribers regarding 70 potential errors; 15 root cause analyses, and six focus groups involving 46 primary health care team members

Results:

The study involved examination of 6,048 unique prescription items for 1,777 patients. Prescribing or monitoring errors were detected for one in eight patients, involving around one in 20 of all prescription items. The vast majority of the errors were of mild to moderate severity, with one in 550 items being associated with a severe error. The following factors were associated with increased risk of prescribing or monitoring errors: male gender, age less than 15 years or greater than 64 years, number of unique medication items prescribed, and being prescribed preparations in the following therapeutic areas: cardiovascular, infections, malignant disease and immunosuppression, musculoskeletal, eye, ENT and skin. Prescribing or monitoring errors were not associated with the grade of GP or whether prescriptions were issued as acute or repeat items.

A wide range of underlying causes of error were identified relating to the prescriber, patient, the team, the working environment, the task, the computer system and the primary/secondary care interface. Many defences against error were also identified, including strategies employed by individual prescribers and primary care teams, and making best use of health information technology.

Conclusion: Prescribing errors in general practices are common, although severe errors are unusual. Many factors increase the risk of error. Strategies for reducing the prevalence of error should focus on GP training, continuing professional development for GPs, clinical governance, effective use of clinical computer systems, and improving safety systems within general practices and at the interface with secondary care.

Contents

Abstract.....	iii
Glossary.....	xi
List of Abbreviations.....	xii
Acknowledgements.....	xiv
Executive Summary.....	xv
Aim:.....	xv
Objectives:.....	xv
Systematic review of the prescribing errors in UK general practice.....	xvi
Systematic review of interventions in primary care aimed at reducing medication-related adverse events.....	xvi
Investigating the prevalence and nature of prescribing and monitoring errors.....	xvii
Investigating the causes of prescribing and monitoring errors, and identifying solutions for preventing error.....	xxi
Recommendations.....	xxviii
Conclusions.....	xxxii
Chapter 1: Introduction.....	1
1.1 Aim:.....	2
1.2 Objectives:.....	3
Chapter 2: Defining prescribing error in primary care.....	4
2.1 Background.....	4
2.2 The challenge of defining error.....	4
2.3 Our definition of a prescribing error.....	6
2.4 Critiques of our definition.....	7
2.5 Reflections on defining error in practice.....	8
2.6 Specific issues in primary care.....	10
Chapter 3: Systematic reviews.....	12
3.1 Update of systematic review of medication errors in UK primary care.....	12

3.2 Update of systematic review of interventions in primary care aimed at reducing medication related adverse events and hospital admissions.....	16
Chapter 4: Methods used to identify the prevalence and nature of prescribing and monitoring errors.....	19
4.1 Recruitment.....	19
4.2 Quantitative data collection.....	20
4.3. Identifying errors and other types of prescribing problem.....	22
4.4 Collection of data on potential omission errors relating to not prescribing for an existing condition.....	24
4.5 Collection of data on discrepancies and potential errors relating to hospital discharge communications.....	25
4.6 Data entry.....	25
4.7 Data cleaning.....	27
4.8 Data extraction.....	28
4.9 Assessing the severity of the prescribing errors.....	29
4.10 Quantitative data analysis.....	30
Chapter 5: Methods used to explore the causes of error and associated defences.....	32
5.1 Selection of participants for face-to-face interviews.....	32
5.2 Selection of participants for focus groups.....	32
5.3 Interview schedule for the face-to-face interviews.....	33
5.4 Interview schedule for the focus groups.....	33
5.5 Training the interviewees.....	33
5.6 Conducting the interviews.....	34
5.7 Conducting the focus groups.....	34
5.8 Location of interviews and focus groups.....	34
5.9 Interview and focus group participants.....	35
5.11 Transcription of interviews and focus groups.....	39
5.12 Qualitative data analysis.....	39

5.13 Root Cause Analysis.....	42
Chapter 6: The prevalence and nature of medication errors	43
Summary	43
6.1 Sample characteristics.....	45
6.2 Prevalence of medication problems	51
6.3 Types of prescribing and monitoring errors	52
6.5 Analysis of omission errors related to failure to prescribe a drug for an existing clinical condition	68
6.6 Analysis of data regarding reconciliation of hospital discharge medication.....	68
Chapter 7: Error producing conditions	71
Summary	71
7.1 Introduction.....	73
7.2 The Prescriber	73
7.3 The Patient	81
7.4 The Team	84
7.5 The Working Environment	87
7.6 The Task.....	92
7.7 The computer system	98
7.8 The Primary Secondary Care Interface	103
Chapter 8: Findings from the root cause analyses.....	108
8.1 Prescriber factors.....	108
8.2 Patient factors.....	108
8.3 Team factors.....	108
8.4 Communication factors	109
8.5 Work environment.....	109
8.6 Task factors	109
Chapter 9: Defences against medication errors in general practice	113
Summary	113

9.1 Introduction.....	116
9.2 Issuing new prescriptions.....	118
9.3 Supporting ongoing patient decision-making.....	125
9.4 Dispensing medication.....	128
9.5 Repeat prescribing.....	130
9.6 Monitoring patients	137
9.7 Amending prescriptions based on outside correspondence	145
9.8 Processes supporting medicines management	149
Chapter 10: Discussion	162
10.1 Summary of main findings.....	162
10.2 Discussion of the methods used in the study	163
10.3 Discussion of the findings in relation to the objectives of the study	166
10.4 Recommendations arising from the PRACtICe Study	178
10.6 Conclusion.....	182
References.....	183
Appendices	187

Tables

Table 1: Characteristics of the interview participants.....	37
Table 2: Summary of participants contributing to the six focus groups	39
Table 3: Characteristics of the 15 English general practices involved in the PRACtICe study	46
Table 4: Comparison of characteristics general practices involved in the PRACtICe study with National figures for England.....	46
Table 5: Age distribution of patients	47
Table 6: Distribution of prescription items reviewed by British National Formulary chapter	48
Table 7: Top 20 drugs most commonly prescribed	49
Table 8: Distribution of different types of formulation	50

Table 9: Types of prescriber that issued the prescription items in the study	50
Table 10: Percentage prevalence of prescriptions with different types of medication errors	51
Table 11: Distribution of different types of prescribing errors	52
Table 12: Distribution of different types of monitoring error.....	53
Table 13: Drugs most commonly associated with prescribing errors	54
Table 14: Proportion of prescribing errors from different British National Formulary chapters	55
Table 15: Drugs associated with monitoring errors.....	56
Table 16: Proportion of monitoring errors from different British National Formulary chapters	57
Table 17: Drug preparations most commonly associated with information incomplete on the prescription.....	57
Table 18: British National Formulary chapters associated with incomplete information on prescriptions.....	58
Table 19: Drug preparations associated with frequency errors	59
Table 20: Error types most commonly associated with severe, moderate and minor errors	61
Table 21: An illustrative sample of minor and moderate errors, and all eleven severe errors	62
Table 22: Patient level model of risks associated with prescribing or monitoring errors .	64
Table 23: Prescription level model of risks associated with prescribing or monitoring errors	66
Table 24: Similarities and differences between medications at hospital discharge and those that patients were taking prior to admission	69
Table 25: Summary of the issues noted in the medications in the discharge summary communication	70
Table 26: Descriptions of potential errors where Root Cause Analysis was undertaken	110
Table 27: Summary of categories associated with different error producing conditions for each root cause analysis.....	112
Table 28: Defensive strategies which can improve the safety of issuing new prescriptions.....	118

Table 29: Defensive strategies which may help improve safety by supporting patient decision making	125
Table 30: Defensive strategies which can improve the safety of dispensing medicines	129
Table 31: Defensive strategies which can improve the safety of repeat prescribing	131
Table 32: Defensive strategies which can improve the safety of patient monitoring....	144
Table 33: Defensive strategies which can improve the safety of amending prescriptions based on outside correspondence.....	148
Table 34: Defensive strategies which can improve the contribution of significant event reporting to medication safety	150
Table 35: Defensive strategies which can improve the safety of processes which support medicines management	151
Table 36: Examples of changes to practice systems of working in response to medication-related significant events.....	154

Figures

Figure 1: Flow chart of papers identified, screened and evaluated	15
Figure 2: Example of a Microsoft Access data entry screen for recording patient demographics and prescriptions.....	26
Figure 3: Example of a Microsoft Access data entry screen for recording detailed information on possible prescribing errors.	27
Figure 4: A Map illustrating the multiple error-producing conditions within the category of 'The prescriber'.	41
Figure 5: Medicines management processes in general practice derived from interview data.....	117

Box

Box 1: Classification of different types of errors.....	24
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Appendices

Appendix 1: Practice Information Sheet.....	188
Appendix 2: Form used for collecting demographic and prescription data on patients.	191
Appendix 3: Form used for collecting detailed information on potential medication errors.	192
Appendix 4: Form used for collecting data on potential omission errors related to not prescribing for an existing condition	194
Appendix 5: Form used for information on medicines reconciliation for patients with a hospital discharge communication.....	195
Appendix 6: Medicines requiring blood test monitoring.....	199
Appendix 7: Examples of judgements made by the error judging panel on scenarios identified as part of the study.....	200
Appendix 8: Examples of scenarios used in the questionnaire assessing the severity of prescribing and monitoring errors made by general practitioners.....	210
Appendix 9: Quantitative analysis plan	211
Appendix 10: Participants for face-to-face interviews letter and information sheet.....	215
Appendix 11: Participants for focus group letter and information sheet	219
Appendix 12: GP and Practice Staff interview schedule	223
Appendix 13: Topic Guide for Focus Groups.....	227

Glossary

Dispens-IT®	Software designed for use in dispensing general practices.
EMIS	Type of GP computer system supplier.
Monitoring error	A monitoring error occurs when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. In our study it is the absence of tests, for specific drugs, being carried out at the frequency listed in the criteria, with tolerance of +50%. If a patient refused to give consent for a test, then this would not constitute an error.
NOMAD® pack	A monitored dosage system aimed at helping patients to manage their medicine taking.
Prescribing error	A prescribing error occurs when, as a result of a prescribing decision or prescription-writing process, there is an unintentional, significant: reduction in the probability of treatment being timely and effective, or increase in the risk of harm when compared to generally accepted practice.
QSR-N-Vivo®	A qualitative data analysis package.
ScriptSwitch®	Prescribing decision support software (with a particular emphasis on helping general practices to control their prescribing costs).
SystemOne®	A type of GP computer system supplied by the company, TPP.
TPP	Type of GP computer system supplier.

List of Abbreviations

A&E	Accident and Emergency
ACEI	Angiotensin Converting Enzyme Inhibitor
BD	Twice daily
BNF	British National Formulary
CHD	Coronary heart disease
CI	Confidence Interval
CNS	Central Nervous System
Comm Pharm	Community Pharmacist
COPD	Chronic obstructive pulmonary disease
EMIS	Egton Medical Information Systems
ENT	Ear, Nose and Throat
GP	General Practitioner
GP Reg	General Practitioner Registrar
HIT	Health Information Technology
ID	Identification Code
INR	International Normalised Ratio
IQR	Inter Quartile Range
MCAAs	Multi-compartment compliance (adherence) aids
Med Stud	Medical Student
MR	Modified Release
NCAS	National Clinical Assessment Service
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
NSAID	Non-Steroidal Anti-Inflammatory Drug
OR	Odds Ratio
P	P-value
PCT	Primary Care Trust
PCT Pharm	Primary Care Trust Pharmacist
Prac Manager	Practice Manager
Presc Clerk	Prescribing Clerk

QOF	Quality and Outcomes Framework
RCA	Root Cause Analysis
Rec Manager	Receptionist Manager
Snr Recep	Senior Receptionist
SPSS	Statistical Package for Social Sciences
TDS	Three times daily
TPP	The Phoenix Partnership
VTS	Vocational Training Scheme (for GP training)

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Executive Summary

Aim:

To determine the prevalence and nature of prescribing errors in general practice; to explore the causes, and to identify defences against error.

Objectives:

- To update a recently completed systematic review of medication errors in primary care.
- To report on a current Cochrane systematic review of interventions in primary care aimed at reducing medication-related adverse events.
- To investigate the prevalence, nature and causes of the prescribing errors made by general practitioners.
- To determine the prevalence, nature and causes of monitoring errors, for prescribed medications that require monitoring.
- To explore whether the prevalence and nature of errors vary according to the grade of GP.
- To explore whether the prevalence and nature of errors vary according to other factors including the characteristics of general practices, patients and prescriptions.
- To explore how general practices incorporate information from hospital discharge prescriptions and any associated errors.
- To find out what informal or formal safeguards exist in general practice to protect patients against potential harm from prescribing errors.
- To explore systems that are used, or could be used, to report prescribing errors in general practice.
- To explore what might be unique to general practice culture that might have an impact on prescribing error rates and incident reporting.
- To make recommendations for best practice, and educational interventions to reduce prescribing errors in general practice.

Systematic review of the prescribing errors in UK general practice

We updated a systematic review that members of our team had published in 2009. This identified one further study, which investigated the prevalence of medication errors in care homes in the UK.

The authors found that 39% of 256 residents had one or more prescribing errors, with 8.3% of prescriptions (or intended prescriptions) affected. The most common types of prescribing error were “incomplete information” (37.9%), e.g. no strength or route was specified; “unnecessary drug” (23.5%), “dose/strength error” (14.4%) and “omission” (11.8%).

Monitoring errors, which were studied in a list of drugs that an expert group had deemed to require monitoring, occurred in 27 (18.4%) residents (or in 14.7% of prescriptions for these drugs). Of these 32 monitoring errors, 90.6% were due to a failure in requesting monitoring.

Systematic review of interventions in primary care aimed at reducing medication-related adverse events

We identified 43 studies which satisfied our inclusion criteria, including 20 pharmacist-led interventions that reported hospital admissions as an outcome; 10 educational interventions targeting primary health care professionals that reported preventable drug-related morbidity as an outcome; and 13 complex interventions that included a component of medication review aimed at reducing falls in the elderly (the outcome being falls). Meta-analysis found that pharmacist-led interventions were not effective at reducing hospital admissions OR 0.92 (95% CI 0.76, 1.10 n=15) and suspected adverse drug events OR 0.65 (95% CI 0.26, 1.59 n=3). Interventions that included a medicines management component to reduce falls in at risk patients did not have significant impact (OR 0.93, 95% CI 0.71 to 1.22, n=10). Pooling the results of studies in the other categories failed to demonstrate any significant effect on the main outcomes.

Investigating the prevalence and nature of prescribing and monitoring errors

Methods

Setting: English general practices.

Participants: Fifteen general practices with diverse characteristics from three primary care trusts (PCTs).

Sampling of patient records: A 2% random sample of patient records in each general practice was selected for assessment of prescribing and monitoring errors.

Data collection: Data were collected by four pharmacists who were specially trained to identify potential errors from GP records. The pharmacists undertook a retrospective review of unique prescriptions issued to patients in the 12 months prior to data collection. They identified any potential prescribing or monitoring errors, having taken account of detailed information in patients' medical records relating to patient characteristics, co-morbidities, other medications, allergies and the need for blood test monitoring. The pharmacists also collected data on potential omission errors, and medicines reconciliation for patients who had been discharged from hospital during the 12 month data collection period.

Error definition: A prescribing error in this study was defined as follows: "A prescribing error occurs when, as a result of a prescribing decision or prescription-writing process, there is an unintentional, significant: reduction in the probability of treatment being timely and effective, *or* increase in the risk of harm when compared to generally accepted practice."

In addition, the following definition was used for a monitoring error: "A monitoring error occurs when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. It includes the absence of tests being carried out at the frequency listed in the criteria, with tolerance of +50%. If a patient refused to give consent for a test, then this would not constitute an error".

Judgement of potential errors: The details of all potential errors were discussed by a panel (one GP, one clinical pharmacologist and three pharmacists) to decide whether they fitted our error definition, and if so, how the error should be classified. The severity of errors identified was judged on a validated 0-10 scale (0=no risk of harm; 10=death) by a separate panel (two GPs, two pharmacists and one clinical pharmacologist).

Data entry: Data were entered onto a Microsoft Access database and all data entries were double checked and corrected where necessary.

Data analysis: Descriptive analyses of the prevalence and nature of prescribing and monitoring errors were conducted in Stata, Version 11.2, as were modelling analyses of the factors associated with error at patient and prescription levels. Descriptive analysis of the severity of errors was conducted in Microsoft Excel and SPSS, Version 16.

Results

The mean list size of the 15 general practices was 5,916 (standard deviation: 3,014); ten (66.7%) were involved in GP training, and two (13.3%) were dispensing.

Compared with figures for England the general practices involved in the PRACTICE study were similar to other English practices in terms of mean list size, number of GPs, and Quality and Outcomes Framework scores. The general practices involved in the PRACTICE study appeared to have higher deprivation levels.

The study involved examination of the records of 1,777 patients. These patients had a mean age of 39.3 years (standard deviation: 22.7 years) with similar age distribution to that of the English population in 2010; 884 (49.8%) were female. Of the 1,777 patients, 1,200 (67.5%) had at least one prescription during the 12 month retrospective review of their records.

Collectively, the pharmacists reviewed 6,048 unique prescription items. Of these, 2,929 (48.4%) were acute prescriptions; 3,119 (51.6%) were repeat prescriptions, and 770 (12.7%) were items that were considered to require blood test monitoring. Most of the 6,048 prescriptions (4,859; 80.3%) were issued by GP partners, 779 (12.9%) by salaried GPs, 185 (3.1%) by locum GPs, and 133 (2.2%) by GPs in training.

From the 6,048 prescription items on the database there were the following numbers of medication problems: 247 prescribing errors; 55 monitoring errors; 427 examples of sub optimal prescribing, and eight legal problems.

The prevalence of prescribing or monitoring errors for different groups of patients over the 12 month data collection period was as follows:

- All patients (n=1,777): 12% (95% CI 10.5%-13.6%)
- Patients who had received at least one medication (n=1,200): 17.8% (95% CI 15.7%-20%)
- Patients aged 75 years and older who had received at least one medication (n=129): 38% (95% CI 29.5%-46.5%)
- Patients who had received five or more drugs over the data collection period (n=471): 30.1% (95% CI 26.6%-35%)
- Patients who had received 10 or more drugs over the data collection period (n=172): 47% (95% CI 39%-54%)

The percentage prevalence of prescriptions with prescribing or monitoring errors was 4.9% (95% confidence intervals (CI) 4.4%-5.4%). The most common types of prescribing error were 'incomplete information on the prescription' (74; 30.0%); 'dose/strength errors' (44; 17.8%) and incorrect timing of doses (26; 10.5%). The most common type of monitoring error was 'failure to request monitoring' (38; 69.1%).

For the 302 prescribing and monitoring errors, the median severity score was 3.3 (interquartile range (IQR) 2.2, 4.4; minimum: 0.7; maximum: 8.6). The 55 monitoring errors had a median score of 3.8; the 247 prescribing errors had a lower median score of 3.0. Overall, 128 (42.4%) errors had scores of less than 3, and were thus deemed to be minor; 163 (54.0%) had scores of 3 to 7 and were thus moderate; 11 (3.6%) had scores greater than 7 and were thus severe. Thus, one in 550 of all prescriptions (11/6048, 0.18%) were associated with severe error.

Modelling of associations between prescribing and monitoring errors (compared with no prescribing or monitoring problems) was undertaken at the patient-level and the prescription-level using mixed effects logistic regression techniques. The following significant associations were found in the patient-level model:

- For each additional unique medication item that the patient had received over the course of the 12 month retrospective data collection there was 16% increased risk of error (odds ratio 1.16, 95%CI 1.12-1.19, P<0.001)
- Women were less likely than men to have a prescribing or monitoring error (odds ratio 0.66, 95%CI 0.48-0.92, P=0 .013)
- The following age groups were more likely (than age group 15-64 years) to have a prescribing or monitoring error:
 - 0-14, odds ratio 1.87 (95%CI 1.19-2.94, P=0.006)
 - 65-74, odds ratio 1.68 (95%CI 1.04-2.73, P=0.035)
 - ≥ 75, odds ratio 1.95 (95%CI 1.19-3.19, P=0.008)
- Compared with a list size of 5000-10,000, patients in practices with a list size of greater than 10,000 had reduced risk of error: odds ratio 0.56 (95%CI 0.31-0.99, P=0.047)

The following significant associations were found in the prescription-level model:

- For drugs on the monitoring list there was an increased risk of error (odds ratio 3.18, P<0.001)
- For the following drug groups (compared with gastrointestinal drugs) there was an increased risk of error:
 - Cardiovascular (odds ratio 2.37, 95%CI 1.03-5.45, P=0.042)
 - Infections (odds ratio 2.67, 95%CI 1.17-6.11, P=0.02)
 - Malignant disease and immunosuppression (odds ratios 6.77, 95%CI 1.71-26.84, P=0 .006)
 - Musculoskeletal (odds ratio 6.97 95%CI 3.06-15.88, P <0.001)
 - Eye (odds ratio 4.92, 95%CI 1.12-21.62, P=0 .035)
 - ENT odds ratio 4.6, 95%CI 1.29-16.42, P = 0.019)
 - Skin (odds ratio 5.78, 95%CI 2.04-16.36, P = 0.001)

Thirty-seven cases involving medicines reconciliation at hospital discharge were examined in detail. Prior to admission the 37 patients were taking a total of 194 medications, and 29 (15%) of these were discontinued by the hospitals. In 36 patients (97%) there was a difference between the medications that the patient was taking before admission and those listed in the discharge summary. According to the hospital

discharge communications, the 37 patients were supposed to be taking a total of 252 medications. Twenty-six (10.3%) of these involved a change in dose of a drug that the patient was taking prior to admission; in none of these cases was the dose change highlighted in the discharge communication. Eighty-seven (34.5%) of the discharge medications were newly prescribed and for only seven (8%) of these was the new prescription highlighted in the discharge communication. Following discharge, 24 (28%) of the 87 drugs newly prescribed by the hospital were either not continued, or there was some discrepancy between the prescribing advice of the hospital and the subsequent prescription. For the medications that had been stopped by the hospitals, none was restarted by the practice within a month of hospital discharge.

At the patient level, discrepancies were found between the medicines on the hospital discharge communication and those subsequently prescribed by the practices in 16 patients (43.2%).

Investigating the causes of prescribing and monitoring errors, and identifying solutions for preventing error

Methods

We undertook the following:

- Interviews with prescribers
- Focus groups with primary health care team members
- Root cause analyses

Interviews with prescribers

Face-to-face interviews were undertaken with 34 prescribers with the aim of exploring the causes of prescribing and monitoring errors. A total of 70 errors were discussed with interview participants. All but two of the interviews were audio-recorded and transcribed.

Focus groups

Six focus groups, involving 46 primary health care team members, were held in participating general practices across the three PCTs. The main issues explored in the focus groups were: safeguards in general practice to protect patient against potential harm; reporting prescribing errors in general practice, and general practice safety culture. All of the focus groups were audio-recorded and transcribed.

Root cause analyses

The pharmacists undertook 15 root cause analyses relating to a wide range of different types of prescribing and monitoring errors; two examples of suboptimal prescribing, and one case that was judged not to be an error.

Qualitative data analysis

Data analysis aimed to identify major themes from the interviews and focus groups. A robust and complete analysis was carried out using the framework provided by Reason's Accident Causation Model. A 'conceptual framework' was developed, by which the raw data could be labelled and sorted. A workable list of main- and sub-themes was developed and applied systematically to the whole data set with the aid of the computerised qualitative data analysis software QSR N-Vivo version 8.0. The index was then mapped to the categories outlined in Reason's Accident Causation Model, and the coded data were then sorted and synthesised by grouping data with similar content together under the different themes and sub-themes.

Researchers made sense of the data by looking at particular themes across all practices in order to understand the range of views and experiences of interviewees. The researchers began to build explanations for the recurring patterns and associations in the data. This process involved interrogating the dataset as a whole to identify linkages between sets of phenomena and exploring why such linkages occurred.

Causes of prescribing and monitoring errors: error producing conditions

Seven categories of error-producing condition (perceived to contribute to an increased risk of prescribing and monitoring errors) were described and explored in-depth. The

main findings presented for each high-level condition were as follows:

The Prescriber - five conditions were found to affect 'The Prescriber', namely their *therapeutic training, drug knowledge and experience, knowledge of the patient, perception of risk, and physical and emotional health*. Undergraduate therapeutic training was felt by many to have been insufficiently taught at University. The "jump" from being a GP trainee to a salaried GP was also perceived to have been quite high. One example, in particular, emphasised not only the importance of hands-on experience with chronic disease patients during GP (vocational training scheme) training, but also the need for trainees to have experience treating a range of patients at varying stages of their illnesses. Some established GPs admitted becoming '*slightly blasé*' about prescribing for their long-term patients, thus running the risk of overlooking certain things. Prescribers' perception of risk appeared to be influenced by previous experience of a similar situation and the severity of potential harm associated with the drug.

The Patient - *patient characteristics* (including personality, literacy issues, and language barrier) and the *complexity of the individual case* were found to have contributed to prescribing errors. Some particular examples highlighted a tension between the GP's responsibility to improve or maintain their patient's health, and their view on the patient's responsibilities for their own health.

The Team - *poor communication* and *nurses' quasi-autonomous role* within the team were considered to be two key conditions influencing the occurrence of prescribing errors in general practice. The communication between practice colleagues appeared to vary widely, with some feeling isolated whilst others felt very close and supported by their colleagues. Two important factors may explain these different GPs' perspectives, including the length of time the GP had been working in the practice and the frequency of formal / informal meetings within the practice.

Nurses' '*quasi-autonomous role*' in chronic disease management was felt to be associated with an increased risk of prescribing errors in general practice, particularly because of the need to interrupt GPs to have prescriptions signed when the patient had not been assessed by the GP.

The Working Environment – High workload, time pressures and associated stress were felt to be important factors making error almost inevitable. The failure of appointment systems to cope with patient demand was perceived as a particular source of stress. Distractions and interruptions were common for some GPs and thought to be an important cause of error because of their effects on disrupting prescribers' thought processes.

The Task – We focused on repeat prescribing systems and patient monitoring. Some safety issues were identified in the ordering and processing stage of repeat prescribing, but failure to properly review some patients was probably the most important cause of error. General practices had various systems aimed at ensuring timely blood-test monitoring for patients, but sometimes these broke down. The most important problem identified was in a practice where GPs prescribed warfarin without access to INR results.

The Computer System – There were many positive comments about the role of clinical computer systems in preventing error, but some problems were highlighted including selecting the wrong drug or wrong dosage instructions from pick lists; overriding important drug-drug interaction alerts; unnecessary/inappropriate alerts; the need to maintain an accurate electronic health record, and staff sometimes expecting too much from the computer system.

The Primary Secondary Care Interface - The quality of secondary care correspondence appeared to vary a lot, depending on the hospital and department. The ambiguous wording of hospital letters was also felt to be partly responsible for the failure of some GPs to make changes recommended by specialists. GPs recognised the need to update their patients' computer records promptly with hospital information (once received), and individual practices' processes to be in place verifying that these changes have been made. Three important factors appeared to influence GPs' decisions to prescribe medications recommended by specialists, including local guidance, whether the drugs were commonly used in general practice, and whether the GP perceived the harms to outweigh the benefits for the patient.

Root cause analyses

Fifteen root cause analyses were undertaken, covering a wide range of different types of prescribing and monitoring errors, along with two cases that were judged to represent sub-optimal prescribing and one that was subsequently judged to be not an error.

A number of error producing conditions were identified from the root cause analyses, which broadly mapped upon those identified from the interviews and focus groups.

Defences

On the basis of the interviews and focus groups, defences against medication errors in general practice have been identified at multiple stages in the medicines management process:

- Issuing new prescriptions
- Supporting patient decision making
- Dispensing prescriptions
- Repeat prescribing
- Monitoring patients
- Amending prescriptions based on outside correspondence
- Processes supporting medicines management.

These defences have been grouped as:

- Personal prescriber strategies
- Practice-wide strategies
- Health Information Technology (HIT) strategies.

Key personal prescriber strategies include:

- Read aloud printed prescriptions to help ensure patient understanding and to allow the prescriber to check the accuracy of the prescription
- Clarify prescribing recommendations made by specialists where these go beyond the GP's comfort zone
- Review newly prescribed medicines within six weeks

- Add medicines to the repeat list only when patients are stable on them
- Confirm important information with patients even when they are well known to the prescriber
- Ensure that prescribers are competent to use all of the important features of e-prescribing and other IT-support systems.

Key practice-wide strategies include:

- Adopt a formulary to increase familiarity with medicines prescribed
- Strongly discourage verbal requests for repeat prescriptions
- Train non-medical staff to manage requests for non-repeat prescriptions and consider using dedicated staff to manage repeat prescriptions, with additional staff trained as back-up
- Highlight repeat prescriptions with queries so they receive more attention when considered for signing off by GPs and other prescribers
- Perform face-to-face medication reviews
- Check INR results before generating repeat prescriptions for warfarin
- Do not delegate responsibility for difficult patients to junior or locum GPs
- Schedule necessary blood tests for one week before medication reviews
- Update prescribing records as soon as possible (within 48 hours) of receiving correspondence from specialists
- Clarify prescribing changes with specialists if correspondence not available
- Build and maintain a strong safety culture based on open, blame-free, communication
- Appoint a prescribing lead for each practice to lead on protocol reviews and best prescribing-practice.

Secondary care strategies

- Ensure specialists' correspondence highlights new medicines, changes to medicines and reasons for changes
- Ensure specialists' requests for unusual medicines state duration, key adverse effects, and monitoring requirements

Key Health Information Technology strategies include:

- Code allergies in electronic clinical records
- For high risk medicines: programme robust alerts to highlight risky prescribing; block inappropriate medication request intervals; automatically insert weekly dosage instructions for methotrexate
- Provide on-line access to clinical/medicines information resources, linking directly from clinical computer systems
- Embed an electronic-formulary within the e-prescribing system
- Use the electronic-formulary to guide prescribing to safer alternatives
- Avoid similar drug names being adjacent in pick-lists
- Allow drug interaction alerts with severity gradings and brief descriptions of the problems associated with specific interactions
- For general practices using the EMIS computer system, use 'practice notes' to improve communication and provide an audit trail for unauthorised repeat prescribing requests, errors, and new prescribing information
- Run searches on clinical records system to identify potential prescribing errors, and patients requiring blood-test monitoring
- Programme computer to alert when patients taking warfarin go 12 weeks or longer since their last INR test
- Use screen alerts and repeat prescribing dates to highlight need for monitoring
- Amend e-prescribing records if accepting community pharmacists' interventions
- Familiarise locums with health information technologies available in practices

Recommendations

A number of recommendations have emerged from this study for reducing the prevalence of prescribing errors in general practice and these are outlined below.

1) GP training

Many of the types of error identified in the PRACTICE Study could have been prevented with better training in safe prescribing in general practice. We recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. We recommend that discussions focus on ways of strengthening training in, and assessment of, safe prescribing and medicines management. Options include:

- Reviewing the RCGP curriculum to give greater prominence to therapeutic knowledge, and the skills and attitudes needed for safe prescribing
- Development of an educational package to enable GPs in training to assess the safety of their prescribing (e.g. by structured examination of, and reflection on, a sample of their prescription items)
- Development of an educational package to help GPs in training (and established GPs) to improve their knowledge and skills in undertaking structured medication reviews with the aim of identifying and correcting important prescribing and monitoring errors
- Making available within the RCGP Trainee ePortfolio a facility to enable GP associates in training to record educational activities, audits, and reflections specifically relating to prescribing
- Including in the RCGP membership examination, assessments of prescribing competence, such as the ability to write error-free prescriptions and to detect, and correct, errors when undertaking simulated medication reviews

- Additional educational support for newly qualified GPs to help them make the transition to providing on-going medicines management for patients with complex long-term conditions.

2) Continuing professional development for GPs

Many of the types of error identified in the PRACTICE Study could have been prevented with greater attention to safe prescribing in the continuing professional development of GPs. Some of the recommendations made above for GP training may be relevant to established GPs. In addition, we recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. We recommend that discussions centre on the following options for continuing professional development:

- Development of an educational package highlighting key learning points from the PRACTICE Study to support reflection and, where appropriate, for use in identifying GPs' personal development needs
- Development of strategies to support GPs in dealing appropriately with high-risk prescribing scenarios (balancing risks, benefits, patient requests and the need to avoid error)
- Development of strategies to help GPs make best use of information technology to support safe prescribing
- Development of strategies for improving prescribing safety systems in general practices.

3) Clinical governance

Many of the types of problem identified in the PRACTICE Study could have been identified and corrected using appropriate clinical governance procedures, particularly in relation to hazardous prescribing and failure to undertake timely blood test monitoring for certain drugs. We recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and

systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. We recommend that discussions centre on promoting the following clinical governance methods to identify, correct and report prescribing errors:

- Conducting audits using prescribing safety indicators⁵⁰ and correcting problems identified using evidence-based approaches (such as support from pharmacists, as demonstrated in the PINCER trial³⁴)
- Conducting significant event audits
- Reporting adverse prescribing events (and near misses) through the National Reporting and Learning System

4) Effective use of clinical computer systems

General practice clinical computer systems contain a number of features aimed at improving the safety of prescribing. As noted above, we recommend that general practices develop strategies to ensure that they make best use of the safety features that are already present on their systems.

In addition, we recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. We recommend that discussions centre on whether improvements can be made in the following areas:

- The training of GPs and practice staff so that they are able to make best use of prescribing safety features
- The use of pre-specified “order sentences” to encourage prescribers to provide appropriate dosage instructions
- Context-specific dosage guidance taking account of patient factors such as age and renal function

- Alerts to the most common and important examples of hazardous prescribing (in addition to drug-drug interaction alerts which are present on all GP clinical computer systems in the UK)
- Alerts to the need for blood test monitoring for certain drugs

5) Improving safety systems

General practices vary in the systems they use to support safe medicines management within the practice and at interfaces in health care (such as community pharmacy, community nursing, care homes and secondary care). We recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. Specifically, we recommend that discussions focus on the following proposals:

- General practices review the procedures they have in place for repeat prescribing, medication monitoring, medication reviews and communication at interfaces in health care to help ensure that these are as safe as possible in the context of high workload and multiple competing demands on staff
- Primary care organisations, general practices, community pharmacies and acute trusts take account of recommendations for managing patients' medicines after discharge from hospital, such as those issued in England by the Care Quality Commission³⁹
- General practices review the procedures they have in place for minimising interruptions to clinical staff
- Further research is commissioned to establish the organisational policies, procedures and practices that help to ensure safe medicines management in primary care.

Conclusions

From a 12-month retrospective review of the records of a 2% random sample of patients from 15 general practices in England, prescribing or monitoring errors were detected for one in eight patients, involving around one in 20 of all prescription items. The vast majority of these errors were of mild to moderate severity, with one in 550 items being associated with a severe error. The following factors were associated with increased risk of prescribing or monitoring errors: male gender, age less than 15 years or greater than 64 years, number of unique medication items prescribed, and being prescribed preparations in the following therapeutic areas: cardiovascular, infections, malignant disease and immunosuppression, musculoskeletal, eye, ENT and skin. Prescribing or monitoring errors were not associated with the grade of GP or whether prescriptions were issued as acute or repeat items.

On the basis of interviews with prescribers, focus groups with general practice staff and root cause analyses, a number of important error producing conditions, and defences against error, were identified. Error producing conditions were associated with a wide variety of factors concerning the prescriber (therapeutic training, therapeutic knowledge and experience, knowledge of the patient, perception of risk, and physical and emotional health); the patient (including personality, engagement with health services, literacy and language issues); the team (including communication problems, interruptions, and the 'quasi-autonomous' role of nurses); the task; the work environment, the computer system, and the primary-secondary care interface (significant problems were highlighted concerning correspondence about medications particularly at the time of hospital discharge).

The deployment of a wide range of defences against error were identified in relation to the multiple stages of the medicines management process. These defences include strategies that can be used by individual prescribers, practice wide strategies, and the effective use of health information technology.

As a result of this study a number of recommendations have been made in relation to GP training, continuing professional development, clinical governance, the effective use of clinical computers, and improving systems to support safe medicines management.

Chapter 1: Introduction

The prescribing of medicines is an essential skill required by doctors. For every prescribing decision the potential for benefit needs to be balanced against the risk of harm. The prescriber must use clinical knowledge and improvisational skills to apply a body of rules (e.g. contra-indications, risk factors) to a specific prescribing decision. The challenge of prescribing has increased as new drugs are developed, and older and more severely ill patients are treated¹.

The prescription of drugs is the most common form of treatment and errors that occur in the prescribing process have the potential to cause significant morbidity and mortality. Over 900 million items are dispensed in the community in England each year². However, mistakes happen in the prescription of these medicines. In primary care, reported prescribing error rates vary from less than 1%³ to over 40%⁴, the later being a study conducted in Sweden, where failure to report the indication for a drug was considered an error. This variation in error rates is likely to be significantly affected by the definition of error used and the rigour with which detection of error is undertaken. Prescribing errors are a potentially preventable source of harm to patients and are therefore an important target for improvement.

There is relatively little known about prescribing errors in general practice in the UK. In one study, prescriptions presented to pharmacies were screened for prescribing errors by community pharmacists; prescribing errors were identified in 7.5% of prescribed items⁵. Most of the errors identified in this study were administrative ones but some were serious. Another study (which will be described in more detail in Chapter 2) conducted in care homes showed that 39% of 256 residents had one or more prescribing errors, with 8.3% of prescriptions (or intended prescriptions) affected⁶. Furthermore, the National Patient Safety Agency (NPSA) has reported that 26% of the general practice incidents that were reported to the National Reporting and Learning Service (NRLS) were related to medications⁷. The National Clinical Assessment Service (NCAS) recently reported that over the previous eight years, 34% of their referrals have been concerning general medical practice. However, there is little evidence about the prevalence or causes of prescription errors in this area. Figures published by the

Medical Defence Union in 2000 indicated that 25% of adverse incidents that resulted in litigation claims in general practice were a result of medication errors, suggesting not only a implication for patient safety but an adverse impact on practitioners⁸.

There have been relatively few large-scale studies of prescribing errors in general practice, or detailed investigation of underlying causes and defences.

The accident causation model and prescribing errors

We have previously used Reason's accident causation model⁹ to analyse the causes of prescribing and administration errors in both primary and secondary care. Briefly, according to this model, 'latent' failures within the system, and error-producing conditions within the environment, lead to active failures on the part of the person at the 'sharp end' of a system – the prescriber, in the case of prescribing errors. Active failures can be sub-divided into mistakes (selecting the wrong plan to achieve the desired goal), slips (intending to do one thing, but doing another), lapses (forgetting to do something) or violations (not following the rules). Defences in the system may, or may not, identify an error and rectify it before it results in harm. Prescribing errors are typically of two types. Firstly, they can occur during the application of clinical knowledge to the individual patient in order to reach a prescribing decision; these are likely to be knowledge or rule-based mistakes. Secondly, errors can occur during the process of converting the prescribing decision into a prescription. These prescription writing errors are likely to be slips and lapses.

Contributing factors may include lack of training or environmental, team, technology or task factors that affect performance of the prescriber. These in turn arise owing to the 'latent' conditions that are brought about by wider social factors, such as organisational, cultural or professional norms.

1.1 Aim:

To determine the prevalence and nature of prescribing errors in general practice; to explore the causes, and to identify defences against error.

1.2 Objectives:

- To update a recently completed systematic review of medication errors in primary care.
- To report on a current Cochrane systematic review of interventions in primary care aimed at reducing medication-related adverse events.
- To investigate the prevalence, nature and causes of the prescribing errors made by general practitioners.
- To determine the prevalence, nature and causes of monitoring errors, for prescribed medications that require monitoring.
- To explore whether the prevalence and nature of errors vary according to the grade of GP.
- To explore whether the prevalence and nature of errors vary according other factors including the characteristics of general practices, patients and prescriptions.
- To explore how general practices incorporate information from hospital discharge prescriptions and any associated errors.
- To find out what informal or formal safeguards exist in general practice to protect patients against potential harm from prescribing errors.
- To explore systems that are used, or could be used, to report prescribing errors in general practice.
- To explore what might be unique to general practice culture that might have an impact on prescribing error rates and incident reporting.
- To make recommendations for best practice and educational interventions to reduce prescribing errors in general practice.

Chapter 2: Defining prescribing error in primary care

2.1 Background

The definition of medication error has long been a contentious issue, with different definitions used by different groups. For example, a recent systematic review of medication error definitions and characteristics found 26 different wordings for a generic definition of a medication error¹⁰. Such variation makes it difficult to make comparisons within and between studies.

When conducting research into the prevalence or incidence of specific types of medication error, detailed operational definitions are required to clarify what should be included, and excluded as an error. When embarking on a major study of prescribing errors in a UK hospital over a decade ago¹¹, we reviewed the definitions of prescribing error that had been used in studies of prescribing errors published at the time, and found them frequently ambiguous or not stated. Even where definitions were given, they varied widely, and generally included insufficient detail for operational use in a quantitative study. We therefore used a Delphi group to develop and validate an operational definition of a prescribing error for research use¹¹, which is now widely used. Our definition was published in 2000, and was developed largely with hospital practice in mind. Here we now review this definition in the light of the subsequent literature, and our experience of using it in a large number of studies, including in UK primary care in the present study. First, however, we comment on the challenges in defining error.

2.2 The challenge of defining error

Whether or not an act is an error is a value judgement, and as such it is subjective and contestable. Any attempt to make a 'scientific' definition – one based entirely on scientific facts, such as the interaction of a drug with a receptor – will inevitably fail because, as Aristotle pointed out, the worlds of facts and values are different. Definitions of error therefore use (or imply) words that include value judgments: 'failure', '(in)appropriate', 'should', 'right' etc. The less these words are explained or operationalised, the more variability there will be in their interpretation. 'Error' needs to be unpicked so that there is a greater understanding of the values that constitute it; not least in recognising the social, cultural and organisational norms that are embedded in it.

We need to find a useful level of explication in the language of errors – not so general as to allow wildly different interpretations, yet not so detailed as to become unusable. We need a definition of error that recognises the different contexts and cultures of care – one that applies equally in the intensive care unit of a well-funded teaching hospital in the West, in a military field hospital and in a hospital in a poor country. The art in the definition of error is to give enough information to help people apply the rules in the real world, without trying to define all possible situations.

We next highlight three important points in relation to error definitions.

First, an error definition should be appropriate for the purpose for which it is intended. For example, a definition of an error to inform staff of what needs to be reported on an organisation's incident report system is likely to differ in scope and detail to a definition used in a quantitative research study of error rates. Hence when Yu¹² looked at variation in terminology and definitions given by key organisations' websites, this research ended up relating to setting the scope of policy and practice, rather than, for example finding operational definitions.

Second, definition is not the same as classification. Several researchers have attempted to use our list of examples¹¹ of what should, and should not, be included as errors, as a classification system. This is not the purpose for which they were intended. Definition comes first, and classification comes next. Having agreed those events that should be included as error, classifications may then be of several types, depending on the purpose of the classification. Examples include classification in terms of clinical consequences, potential clinical importance, psychological cause of the error, and type of discrepancy (e.g. wrong drug, wrong dose). It may be appropriate to classify in several ways within the same study in order to describe the errors in a meaningful way, and one approach should not necessarily exclude the others.

Third, the literature is potentially confusing, as some authors use different words to use the same thing, and/or the same words to mean different things. In the past, since most research focused on medication administration errors, rather than other types of error, the term "medication error" has been used to mean "medication administration error"¹³⁻¹⁵, and thus many definitions of a "medication error" have been only of medication administration errors. The context of the research question and methods usually make it

clear that the definition just refers to administration. Other commentators have not recognised this and have therefore criticised such definitions as being restrictive¹⁰.

2.3 Our definition of a prescribing error

Our definition of a prescribing error¹¹ was developed following a Delphi process with 34 judges, comprising physicians, surgeons, pharmacists, nurses and risk managers. The definition is: “A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant

- reduction in the probability of treatment being timely and effective or
- increase in the risk of harm when compared with generally accepted practice”.

This definition is accompanied by lists of 27 situations that should be included as prescribing errors, eight that should not, and seven for which the judgement will depend on the individual clinical situation. These scenarios were not intended to be exhaustive, but to provide some clarity on examples of potentially contentious cases in order to help decide whether these should be included or excluded as errors.

Some key points associated with our definition:

- “unintentional” – this is intended to exclude risk of harm due to malicious acts
- “compared with generally accepted practice” – this is included as belief in preventability depends on it being referenced to generally accepted practice. Some authors set extremely high standards for practice which result in a plethora of ‘errors’, which have no credibility to practitioners or policy makers, so are not an effective tool for change. For example we could (theoretically) avoid all cases of penicillin allergy by never using drugs with a penicillin structure in penicillin-naive patients. However, accepted practice is to use penicillin and so according to our definition, prescribing penicillin in a patient with no history of allergy would not be considered an error provided it was otherwise an appropriate choice of drug.
- “significant” – this word was included for three reasons: (1) it was considered important to differentiate between clinically meaningful prescribing errors and those cases where some optimisation of treatment was possible but where a prescribing error could not be said to have occurred; (2) it was recognised that

cognitive errors could occur in the prescribing process without there being any adverse consequences for the patient. For example, a doctor may prescribe drug X instead of the intended drug Y, but if both are equally safe and effective then the cognitive error is not clinically important. It was therefore considered that the word “significant” was necessary, and that the definition should apply to “clinically meaningful” prescribing errors; (3) to ensure that any research findings would be thought of as relevant and worthy of addressing.

2.4 Critiques of our definition

Although our definition is widely used, there have been a small number of critiques of it since it was published.

First, it has been suggested that developing definitions using consensus-based methods such as the Delphi technique is flawed^{16, 17, 18}, being caricatured as definition by committee. However, we disagree, as we believe it is vital that results are credible to practitioners so they take them seriously, and so that findings can be a drive towards action. By creating a consensus of professionals we provide validity to our definition. We were concerned that otherwise, definitions would lack face validity to many prescribers, such as Betz and Levy’s¹⁹ definition which includes ‘prescribing a medication without sufficient education of the patient’ as a prescribing error. In particular, the Delphi technique was specifically used to eliminate many of the problems commonly associated with committee-based decision making, since our group did not meet in person and thus dominance by one or more individuals, and concerns about ‘raising one’s head above the parapet’ were not an issue.

Second, our inclusion of only “clinically meaningful” prescribing errors has been criticised, on the basis that the occurrence of any error may indicate a weakness in the system, and that an error which does not harm the individual patient concerned may harm others¹⁷. We agree with both of these points, and contrary to suggestions in the literature¹⁸, our definition does not exclude non-harm errors.

Third, Ferner and Aronson¹⁷ have commented that comparing to “generally accepted practice” may not be appropriate, if generally accepted practice is poor. This was something we considered in our original definition work, and included it as it was found

that a comparator was needed within the definition as “reduction” and “increase” implied a baseline. Ferner and Aronson instead suggest that an “attainable standard” should be used instead, but without specifying what that attainable standard should be, nor in what settings, by whom and under which conditions the standard should be attainable. In our definitions paper¹¹, failures to adhere to standards such as hospital or national guidelines, or the drug’s product licence, were not considered errors by the Delphi group. This calls into question the validity of prescribing error studies that define errors based on deviations from such standards and highlights the complexities of medical decision making. We discuss some of these issues further, later in this chapter.

Finally, Ferner¹⁶ questioned whether our definition would be taken up widely by others, citing a survey of adverse event reporting in 132 intensive care units, showing that many different definitions are used²⁰. However, adverse drug events and prescribing errors are not synonymous, and the purposes of self reporting and research are different, and so we would not expect to see our definition used in this context. Instead, a recent systematic review of studies presenting the incidence or prevalence of prescribing errors in handwritten inpatient medication orders revealed that 11 of 65 included studies used our definition²¹; no other definition was quoted as frequently and the majority of other studies either used their own definition or did not give any definition at all. A recent search (August 2011) on Web of Science reveals 73 citations of our original paper.

We next consider in more detail some practical aspects of defining prescribing error in research studies, and how these were applied in the present study.

2.5 Reflections on defining error in practice

First, we have found that an evolving list of what we have termed “case law” is needed, in addition to the definition itself. This case law is initially based on the published list of examples of what should, and should not, be included as an error. However additional case law tends to be needed as a study evolves. In most studies we have therefore used an adjudication panel, and draw up case law for the study in question as we go along²². This was the approach taken in the present study.

Second, it may be necessary to consider and define the boundary of the system. For example, is a community pharmacist - who “translates” a GP’s Latin abbreviations for the

patient - part of the system, or are they in receipt of a prescribing error? And in a hospital in which an admissions pharmacist is often relied upon to ascertain the patient's drug history, is it a prescribing error if the admitting doctor does not prescribe the patient's usual medication correctly on admission? Assumptions and expectations are inevitable, and it is important to make these as explicit and standard as possible within a particular study. This is discussed in more detail later on in relation to the present study.

Third, it is important to be aware that the definition of what is, and is not, an error can be date-specific as a result of developments in clinical knowledge. For example, use of COX-II inhibitors would have been considered appropriate in many patient groups several years ago. Now, however, prescribing a COX-II in a patient with a risk of cardiovascular disease would probably be judged as being an error. Similarly, until recently, it was recommended that women taking the combined oral contraceptive pill would require additional contraception if prescribed a broad spectrum antibiotic, and so prescribing such an antibiotic without advising accordingly would be considered an error. However this advice has now been rescinded and so prescribing a non-enzyme inducing antibiotic would not be an error. This raises the issue of how such issues should be dealt with in an error study which includes prescribing that was initiated in the past. For any given study, clear guidelines are needed to explain how this will be addressed. For the present study, we decided whether or not something should be counted as an error based on the information that would have been available at the time of the relevant prescription.

Fourth, we have found that a reduction in the probability of treatment being "timely and effective" can be difficult to identify. In practice, we have included underdosing of antimicrobial agents to be an error, as this might be expected to lead to a treatment being less effective, as well as increasing the risk of societal harm due to an increase in antimicrobial resistance. However, underdosing for a condition that is not serious and where failure to prescribe the recommended dose is unlikely to have a deleterious effect on the patient, was generally not considered an error in the present study.

Fifth, we have found that prescribing error and documentation are linked, particularly in studies where investigators are retrospectively assessing prescriptions and medical records. For example, if a contra-indicated drug, such as a combined hormonal contraceptive in a patient with two or more risk factors for thromboembolism, is

prescribed with a clear and defensible justification documented, this would not be a prescribing error. However, if no such reasoning is documented, a prescribing error would be assumed to have occurred.

Finally, sometimes there are cases where a lack of information makes it impossible to make a valid judgement on whether or not an error has taken place. In such cases, no error should be recorded, and it may also be appropriate to take such cases out of the denominator when calculating incidence or prevalence.

2.6 Specific issues in primary care

As well as these general issues, the present study highlighted additional specific points relating to primary care.

First, as mentioned above, we have to consider the role of the community pharmacist (or dispenser in a dispensing practice), who we assumed would generally “translate” instructions to make them meaningful to the patient. For example, a doctor might prescribe metolazone “2.5mg each morning”, which necessitates giving half of a 5mg tablet. A patient could potentially be confused by the instructions to take “2.5mg”. However it is reasonable to assume that the dispensing pharmacist will translate this into “half a tablet”. The same applies for the use of Latin abbreviations such as “OD” to mean once daily, or prescription of rectal medication as “take one suppository daily”. We therefore decided not to include the prescription of brief or abbreviated instructions as errors. However, we recognise that in other contexts, where instructions from the prescriber are automatically produced verbatim on the dispensing label (such as with the Electronic Prescription Service Release 2), this correction may not always take place. For the present study however, we felt that a consistent rule was needed. For cases that involved potential duplication, such as the prescription of both co-dydramol and paracetamol, we did count these as errors unless the prescriber clearly stated that they should not be taken together. Although a dispensing pharmacist should include appropriate instructions not to take both at the same time, and to remain within a maximum of 8 tablets a day of the two combined, it could not be assumed that the two prescriptions would be taken to the same pharmacy if written at different times, and thus a pharmacist might not identify the duplication.

Second, in primary care, we have to consider how to handle items left on repeat prescription but not actually requested by the patient. We were looking only at issued prescriptions in the present study, so did not include these cases as errors. However, we recognise that there may be a risk of harm if the patient or carer does request these items, and if this request is processed.

Third, where there was a lack of specific information about dosage instructions and/or route of administration, we had to take into account the patient's likely behaviour, or that of a carer. For example, if a prescription for eye drops did not specify which eye, we did not classify this as a prescribing error if this was for a symptomatic condition, since patients would be likely to know which eye was painful or infected. However for drugs which were to treat an underlying, potentially asymptomatic, condition such as glaucoma, we did judge this as an error. This judgement also depended on the risks associated with the drug. For example, potent topical corticosteroids which did not have specific instructions about where to be applied, and how often were counted as errors. For medication which is provided with a detailed patient information leaflet and only one main indication / administration schedule, and/or is available over-the-counter for the relevant indication, such as GTN tablets and paediatric paracetamol suspension, an error was not counted if it was felt that the dosage instructions provided on the packaging would sufficiently inform the patient. Another example is the oral contraceptive pill, which comes with detailed instructions and is presented as a calendar pack clearly showing that one tablet is to be taken daily. A prescription for "take as directed" was therefore not included as a prescribing error. Similarly, where medication was prescribed without stating the number of tablets to be taken each time, e.g. furosemide tablets 40mg "once daily", provided the default dose of taking one tablet/capsule each time would be an appropriate dose, this was not counted as an error. Very high risk drugs, and/or those where a wide range of doses are likely, such as oral corticosteroids, were judged as errors if the dosage instructions were unclear.

Chapter 3: Systematic reviews

We performed two systematic reviews. The first was an update of a review published in 2009 which included 27 studies, focused on the UK literature, and examined studies relating to errors at each point in the medicines management process from a primary care perspective²³. The second was an update of an international review published in 2006 of interventions in primary care aimed at reducing medication related adverse events and hospital admissions²⁴.

3.1 Update of systematic review of medication errors in UK primary care

3.1.1 Background

In 2009, Garfield and colleagues²³ reviewed the UK literature to identify medication errors and describe them using a 'systems approach'. The authors mapped the medication errors in primary care and assessed the quality and reliability of the whole medicines system at each stage of medication usage. Quality and reliability of the system were determined by the prevalence of: prescribing and other medication errors, patients' non-adherence, and failures in drug effectiveness.

The study identified several quality issues at every stage of the process. In particular, error rates of 50% or more were identified in areas which included repeat prescribing, communication and patient adherence. Furthermore, it was found that some areas of the system seemed to lack research, i.e. assessment of the accuracy of GP medication records; it was also concluded that research in areas such as repeat prescribing needed updating. Of particular relevance to the present study, only one study of prescribing errors in general practice was identified, with an error rate of 7.46% of prescribed items, and one study of medication review, which showed that 72% of patients had not had their medication reviewed within 15 months.

Several methodological issues were identified within the literature explored; some studies were not able to detect all errors due to inconsistencies in their error assessment methods. Other methodological pitfalls regarded the sampling strategies applied; in

particular, studies that were conducted in a single site, or used a convenience sample; or that provided no information regarding the participants' selection process.

Based on the shortcomings of the literature, Garfield et al.²³ identified ways in which the medication system could be improved and made safer. The principles of system improvement and quality management would suggest the focus should be on the processes that are most important to the patient and the greatest sources of error. The authors also underlined the importance of feedback loops within the system, such as medication reviews and monitoring of patients on higher risk medicines, which may reduce the avoidable harm that patients may suffer.

The present study aimed to update Garfield and colleagues' review of the literature maintaining a focus on prescribing errors in primary care in the UK.

3.1.2 Methods

We used identical methods to those used by Garfield et al.²³ to systematically identify relevant papers published in English, from January 2009 to February 2011. The electronic databases Medline, Embase; Kings Fund, International Pharmaceutical Abstracts; Pharmline; CINAHL; and Psycinfo were searched using the key words: 'medication error' or 'prescribing error', together with 'primary healthcare', 'general practice', 'family practice', 'patient discharge', 'patient admission', 'medical records', 'continuity of patient care' or 'hospital-physician-relations'. A manual search of the reference lists of relevant papers and reviews was conducted in order to identify any additional studies.

We aimed to include only studies which were conducted in the UK and which reported the frequency of medication errors in primary care; these included prescribing errors in outpatient referrals or admissions to secondary care, which can affect medication prescribing later in primary care²³. All definitions of error were included. Studies were not included if they relied only on spontaneous reports, were not available in national libraries, did not report the method used for measuring errors, were studies of discrepancies on admission to hospital which only compared medication histories of different healthcare professionals in secondary care, or focussed on one medication or therapeutic group.

One reviewer assessed the title and abstract of all records identified by the electronic searches for relevance. In order to affirm inter-rater reliability a second independent reviewer screened 10% of the articles. We retrieved full text copies of all potentially relevant papers and identified studies that met the inclusion criteria.

3.1.3 Results

We identified 2,465 potentially relevant studies through database searches and reference lists (Figure 1)

We removed 116 citations that were duplicate references to articles already retrieved. We then excluded 2160 further studies based on our exclusion criteria. This resulted in 139 references that we reviewed further for preliminary data extraction. After a detailed assessment, we excluded further a 138 papers, which resulted in only one additional relevant study published since the earlier review by Garfield et al.

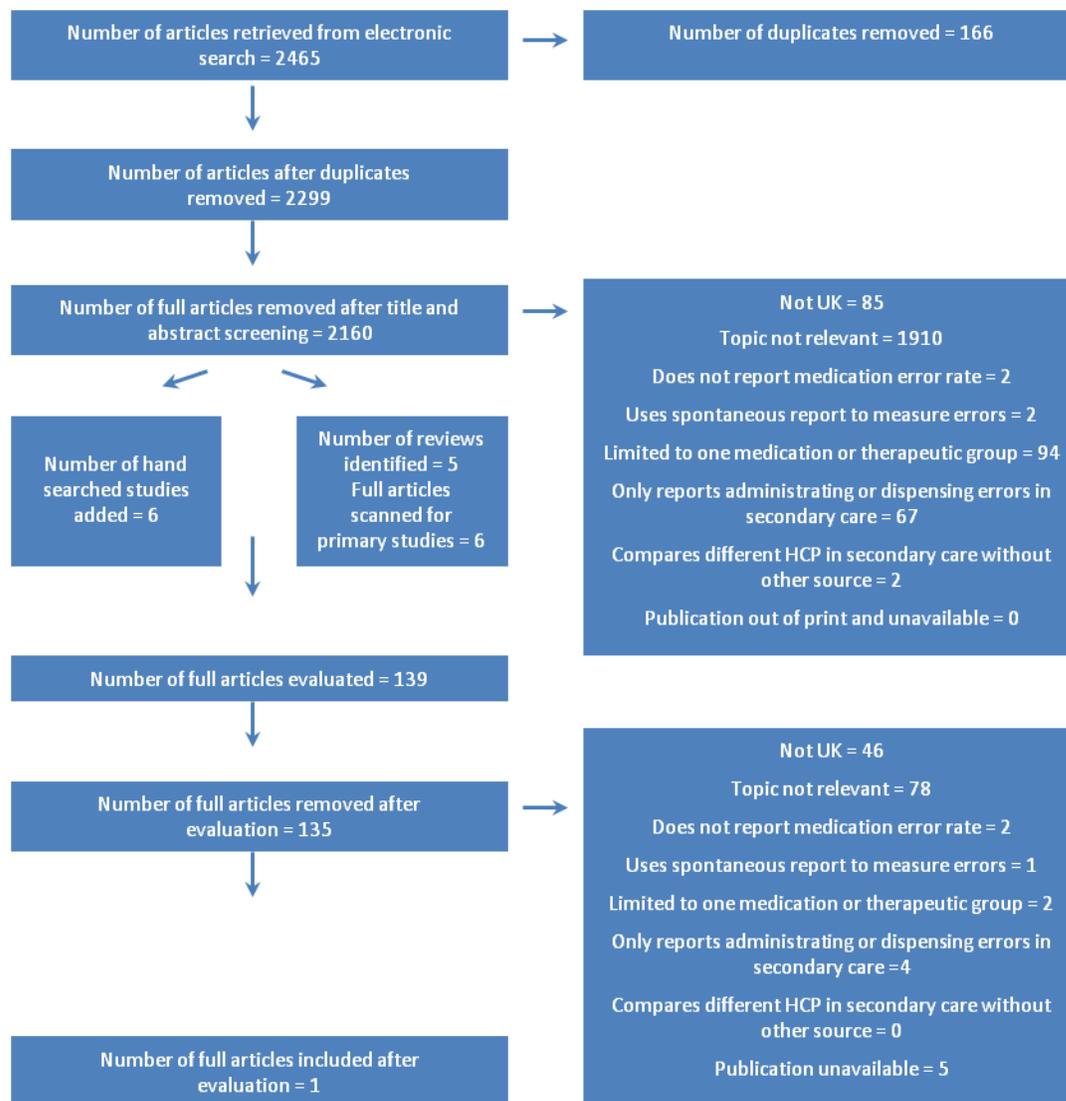


Figure 1: Flow chart of papers identified, screened and evaluated

Description of the included study

The only study that met the inclusion criteria was by Barber and colleagues⁶. These authors evaluated the incidence of medication errors (prescribing, monitoring, dispensing and administration) in a random sample of 256 care home residents from 55 homes in three different geographical areas of England. Focusing here on the prescribing and monitoring errors, these were identified by medication reviews, which were conducted by one pharmacist in each geographical area. The study then explored the causes of errors through observation and from interviews with home personnel, doctors and pharmacists. The severity of the errors was based on potential harm for the

patient and was assessed by expert judgement on a validated linear scale ranging from 0 to 10, where 0 equated to no harm and 10 corresponding to an error that would result in death.

Two thirds of patients suffered at least one medication error of some sort each day. It was found that prescribing errors occurred in 100 residents (39.1%) and in 8.3% of prescribing acts. A total of 153 prescribing errors were identified. The most common types of prescribing error were “incomplete information” (37.9%), e.g. no strength or route was specified; “unnecessary drug” (23.5%), “dose/strength error” (14.4%) and “omission” (11.8%). Monitoring errors, which were studied in a list of drugs that an expert group had deemed to require monitoring, occurred in 27 (18.4%) residents (or in 14.7% of prescriptions for these drugs). Of these 32 monitoring errors, 90.6% were due to a failure in requesting monitoring. The drugs most commonly involved in monitoring errors were diuretics (53.1%), ACE inhibitors (15.6%), amiodarone (12.5%) and levothyroxine (9.4%). The mean harm scores for prescribing and monitoring errors were 2.6 and 3.7 respectively. The mean harm score for prescribing errors was 2.6 (95% CI 2.4-2.8) and for monitoring errors it was 3.7 (3.4-4.0). These scores were higher than for other types of medication error identified in this study.

3.2 Update of systematic review of interventions in primary care aimed at reducing medication related adverse events and hospital admissions

Our previous systematic review, published in 2006,²⁴ identified 38 relevant studies, including 17 pharmacist-led interventions and 13 complex interventions that included a component of medication review aimed at reducing falls in the elderly. Meta-analysis found that pharmacist-led interventions were effective at reducing hospital admissions, but restricting analysis to the randomised controlled trials failed to demonstrate significant benefit. Pooling the results of studies in other categories did not demonstrate any significant effect. Below we present a summary of our updated systematic review. The full version will appear as a Cochrane systematic review.

3.2.1 Objectives

To identify and evaluate studies of interventions in primary care aimed at reducing medication-related adverse events that result in morbidity, hospital admission and mortality.

3.2.2 Search methods

We systematically searched 14 electronic databases for published and unpublished data. Bibliographies of retrieved papers were searched and first authors and experts contacted in an attempt to locate additional studies. There was no restriction on language of publication.

3.2.3 Selection criteria

All interventions applied in primary care settings which aimed to improve patient safety by reducing adverse events resulting from medication overuse or misuse were considered. Randomised controlled trials, controlled trials, controlled before and after studies, and interrupted time series studies were eligible for inclusion.

3.2.4 Data collection and analysis

Study quality assessment and data extraction were undertaken using the Cochrane Effective Practice and Organisation of Care data collection checklist and template. Meta-analysis was performed using a random effects model.

3.2.5 Results

716 studies were initially identified, of which 43 satisfied our inclusion criteria. These were categorised as follows: 20 pharmacist-led interventions that reported hospital admissions as an outcome; 10 educational interventions targeting primary health care professionals that reported preventable drug-related morbidity as an outcome; and 13 complex interventions that included a component of medication review aimed at reducing falls in the elderly (the outcome being falls). Meta-analysis found that pharmacist-led interventions were not effective at reducing hospital admissions OR 0.92 (95% CI 0.76, 1.10 n=15) and adverse drug events OR 0.65 (95% CI 0.26, 1.59 n=3). Interventions which included a medicines management component to reduce falls in at risk patients did not have significant impact (OR 0.93, 95% CI 0.71 to 1.22, n=10). Pooling the results of studies in the other categories failed to demonstrate any significant effect on the main outcomes. No study was found which recorded death as an outcome.

3.2.6 Conclusions

Currently there is no evidence which indicates that medication reviews when combined with other interventions are effective in reducing falls in at risk patients. There is currently no evidence for the effectiveness of other interventions which aim to reduce hospital admissions or preventable drug-related morbidity.

Chapter 4: Methods used to identify the prevalence and nature of prescribing and monitoring errors

The project started in mid February 2010 and was completed in September 2011. Research ethics committee approval was obtained from Nottingham Research Ethics Committee 1 27th of May 2010. NHS Research and Development approval was obtained from participating primary care trusts.

4.1 Recruitment

4.1.3 Recruitment of primary care trusts

We approached three primary care trusts (PCTs) with differing characteristics (inner-city London, urban and suburban/rural) to act as sites for the recruitment of general practices. The following PCTs were approached and each agreed to take part in the study:

- City and Hackney PCT, London
- Luton PCT
- Nottinghamshire County Teaching PCT.

4.1.2 Recruitment and training of pharmacists

Initially, three pharmacists were recruited to be involved in the data collection; one pharmacist for each PCT. These pharmacists were given a day's training by the research team, which focused on the definition of prescribing and monitoring errors and their identification in general practice. In addition, pharmacists were trained on interviewing techniques as well as performing Root Cause Analyses (RCA).

One of the three pharmacists had to withdraw from data collection due to maternity leave in December 2010, therefore another PCT pharmacist was recruited in mid January 2011. The newly appointed pharmacist was given half a day training involving the definitions of prescribing and monitoring errors, the identification of these errors as well as how to conduct root cause analyses.

4.1.3 Recruitment of General practices

All practices within City and Hackney PCT, and Luton PCT were approached about the study along with all practices belonging to one of the practice-based commissioning clusters in Nottinghamshire County Teaching PCT. We aimed to recruit 15 general practices with five of these from each of the three PCTs. Practices were sent a letter inviting them to take part in the study, and giving them information in the form of a practice information sheet (**Appendix 1**).

In total, 97 practices across the three PCTs were approached to take part in the study and those that did not respond to the mailing were sent a reminder. Thirty practices replied and 20 of these expressed an interest in taking part. Of these, 5 practices in each of the PCTs were purposively selected to be part of the study taking into account the differences in demographic characteristics and quality markers to try to ensure a reasonable match against characteristics of English general practices.

4.2 Quantitative data collection

4.2.1 Data on general practices

The following information was requested from each practice:

- Practice list size
- Age-sex breakdown of practice list with age divided into four bands (0-14, 15-64, 65-74, ≥75 years)
- Number, gender and type of GPs (and other prescribers) in the practice
- Whether or not the practice was a GP training practice
- Whether or not the practice was a dispensing practice
- Deprivation score (based on combined Index Multiple Deprivation 2007)
- Whether the practice was urban or rural
- Practice performance in the quality and outcomes framework:
 - medicines management points, and
 - overall scores
- Clinical computer system used within the practice.

4.2.2 Collection of data to assess the prevalence and nature of medication errors

In each participating general practice, a 2% random sample of patients was selected using computer-generated random numbers. Between August 2010 and April 2011, the pharmacists undertook a thorough review of the medical records of these patients to identify potential prescribing and monitoring errors for each unique prescription item issued in the 12 months prior to the data collection date (n.b. for prescription items that had been issued more than once during the 12-month period, only the latest prescription was assessed). We asked pharmacists to err on the side of being overly-inclusive in identifying possible errors; it was then the role of the research team to decide whether these fitted our pre-specified classification for prescribing and monitoring errors.

We asked the pharmacists to record data on specially developed data collection forms (shown in **Appendix 2**, **Appendix 3**, **Appendix 4**, **Appendix 5** and **Appendix 6**):

- **Appendix 2** presents the form used to record data on the demographics of each patient and all the unique prescription items that they had received in the 12 months prior to data collection
- **Appendix 3** presents the form used to record details of any potential prescribing or monitoring errors identified
- **Appendix 4** presents the form used to record details of any omission errors relating to failure to prescribe for an existing condition
- **Appendix 5** presents the form used to record data relating to medicines reconciliation for patients with a hospital discharge communication in the 12 months prior to data collection.

Definition and classification of prescribing and monitoring errors

A prescribing error in this study was defined as follows¹¹:

“A prescribing error occurs when, as a result of a prescribing decision or prescription-writing process, there is an unintentional, significant: reduction in the probability of treatment being timely and effective

or

increase in the risk of harm when compared to generally accepted practice.”

This definition is accompanied by a list of examples of what should, and should not, be included as an error¹¹.

In addition, the following definition was used for a monitoring error, based on that of Alldred et al²⁵:

“A monitoring error occurs when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. It includes the absence of tests being carried out at the frequency listed in the criteria, with tolerance of +50%. This means for example, that if a drug requires liver function tests at 6 monthly intervals, we would class as an error if a test has not been conducted within 9 months. If a patient refused to give consent for a test, then this would not constitute an error”.

When identifying potential monitoring errors, the pharmacists were asked to refer to a list we created of medicines needing blood test monitoring. This list is shown in Appendix 6.

Classification of different types of error

In addition to identifying potential prescribing and monitoring errors, the pharmacists were asked to classify these into different types of error. These are shown in **Box 1**.

4.3. Identifying errors and other types of prescribing problem

Each potential error identified by the pharmacists was discussed by a multidisciplinary error judging panel (including a GP (AA), a clinical pharmacologist (AF) and three pharmacists (NB, BDF and MG)) using the above definitions. In addition, it became apparent that there were some problems that did not fit within our error definition, but nevertheless represented less than ideal practice. We created a category of “suboptimal prescribing” for these problems. The pharmacists also identified prescriptions associated with legal issues, but which did not fall into our definitions of error; these were given a separate category of “legal problem”.

Over the course of the project, the error judging panel had 15 meetings by teleconference, usually of an hour in length. Prior to each meeting a set of the potential errors was sent round the team. The panel came to a consensus decision on whether the potential error should be classified as:

- Prescribing error
- Monitoring error
- Sub optimal prescribing
- Legal problem
- No problem

In addition, the panel agreed on whether the classification of the type of error, or problem, recorded by the pharmacist (see Box 1) was appropriate, and corrected this where necessary.

In the vast majority of cases, the pharmacists provided sufficient information for the panel to make a judgement. Where this was not the case, we asked the pharmacist to go back and provide further details.

During the study, as a result of the discussions of the error judging panel, we developed a more detailed list of “case law”, describing what should, and should not, be included as an error, together with justification of these decisions(see **Appendix 7**). This cumulative document was referred to as the study evolved, to ensure that our judgements were consistent and appropriate. The following principles were established:

- More than one error could be recorded per prescription.
- If an overdose involved the addition of more than one prescribed item, e.g. a mixture of 50 mg and 100 mg tablets, the error was counted only once.
- To avoid duplication of errors in the database, any drug interaction error was recorded against the second of the two drugs prescribed.
- Potential errors from dispensing practices were judged in the same way as those from non-dispensing practices.
- The use of Latin on prescriptions was judged not to be a problem as it was assumed that these instructions would be converted to English by a pharmacist or dispenser.
- If a case involved a dosing error and a frequency error, this was recorded as just one error: a ‘dose/strength’ error.
- No error was recorded if lack of information made it impossible to make a valid judgement on whether or not an error has taken place.

Box 1: Classification of different types of errors

Prescribing errors	Monitoring errors
1. Unnecessary drug	1 Monitoring not requested
2 Incorrect drug	2 Requested but not done
3 Duplication	3 Results not available
4 Allergy error	4 Results not acted upon
5 Contraindication error	
6 Interaction error	
7 Dose/strength error	
8 Formulation error	
9 Frequency error	
10 Timing error	
11 Information incomplete	
12 Generic/brand name error	
13 Omission error relating to failure to prescribe concomitant treatment	
14 Not classified	
15 Inadequate documentation in medical records ^a	
16 Quantity error ^a	
17 Inadequate review ^a	
18 Duration error ^a	

^a These classification categories were added after discovering types of error that did not fit into those initially listed as 1-13.

4.4 Collection of data on potential omission errors relating to not prescribing for an existing condition

The pharmacists collected data using a specially developed form (see **Appendix 4**) to identify potential omission errors relating to failure to prescribe for an existing condition. An example might be failure to prescribe a statin to a patient with coronary heart disease.

4.5 Collection of data on discrepancies and potential errors relating to hospital discharge communications

The pharmacists used another specially developed form (see **Appendix 5**) to record detailed information on medicines reconciliation on patients who had been discharged from hospital during the 12-month data collection period. The latest hospital discharge was used if patients had more than one during the 12-months.

4.6 Data entry

All data received from the 15 participating general practices were entered into a Microsoft Access database using custom made forms. The forms were designed to fit the style of the actual hard paper copies of the data collection forms used by the pharmacists when collecting data from the patient records reviewed in each practice. For example, **Figure 2** shows a sample form used to enter patient demographic information onto the database (see **Appendix 2** for comparison with the paper form). This information included practice identity code, patient identity code, age, gender and number of months the patient was registered at the practice. The form also had a drop-down menu for entering all the prescriptions issued to the patient during the 12 months review period of the study. For each prescription, we were able to enter information on the type of prescriber (e.g. GP partner, locum, non-medical prescriber, etc), whether the medicine prescribed was a repeat or acute prescription, whether or not the medication was on a list we created of drugs requiring blood-test monitoring (see **Appendix 6**), and whether the pharmacist identified a potential prescribing or monitoring error.

For every medicine with a potential error, we entered information on a custom-made form (Figure 3), which was similar to the form shown in **Appendix 3**. On this form, we captured information pertaining to the name, formulation, strength, quantity and dose of the prescribed medicine. We transcribed the description of the potential problem and potential explanations for why the error might have occurred, as recorded by the pharmacists collecting data. We entered information on whether the problem was a single or multiple event, associated with an adverse event or had been reported to the PCT or NPSA. We also specified the actual error classification determined by our multidisciplinary error judging panel (i.e. prescribing error, monitoring error, suboptimal prescribing, legal error or not an error).

GMC Input - Form 1 - Microsoft Access

Home Create External Data Database Tools

View Paste Copy Format Painter Font Rich Text Refresh All Save Spelling Filter Selection Advanced Size to Fit Form Windows Switch Windows Find Replace Go To Select Find

FORM 1: Prescribing Record Sheet

Previous Add Record Next Delete Record Search Query

Database Unique Id Number: 61 Date: 30-Sep-10 Form 3

Initials of pharmacist doing review: GG Male Female 1 Form 4

Practice ID Code: N2 Age: Years: 88 Months: 0 Form 5b

Patient ID Code: 7212

Months registered with practice during the data collection period: 12

If no prescriptions for this patient, tick here and move on to next patient

RX ID	Drug name/form/Chapter/Section		Is this drug on the drug monitoring list		Acute (A) or Repeat (R)		GP Type	No. of possible RX error(s)	No. of possible monitoring error(s)
			Yes	No	A	R			
F2 FS 438 447	Coro-Nitro Pump Spray®	Aerosol spray	2	2.6.1	<input type="radio"/>	<input checked="" type="radio"/>	GP partner	1	0
F2 FS 439 1055	Aspirin	Tablets	4	4.7.1	<input type="radio"/>	<input checked="" type="radio"/>	GP partner	1	0
F2 FS 440 77	Lansoprazole	Capsules	1	1.3.5	<input type="radio"/>	<input checked="" type="radio"/>	GP partner	1	0
F2 FS 441 634	Simvastatin	Tablets	2	2.1.2	<input type="radio"/>	<input checked="" type="radio"/>	GP partner	1	1
F2 FS 442 2767	Xalatan®	Eye drops	11	11.6	<input type="radio"/>	<input checked="" type="radio"/>	GP partner	1	0
F2 FS 443 245	Furosemide	Tablets	2	2.2.2	<input type="radio"/>	<input checked="" type="radio"/>	GP partner	1	0
F2 FS 444 412	Ramipril	Tablets	2	2.5.5	<input type="radio"/>	<input checked="" type="radio"/>	GP partner	1	0

Form View Num Lock

Figure 2: Example of a Microsoft Access data entry screen for recording patient demographics and prescriptions

Form 2

FORM 2: Prescribing and Monitoring Errors

Previous Add Record Next Delete Record Number of Records 1 of 1

ID Error: 256 RX ID: 225 Drug: 2641 Methotrexate Tablets 10 10.1.3

Strength: 2.5mg tablets

Dosage Instructions: 2.5mg tablets (ten tablets) weekly

Quantity: 40

Initials of Prescriber: MCL

Error Code: Monitoring not requested 21

Has the error been classified? Yes No 2

Classified Comments:

Classification: Not an error Sub-optimal prescribing legal error Prescribing error Monitoring error 5

1) Please describe the potential error
 Methotrexate was started by the practice 8-6-2009. LFTs and FBCs have been done regularly. U+E have only been checked 3-8-2010 and 20-2-2008. Therefore the U+E test is missing around Dec 2009 according to research protocol. Letter dated 19-1-2010 says as he been on methotrexate for a year he can go to 3monthly as per shared protocol.

2) Was the potential error a single event? Yes No 2

3) if the potential error has been repeated, how many weeks / months / years has the error been repeated over?
 Weeks Months Years

4) Why do you think the error occurred? and what happened in the lead up to the error?

5) Has there been any adverse event associated with the possible error? Yes No Uncertain 3

6) If you think there may have been an adverse event associated with the error, please describe this below:

Q7) Was the error reported through the PCT normal reporting procedure? Yes No Unknown 1

Q8) Was the error reported to the NPSA? Yes No Unknown 1

Q9) Is there any evidence that the error has been rectified? Yes No Unknown 1

Figure 3: Example of a Microsoft Access data entry screen for recording detailed information on possible prescribing errors.

4.7 Data cleaning

Firstly, we reconciled the number of patient information forms received from each practice (and entered on the Access database) with the actual list of (anonymised) patients randomly selected by the pharmacists for review. We physically counted all patient information forms received and checked to ensure that these represented a 2% sample of all patients registered at the practice, and that all forms received had been accounted for and uploaded on to the database.

Secondly, we carefully checked for errors in data entry. For instance, we listed all patient and practice identity codes for each practice and cross checked whether these matched information on the physical forms. We did the same for other demographic information like patient age and gender. Where such information was missing on the physical forms, we contacted the practices directly to provide this information.

Furthermore, we checked for potential inconsistencies in patient information. For example, we checked for patients whose age was listed as greater than 100 years or less than 1 year. We confirmed whether this was consistent with the actual patient information forms and corrected any errors. We also checked to confirm that all patients with prescriptions for gender-specific medications had been assigned the correct gender. For instance we checked that patients with prescriptions for female hormonal contraceptives (e.g. Microgynon®) had been assigned female in the Access database. We examined whether patients with a potential monitoring error had been prescribed medicines on the BNF monitoring list. We created additional queries in Microsoft Access to summarise details of all potential medication errors in order to ensure that there was no duplication; that all errors had been reviewed by our multidisciplinary panel and that the relevant information had been updated or added to the database. The classification of any medication associated with a possible error was checked by carefully reviewing the information on the database in relation to recorded judgements made by the expert panel.

Thirdly, we conducted a detailed review of 20 randomly selected data entry forms to assess the frequency of data entry errors. This was found to be greater than 1% and so we employed a pharmacist to carefully check the data entry for all forms and make amendments where appropriate. A detailed log was created of any changes made as a result of this exercise.

4.8 Data extraction

We generated a unique database number for each patient in the database by concatenating the patient ID number with the practice ID number. We designed an update query to generate a table of patient demographic information which was then exported into Stata Version 11.2. We then wrote a series of Microsoft Access queries to extract further information from the Access database. These queries included information per patient on:

- Number of drugs prescribed in the 12 months review period,
- Number of drugs on the monitoring list
- Number of acute prescriptions
- Number of repeat prescription

- Number of prescribing errors, monitoring errors, legal errors, suboptimal prescribing
- Number of types of prescribers.

We merged in turn, each of these queries onto the main patient demographics table to create a complete dataset of patient level information. To this we added information on the type of computer system, rural-urban score, deprivation score, patient list size and the pharmacist who collected information for each patient.

To create a prescription level dataset, we wrote a selection query in Microsoft Access to extract all information on the medicines reviewed. This query included information on the name, strength, quantity, formulation, BNF drug class, BNF drug section, for each medicine. In addition, it captured information on the types of problem associated with the prescription (if any). It also included relevant patient level information like age, gender and unique patient and practice ID codes, as well as information on whether the prescription was issued as a repeat or acute medicine. We exported this query into Stata for further analysis.

4.9 Assessing the severity of the prescribing errors

We used a validated method for assessing the severity of medication errors²⁶, adapted for use with prescribing errors²⁷. Briefly, this involves a panel of five judges each assessing each error in terms of potential clinical importance, using a visual analogue scale. The scale is numbered from zero to 10, where a score of zero represents an error with no potential effects on the patient, and 10 an error that would result in death. Errors with a score of less than 3 are considered to be minor, errors with a score from 3 to 7 inclusive are classified as moderate, and errors with a score greater than 7 are severe.

To assess severity, we identified all prescribing and monitoring errors in the study database. Legal issues were excluded from this analysis, as these were assumed, by definition, to have no clinical significance. A brief description of each error was then produced, describing the age of the patient if relevant, as well as the prescribed drug, dose and strength, and presented alongside a copy of the visual analogue scale (see Appendix 8). Errors that were duplicates of each other were grouped so that only one of the errors was assessed, in order to minimise the judges' workload. For example, we

had multiple errors involving simvastatin being prescribed to be taken “daily” instead of “at night”; the judges assessed only one of these and the resulting score was later applied to each error of this type.

We used a panel comprising two pharmacists and three doctors (two GPs and one clinical pharmacologist), who were each given a £200 gift voucher as reimbursement for their time.

For each error description, the mean score across all five judges was calculated using Microsoft Excel and used as an index of severity²⁶. The mean severity score for each error was added to the Microsoft Access database and each data entry item was double-checked by a pharmacist who made amendments where appropriate. A log was created of any corrections made as a result of this exercise. Data were exported to SPSS 16 for further analysis.

4.10 Quantitative data analysis

The data were analysed based on a framework designed by the research team. This is outlined in Appendix 9.

Most of the data analysis was undertaken in Stata, Version 11.2 (apart from the analysis of severity scores which was done using Microsoft Excel and SPSS Version 16).

Descriptive statistics were produced for a wide range of variables relating to:

- Characteristics of the general practices
- Characteristics of the patients
- Characteristics of the prescribers
- Characteristics of the prescriptions examined
- The types of medication problem identified
- The types of medication error
- Medications and British National Formulary chapters associated with different types of medication error
- Severity scores for errors, including percentage classified as minor, moderate and severe.

Categorical variables were described using frequencies and percentages, and means and standard deviations (SD) or medians and interquartile ranges (IQR) were used to summarise continuous variables, depending on the normality of their distribution.

Multivariable analyses modelling the relationships between the risk of error and selected predictor variables and a priori confounders were performed at the patient and at the prescription-level. The outcome measures were binary variables indicating the presence of one or more prescribing or monitoring errors. Mixed effects logistic regression models were used to estimate odds ratios and 95% confidence intervals (CI). Further details are provided in Chapter 6 and **Appendix 9**.

Chapter 5: Methods used to explore the causes of error and associated defences

This chapter provides details of the methods used for:

- Face-to-face interviews
- Focus groups
- Root cause analysis

The characteristics of the participants for the interviews and focus groups are also provided.

5.1 Selection of participants for face-to-face interviews

Members of the research team (AA and MG) examined the potential errors identified by the pharmacists and selected examples to be discussed at face-to-face interviews with prescribers. A wide range of different types of potential errors were purposefully selected including:

- Those that were considered particularly serious
- Different types of potential prescribing and monitoring errors, including a wide range of examples of these (**Box 1**)
- Potential errors involving problems at the primary/secondary care interface
- Less serious problems, where GPs might wish to debate whether or not an error has taken place.

Potential participants for the interviews were contacted by letter and were provided with an information sheet (**Appendix 10**). Prior to interview participants gave informed written consent.

5.2 Selection of participants for focus groups

We wrote to each of the general practices involved in the study and invited staff to attend one of six focus groups; we asked that staff representing a variety of different types of practice personnel attend.

Potential focus group participants were provided with an information sheet (**Appendix 11**) and prior to the focus group all gave informed written consent.

5.3 Interview schedule for the face-to-face interviews

The interview schedule for the face-to-face interviews (**Appendix 12**) consisted of open-ended questions aimed at exploring the underlying reasons for medication errors. Questions and prompts included in the interview schedule were designed to elicit information on the following issues:

- A detailed discussion of the potential errors identified
- Prescribers' therapeutic training and knowledge
- Patients' characteristics of the potential influence of these on error
- Prescribers' knowledge of the patient
- The way prescribing tasks are organised and structured, including the use of information technology
- Workload and the responsibility for prescribing specialist drugs
- Team structure and communication
- Individual factors relating to the prescriber
- Safeguards that were felt to be particularly important in preventing prescribing or monitoring errors.

5.4 Interview schedule for the focus groups

The interview schedule for the focus groups is shown in **Appendix 13**. The main issues explored in the focus groups were:

- Safeguards in general practice to protect patient against potential harm
- Reporting prescribing errors in general practice
- General practice safety culture.

5.5 Training the interviewees

The research pharmacists who collected data on potential medication errors in the study practices were given training in conducting semi-structured interviews. This training involved instruction in human error theory⁹, instruction in the use of the interview topic

guide (**Appendix 12**), and practical experience of using the interview topic guide in a simulated interview.

5.6 Conducting the interviews

Most of the interviews were conducted by the same research pharmacists who collected data on potential errors in the study practices, although five were conducted by members of the research team (three by AA and two by MG).

Prior to interview, each participant was contacted to arrange a mutually convenient time to meet and provided with an opportunity to ask questions about the study. All participants completed a consent form.

Before the interviews commenced, each participant was asked if they were willing to be audio-taped and reassured that any information supplied would be treated in the strictest of confidence. Thirty-two semi-structured interviews (out of a total of thirty-four) were audio-taped with permission.

Participants were encouraged to speak freely during the interviews without disruption, even if this impacted on the planned flow of the interview schedule. Areas which were not covered, or required further exploration, were followed up later in the interview. All participants were asked towards the end of the interview if there was anything else they would like to add to increase understanding of the issues discussed.

5.7 Conducting the focus groups

Six focus groups were arranged. After obtaining written informed consent and giving a brief introduction one member of the research team (either AA, NB, SC or MG) led the discussions while another member of the team kept note of the contributions made by each participant so that it was possible subsequently to attribute comments made when transcribing the audio recordings. Participants were encouraged to speak openly and to engage in discussion and debate around issues raised.

5.8 Location of interviews and focus groups

The interviews and focus groups took place between October 2010 and May 2011 involving 15 general practices from three Primary Care Trusts in England. All interviews took place in a location of the interviewee's choice (usually the interviewee's own office)

and without the presence of any other individual or member of practice staff. An unoccupied meeting room was almost always selected by practice staff as the location for the focus groups, with little disruption. The focus groups also took place in general practice premises.

5.9 Interview and focus group participants

A summary of participant details, including identification code and experience, is given in **Table 1** and **Table 2**.

The participant identification code is in a format that allows for identification of the characteristics of the interviewees whereby the first part of the code identifies the practice, e.g. PR1, and the second part the type of participant, e.g. GP1 (the first GP interviewed in that particular practice). The abbreviations used for different types of participant are as follows:

- GP = General Practitioner
- Comm Pharm = Community Pharmacist
- Med Stud = Medical Student
- GP Reg = GP Registrar
- PCT Pharm = PCT Pharmacist
- Presc Clerk = Prescribing Clerk
- Prac Manager = Practice Manager
- Rec Manager = Receptionist Manager
- Snr Recep = Senior Receptionist.

For example a participant with the code 'PR13-GP3' would be the third general practitioner interviewed in practice 13.

5.10.1 Interview Participants

A total of 34 participants were interviewed (see **Table 1**). Of these, 20 (59%) were male. Twenty-eight (82%) of the participants had completed their undergraduate training in the UK, while the other six (18%) had studied elsewhere (Australia, India, Italy, Nigeria and Sri Lanka).

The median number of years these participants had worked as GPs was 20 (IQR 12 – 23; range 1 - 30), and 13 (38%) worked part time.

Thirty-eight (85%) of the participants were GP partners (with nine of these describing themselves as senior partners), four (12%) were salaried GPs, and one (3%) was a nurse prescriber.

The median length of time of the interviews was 24 minutes (IQR 14.3 – 32.1; range 6.4 – 46.4).

Table 1 provides further details of each of the interview participants. It can be seen that, in total, 70 errors were discussed with participants.

5.10.2 Focus Group Participants

Table 2 shows summarises the participants contributing to the six focus groups. In total there were 46 participants across the six focus groups with 18 (39%) being GPs, seven (15%) nurses, seven (15%) reception staff, and 14 (30%) other staff. These other staff comprised: three dispensers, three prescription clerks, two practice managers, and one each of the following: community pharmacist, GP registrar, medical student, PCT pharmacist, reception manager, and senior receptionist. Of the 46 focus group participants, 35 (76%) were female.

Table 1: Characteristics of the interview participants

Interview Label	Length of audio recording (minutes)	Sex^a	Medical School	Decade Qualified^b	Clinical interests/speciality	Number Years worked in profession^c	Role within practice	Working Hours^d	Number of potential errors discussed
PR1-GP1	68.0	M	London	1980s	Prescribing advisor	15-19	GP partner	F/T	4
PR1-GP2	36.0	M	Leicester	2000s	Men's health, Dermatology	<5	GP partner	F/T	1
PR2-GP1	21.0	F	Nottingham	1980s	Gynaecology, Depression	25-29	GP partner	P/T	1
PR2-GP2	31.3	F	Nottingham	2000s	Women's Health & Children	5-9	GP Partner	P/T	2
PR2-GP3	39.4	M	Nottingham	1970s	Minor surgery/ injections	20-24	GP partner	F/T	3
PR3-GP1	41.2	M	Nottingham	1980s	Psychiatry / ENT	20-24	GP partner	F/T	2
PR3-GP2	30.4	F	Nottingham	1980s	Gynaecology	25-29	GP partner	P/T	2
PR4-GP1	46.4	M	Nottingham	1990s	None	10-14	GP partner	P/T	2
PR4-GP2	45.5	F	London	1990s	Palliative Care, Contraception, Diabetic	10-14	GP partner	P/T	3
PR5-GP1	19.5	F	London	1980s	Women's Health & Children, Sexual, Mental	20-24	GP Partner	P/T	2
PR5-GP2	29.3	M	London	1980s	Alcohol, Mental health	20-24	Senior GP Partner	F/T	2
PR5-GP3	22.3	F	Sheffield	1980s	None volunteered	10-14	Salaried GP	P/T	1
PR5-GP4	25.6	M	Nottingham	1980s	None volunteered	15-19	GP partner	P/T	0
PR6-GP1	34.5	F	Edinburgh	2000s	Gynaecology, Dermatology	<5	GP Partner	P/T	3
PR6-GP2	29.4	F	Colombo, Sri Lanka	2000s	Gynaecology	5-9	GP Partner	F/T	2
PR6-GP3	12.3	F	Luton	1990s	None recorded	10-14	Nurse Prescriber	F/T	1
PR6-GP4	10.1	F	London	1980s	Paediatrics, Diabetes	10-14	GP Partner	F/T	1
PR7-GP1	26.6	M	Newcastle	1980s	Skin surgery	15-19	GP Partner	P/T	1
PR7-GP2	7.3	M	Newcastle	1980s	Sports medicine, ENT, Diabetes, Orthopaedics	15-19	GP Partner	F/T	1

Interview Label	Length of audio recording (minutes)	Sex ^a	Medical School	Decade Qualified ^b	Clinical interests/speciality	Number Years worked in profession ^c	Role within practice	Working Hours ^d	Number of potential errors discussed
PR7-NU1	27.3	M	Glasgow	1970s	Chronic diseases	20-24	Senior GP Partner	F/T	2
PR7-GP3	45.3	F	Newcastle	1980s	Medicines Management	20-24	GP Partner	P/T	5
PR8-GP1	26.0	M	Liverpool	1980s	Gynaecology	25-29	Senior GP Partner	F/T	2
PR9-GP1	22.3	F	Leeds	1980s	Gynaecology	25-29	Senior GP Partner	F/T	5
PR10-GP1	19.5	M	Italy	1990s	Asthma, COPD, Diabetes	20-24	Senior GP Partner, Clinical Lead	F/T	3
PR10-GP2	16.1	M	India	1970s	None volunteered	30-34	Senior GP Partner	F/T	1
PR11-GP1	N/A	M	London	1970s	None volunteered	25-29	Senior GP Partner	F/T	1
PR11-GP2	N/A	F	Cambridge	1980s	Women's Health & Children	20-24	Senior GP Partner	F/T	1
PR12-GP1	10.3	M	Australia	2000s	None	<5	GP Partner	F/T	1
PR12-GP2	12.5	M	London	1980s	None	25-29	GP Partner	F/T	4
PR13-GP1	13.5	M	Cambridge	1970s	Gastroenterology, Muscular-Skeletal	25-29	Senior GP Partner	F/T	2
PR13-GP2	13.3	M	Italy	1970s	Paediatrics	20-24	GP Partner	F/T	3
PR14-GP1	14.6	M	Sheffield	2000s	Diabetes, Dermatology	<5	Salaried GP	P/T	3
PR14-GP2	19.2	M	Nigeria	1990s	Minor surgery, CVD	5-9	Salaried GP	F/T	2
PR14-GP3	6.4	F	London	1980s	Women's Health	20-24	Salaried GP, Clinical Lead	P/T	1

^a M=male; F=female; ^b Actual dates of qualification are not given in order to preserve anonymity; ^c actual number of years in the profession are not given in order to preserve anonymity; ^d FT=Full-time; PT=Part-time.

Table 2: Summary of participants contributing to the six focus groups

Focus group Number	Length of focus group in minutes	Number of participants in each focus group	Number of GPs	Number of nurses	Number of reception staff	Number of other Staff
FG1	42	7	3	0	1	3
FG2	56	9	3	2	0	4
FG3	60	9	4	1	1	3
FG4	72	7	3	1	2	1
FG5	45	5	2	1	1	1
FG6	35	9	3	2	2	2
Total	Not applicable	46	18	7	7	14

5.11 Transcription of interviews and focus groups

All audiotaped interviews and focus groups were transcribed verbatim by a trained transcriber. Any personal details or information, which could lead to a participant being identified, were removed at the data transcription stage and an identification number applied as discussed in the previous section. All transcribed interviews and focus groups were re-checked for accuracy by a second member of staff (CR). Interviewees were given the opportunity to review their transcripts, but this offer was taken up in only one case and there was no dispute about the contents.

5.12 Qualitative data analysis

This section discusses the analysis of data from both the semi-structured interviews and focus groups. A robust and complete analysis was carried out using the framework provided by Reason's Accident Causation Model⁹.

This systematic and rigorous process was initiated and concurrent with data collection. Throughout the interviewing process, and in discussion with members of the research team (AA and MG) the interviewers thought about the data being gathered, refined questions, pursued ideas and investigated further areas in greater depth.

On completing data collection, we reviewed and sorted the data to make it more manageable. This involved reading and re-reading the transcripts, and identifying themes within each transcript, a concept known as 'content analysis'²⁸. Consideration

was given throughout this analysis to the study objectives and the identified themes of 'prescribing responsibility', 'safety culture', and 'safeguards and defences'.

5.12.1 Identifying a Conceptual Framework

Two members of the team (SC, TA) then generated an index or 'conceptual framework'²⁸ by which the raw data could be labelled and sorted. Development of the conceptual framework or index involved identifying the recurring themes and concepts in the transcripts together with terms used in the interview schedules and surrounding literature. A workable list of main- and sub-themes was developed and applied systematically to the whole data set by three researchers (SC, RH, MG) with the aid of the computerised qualitative data analysis software QSR N-Vivo version 8.0. The field notes taken those interviews, which were not digitally-recorded, were also coded and analysed. The index was then mapped to the categories outlined in Reason's Accident Causation Model, and the coded data were then sorted and synthesised by grouping data with similar content together under the different themes and sub-themes.

5.12.2 Mapping and Interpretation

Two researchers (SC, RH) synthesised the main findings by looking across all practices for data coded against a particular theme, for example 'patients' characteristics', and understanding the range of views and experiences shared by interviewees. The researchers began to build explanations for the recurring patterns and associations in the data. This process involved interrogating the dataset as a whole to identify linkages between sets of phenomena and exploring why such linkages occurred. These linkages were displayed on a series of maps (SC) or memos (RH) to further improve understanding and clarity. For example, **Figure 4** illustrates the multiple error-producing conditions within the category of 'The Prescriber' that were perceived to contribute to an increased risk of prescribing errors. The researcher moved backwards and forwards between the data, using the 'constant comparison' technique, and evolving explanations, until a fit was clearly made. Participants' own reasons for particular phenomena were investigated and the diversity of their explanations explored.

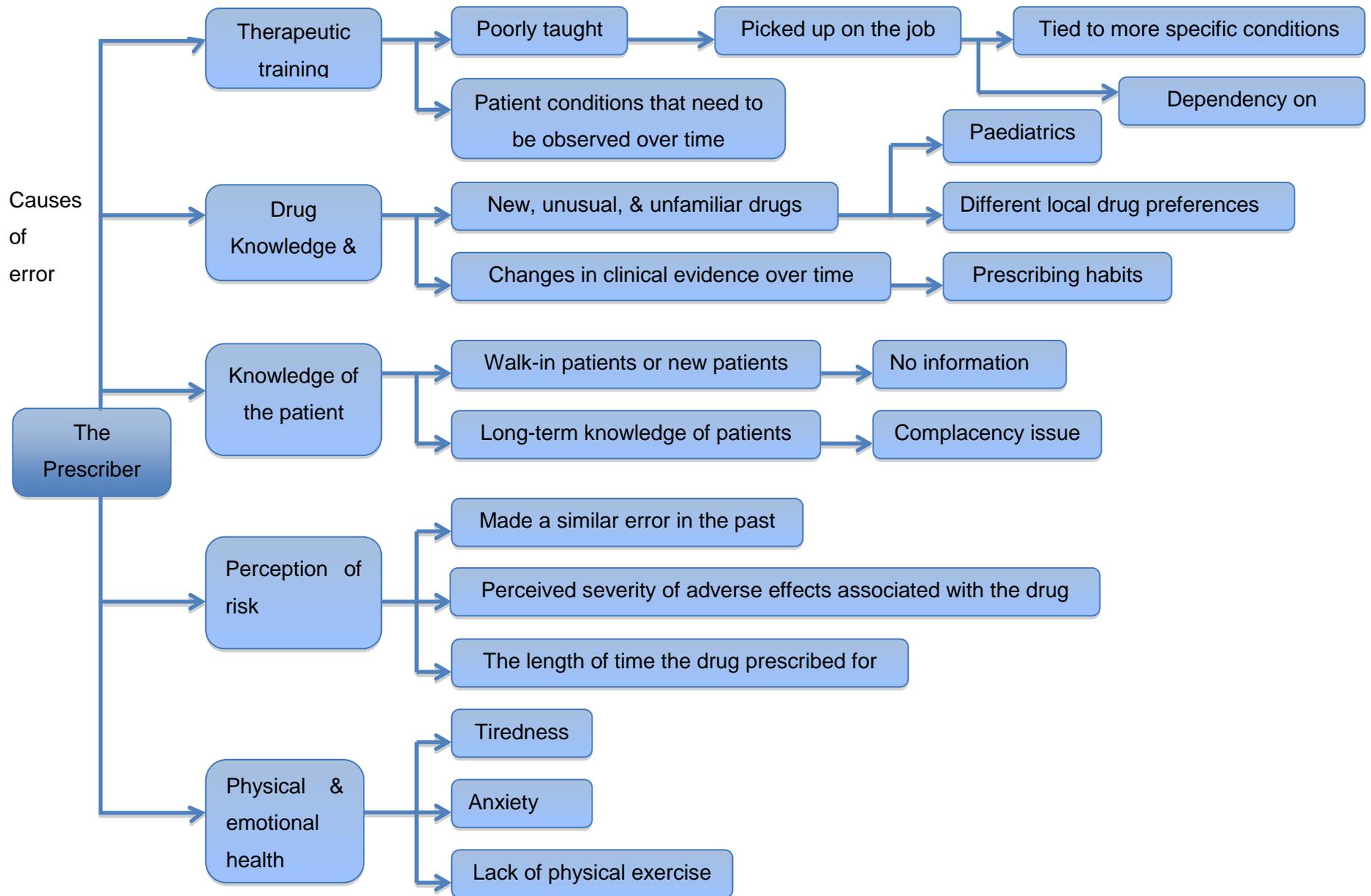


Figure 4: A Map illustrating the multiple error-producing conditions within the category of 'The prescriber'.

5.13 Root Cause Analysis

Root Cause Analysis (RCA) offers a thorough and systematic approach through which the root cause(s) of a patient safety incident can be identified. With this information, solutions can be developed and implemented to reduce the chances of those incidents occurring again.

The pharmacists involved in collecting data in the practices were given training on how to conduct root cause analysis, based on materials available on the NPSA website (<http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/>).

The following approach was taken:

- 1) Identification of the problems. The study team selected a range of the prescribing and monitoring errors that had been identified by the pharmacists in order to cover different types of error and to focus on some of the more serious errors.
- 2) Gathering information. The following approaches were used: detailed review of patients' medical record; interviews with GPs, practice staff and sometimes hospital and community pharmacy staff; examination of protocols and guidance (from the practices themselves, local health communities, or nationally).
- 3) Mapping information. The pharmacists were encouraged to create a chronological narrative of the events associated with the error.
- 4) Analysing information. The pharmacists were asked to undertake a comprehensive review of the evidence in relation to the errors, to identify contributory factors and root causes, and to consider this in the light of local and national procedures and policies.
- 5) Generating solutions. The pharmacists were asked to suggest ways in which similar errors might be prevented in the future.

The pharmacists documented the RCAs and the research team then analysed these to summarise the cases; to identify themes arising from the RCAs, and to consider these in the light of the findings from the analysis of interviews and focus groups.

Chapter 6: The prevalence and nature of medication errors

Summary

The study involved examination of the records of 1,777 patients. Of these, 1,200 (67.5%) had at least one prescription during the 12 month retrospective review of their records.

Collectively, the pharmacists reviewed 6,048 unique prescription items and the following numbers of medication problems were detected: 247 prescribing errors; 55 monitoring errors; 427 examples of sub optimal prescribing, and eight legal problems.

The prevalence of prescribing or monitoring errors for different groups of patients over the 12 month data collection period was as follows:

- All patients (n=1,777): 12% (95% CI 10.5%-13.6%)
- Patients who had received at least one medication (n=1,200): 17.8% (95% CI 15.7%-20%)
- Patients aged 75 years and older who had received at least one medication (n=129): 38% (95% CI 29.5%-46.5%)
- Patients who had received five or more drugs over the data collection period (n=471): 30.1% (95% CI 26.6%-35%)
- Patients who had received 10 or more drugs over the data collection period (n=172): 47% (95% CI 39%-54%)

The prevalence of prescriptions with prescribing or monitoring errors was 4.9% (95% confidence intervals (CI) 4.4%-5.4%). The most common types of prescribing error were 'incomplete information on the prescription' (77; 31.2%); 'dose/strength errors' (43; 17.4%) and timing errors (26; 10.5%). The most common type of monitoring error was 'failure to request monitoring' (38; 69.1%).

The severity of the 302 errors was judged on a validated 0-10 scale (0=no risk of harm; 10=death): 128 (42.4%) were deemed to be minor; 163 (54.0%) moderate; and 11 (3.6%) severe. Thus, 0.18% of all prescriptions (11/6048, or one in 550) were associated with severe error.

Summary Continued

Modelling of associations between prescribing and monitoring errors (compared with no prescribing or monitoring problems) was undertaken at the patient-level and the prescription-level using mixed effects logistic regression techniques. The following significant associations were found in the patient-level model:

- For each additional unique medication item that the patient had received over the course of the 12 month retrospective data collection there was 16% increased risk of error (odds ratio 1.16, 95%CI 1.12-1.19, $P < 0.001$)
- Women were less likely than men to have a medication error (odds ratio 0.66, 95%CI 0.48-0.92, $P = 0.013$)
- The following age groups were more likely (than age group 15-64 years) to have a medication error:
 - 0-14, odds ratio 1.87 (95%CI 1.19-2.94, $P = 0.006$)
 - 65-74, odds ratio 1.68 (95%CI 1.04-2.73, $P = 0.035$)
 - ≥ 75 , odds ratio 1.95 (95%CI 1.19-3.19, $P = 0.008$)
- Compared with a list size of 5000-10,000, patients in practices with a list size of $> 10,000$ had reduced risk of error: odds ratio 0.56 (95%CI 0.31-0.99, $P = 0.47$)

The following significant associations were found in the prescription-level model:

- For drugs on the monitoring list there was an increased risk of error (odds ratio 3.18, $P < 0.001$)
- For the following drug groups (compared with gastrointestinal drugs) there was an increased risk of error:
 - Cardiovascular (odds ratio 2.37, 95%CI 1.03-5.45, $P = 0.042$)
 - Infections (odds ratio 2.67, 95%CI 1.17-6.11, $P = 0.02$)
 - Malignant disease and immunosuppression (odds ratios 6.77, 95%CI 1.71-26.84, $P = 0.006$)
 - Musculoskeletal (odds ratio 6.97 95%CI 3.06-15.88, $P < 0.001$)
 - Eye (odds ratio 4.92, 95%CI 1.12-21.62, $P = 0.035$)
 - ENT odds ratio 4.6, 95%CI 1.29-16.42, $P = 0.019$)
 - Skin (odds ratio 5.78, 95%CI 2.04-16.36, $P = 0.001$)

6.1 Sample characteristics

The following subsections provide details of the characteristics of the general practices, the patients, the prescriptions and the prescribers prior to any analysis of errors.

6.1.1 Characteristics of general practices

The characteristics of the 15 general practices involved in the PRACtICe study are shown in **Table 3**.

Key points are highlighted below:

- The mean list size was 5,916 (standard deviation: 3,014); the smallest practice had 1,600 patients and the largest 11,984.
- Ten (66.7%) of the practices were involved in GP training.
- Two (13.3%) practices were dispensing.

Key characteristics of the practices are compared informally in **Table 4** with national figures for England. General practices involved in the PRACtICe study were similar to other English practices in terms of mean list size and number of GPs and Quality and Outcomes Framework scores. The general practices involved in the PRACtICe study appeared to have higher deprivation levels.

Table 3: Characteristics of the 15 English general practices involved in the PRACtICE study

GP Practice code ^a	Practice list size ^b	Is the practice a GP training practice?	Deprivation score ^c	Is the practice urban or rural?	Whether a dispensing practice?	Clinical computer system used within the practice
PR1	10,500	No	12.6	Rural	No	EMIS LV
PR2	7,100	Yes	17.48	Rural	Yes	EMIS LV
PR3	5,300	No	6.62	Rural	Yes	EMIS LV
PR4	8,800	Yes	16.53	Urban	No	TPP SystmOne
PR5	5,000	Yes	4.23	Urban	No	EMIS LV
PR6	12,000	Yes	43.23	Urban	No	Isoft Premiere
PR7	3,500	Yes	7.93	Urban	No	EMIS LV
PR8	1,600	Yes	38.74	Urban	No	TPP SystmOne
PR9	9,400	No	18.33	Urban	No	EMIS PCS
PR10	4,200	No	47.51	Urban	No	EMIS PCS
PR11	6,000	Yes	44.23	Urban	No	EMIS PCS
PR12	3,300	Yes	53.99	Urban	No	EMIS PCS
PR13	4,700	No	58.64	Urban	No	EMIS LV
PR14	4,700	Yes	44.62	Urban	No	EMIS LV
PR15	2,800	Yes	41.4	Urban	No	EMIS LV

^a Code used for the purposes of the study only; ^b Numbers rounded to the nearest 100 to help preserve anonymity of the general practices; ^c Based on 2007 Index of Multiple Deprivation figures.

Table 4: Comparison of characteristics general practices involved in the PRACtICE study with National figures for England

Characteristic	Mean (standard deviation) across GP practices studied	Mean National Figure ^a
Practice List Size	5,916 (3,014)	6,487 ^a
Number of GPs	5 (2.3)	4.8 ^b
Deprivation using Index of Multiple Deprivation (IMD) 2007 score	30.4 (18.2)	21.7 ^c
QoF medicines management points per practice	99.2% (2.0)	97.2% ^d
QoF total points per practice	92.5% (6.8)	93.7% ^d

^a Calculated from figures for England 2008 (available from <http://www.ic.nhs.uk/webfiles/publications/>)

^b Calculated from figures from the NHS Information Centre for 2010: total GPs in England: 39,409; total general practices: 8,305 (<http://www.ic.nhs.uk>)

^c Mean IMD score for English Lower layer Super Output Areas (LSOAs)(available from <http://webarchive.nationalarchives.gov.uk/20100410180038/http://communities.gov.uk/communities/neighbourhoodrenewal/deprivation/deprivation07/>);

^d 2010 Quality and Outcomes Framework figures for England (available from: <http://www.ic.nhs.uk/qof>)

6.1.2 Characteristics of patients

The study involved examination of the records of 1,777 patients. These patients had a mean age of 39.3 years (standard deviation: 22.7 years), and 884 (49.8%) were female. The age distribution of the patients is shown in **Table 5** compared with 2010 figures for the English population. It can be seen that the age distributions were similar.

Table 5: Age distribution of patients

Age categories	Frequency	Percentage for study patients	Percentage for the English population 2010 ^a
0-14 years	297	16.7	17.6
15-64 years	1,197	67.4	66.1
65-74 years	147	8.3	8.5
75 and over	136	7.7	7.9
Total	1,777	100.0	100.0

^a Figures calculated from national data for 2010 available from: <http://www.ic.nhs.uk/statistics-and-data-collections/population-and-geography/gp-registered-populations/attribution-dataset-gp-registered-populations-2010>

Of the 1,777 patients, 1,200 (67.5%) had at least one prescription during the 12 month retrospective review of their records.

6.1.3 Characteristics of the prescriptions reviewed

Collectively, the pharmacists reviewed 6,048 unique prescription items for 1,200 patients. Of these, 2,929 (48.4%) were acute prescriptions; 3,119 (51.6%) were repeat prescriptions; 770 (12.7%) were items that were considered to require blood test monitoring (see **Appendix 6**).

Including those patients with no prescriptions, the median number of prescriptions per patient was 2 (interquartile range (IQR) 0,5) and the maximum number of unique items prescribed to any patient during the 12 month review of their records was 32. The majority of prescriptions were for females (3,459; 57.2%).

Acute prescription items were recorded for 988 patients and the median number of unique acute prescription items per patient was 2 (IQR 1,3), with the maximum being 19. Repeat prescriptions were recorded for 722 patients the median number of unique repeat prescription items per patient was 1 (IQR 0,4), with the maximum being 24.

The different categories of drug prescribed (by chapter of the British National Formulary) are shown in **Table 6**. It can be seen that the most commonly prescribed drugs were for cardiovascular disease, central nervous system (CNS), infections and skin.

Table 6: Distribution of prescription items reviewed by British National Formulary chapter

Chapter of the British National Formulary	Frequency	Percentage
Gastro-intestinal system	484	8
Cardiovascular system	1,047	17.3
Respiratory system	503	8.3
CNS	987	16.3
Infections	732	12.1
Endocrine	369	6.1
Obstetrics and Gynaecology	222	3.7
Malignant and immunosuppression	21	0.4
Nutrition and Blood	208	3.4
Musculoskeletal	289	4.8
Eye	150	2.5
ENT	144	2.4
Skin	699	11.6
Immunology and vaccines	170	2.8
Anaesthesia	23	0.4
Total	6,048	100.0

The top 20 drugs most commonly prescribed are shown in **Table 7**. It can be seen that these drugs made up almost a third of the prescriptions.

Table 7: Top 20 drugs most commonly prescribed

Preparation name	Frequency	Percentage
Amoxicillin	209	3.5
Paracetamol	169	2.8
Simvastatin	155	2.6
Aspirin	136	2.3
Salbutamol	136	2.3
Influenza vaccine	107	1.8
Omeprazole	107	1.8
Ibuprofen	102	1.7
Ramipril	90	1.5
Flucloxacillin	87	1.4
Levothyroxine	86	1.4
Lansoprazole	76	1.3
Amlodipine	75	1.2
Bendroflumethiazide	73	1.2
Prednisolone	60	1.0
Cetirizine	55	0.9
Co-amoxiclav	51	0.8
Metformin	48	0.8
Atenolol	47	0.8
Diclofenac Sodium	46	0.8
Total	1,915	31.7

Table 8 shows the distribution of different formulations for the 6,048 prescription items. It can be seen that oral medication made up over 70% of prescriptions.

Table 8: Distribution of different types of formulation

Formulation	Frequency	Percentage
Solid oral	3,916	64.8
Topical	850	14.1
Inhalers	411	6.8
Liquid oral	376	6.2
Injections	258	4.3
Eye /ear drops	183	3.0
Pessaries	30	0.5
Rectal	24	0.4
Total	6,048	100.0

5.1.4 Types of prescriber

The distribution of different types of prescriber for the 6,048 prescription items is shown in **Table 9**. It can be seen that the vast majority of prescription items were issued by were GP partners.

Table 9: Types of prescriber that issued the prescription items in the study

Prescriber type	Frequency	Percentage
GP Partner	4,858	80.3
Salaried GP	779	12.9
Locum GP	185	3.1
Training GP	133	2.2
Non-medical prescriber	60	1.0
Other/Unknown	33	0.6
Total	6,048	100.0

6.2 Prevalence of medication problems

From the 6,048 prescription items on the database we identified the following numbers of medication problems:

- 247 prescribing errors
- 55 monitoring errors
- 427 cases of sub optimal prescribing
- 8 legal problems

The prevalence of prescribing or monitoring errors for different groups of patients over the 12 month data collection period was as follows:

- All patients (n=1,777): 12% (95% CI 10.5%-13.6%)
- Patients who had received at least one medication (n=1,200): 17.8% (95% CI 15.7%-20%)
- Patients aged 75 years and older who had received at least one medication (n=129): 38% (95% CI 29.5%-46.5%)
- Patients who had received five or more drugs over the data collection period (n=471): 30.1% (95% CI 26.6%-35%)
- Patients who had received 10 or more drugs over the data collection period (n=172): 47% (95% CI 39%-54%)

Table 10 below shows the percentage prevalence of prescriptions with different types of medication problem along with 95% confidence intervals.

Table 10: Percentage prevalence of prescriptions with different types of medication errors

Variable	Observations	Percentage prevalence	95% Interval	Confidence
Prescribing error	6,048	4.0	3.5	4.5
Monitoring error	6,048	0.9	0.7	1.1
Prescribing or monitoring error	6,048	4.9	4.4	5.4
Legal problem	6,048	0.1	0.03	0.2
Suboptimal prescribing	6,048	6.9	6.3	7.6
Any of the above prescribing problems	6,048	11.8	11.0	12.6

Restricting the analysis to the 770 prescription items that require blood test monitoring in certain circumstances showed a percentage prevalence of monitoring errors of 7.1% (95% CI 5.3, 9.0).

6.3 Types of prescribing and monitoring errors

The distributions of different types of prescribing and monitoring errors are shown in **Table 11** and **Table 12** respectively. It can be seen that almost a third of prescribing errors were associated with information being incomplete on the prescription. Two thirds of prescribing errors were associated with the top four categories of error.

Table 11: Distribution of different types of prescribing errors

Types of prescribing error	Frequency	Percentage
Incomplete information on prescription	74	30.0
Dose/strength error	44	17.8
Timing error	26	10.5
Frequency error	20	8.1
Omission error due to failure to prescribe concomitant treatment	19	7.7
Unnecessary drug	12	4.9
Contraindication error	12	4.9
Incorrect drug	10	4.0
Duplication	9	3.6
Interaction error	9	3.6
Allergy error	3	1.2
Inadequate documentation in medical records	3	1.2
Quantity error	3	1.2
Formulation error	2	0.8
Generic/Brand name error	1	0.4
Total	247	100.0

Table 12: Distribution of different types of monitoring error

Type of monitoring error	Frequency	Percentage
Monitoring not requested	38	69.1
Requested but not done	12	21.8
Results not available	5	9.1
Total	55	100.0

Table 13 shows the drugs most commonly associated with prescribing errors. In total there were 134 different drugs associated with prescribing errors, and the 25 shown in the table account for half of the errors.

Table 13: Drugs most commonly associated with prescribing errors

Preparation name	Frequency	Percentage
Simvastatin	26	10.5
Amoxicillin	7	2.8
Influenza vaccine	6	2.4
Prednisolone	6	2.4
Betamethasone Valerate	5	2.0
Diclofenac Sodium	6	2.4
Ibuprofen	5	2.0
Aciclovir	4	1.6
Allopurinol	4	1.6
Flucloxacillin	4	1.6
Fucibet® (fucidic acid and betamethasone cream)	4	1.6
Hydrocortisone cream	4	1.6
Meloxicam	4	1.6
Naproxen	4	1.6
Co-amoxiclav	3	1.2
Dalacin T® (clindamycin topical solution)	3	1.2
Elocon® (mometasone topical preparations)	3	1.2
Fucidin H® (fucidic acid and hydrocortisone cream)	3	1.2
Gabapentin	3	1.2
Paracetamol	3	1.2
Sofradex® ear/eye drops	3	1.2
Carbamazepine (Tegretol®)	3	1.2
Timolol	3	1.2
Trimovate® cream	3	1.2
Xalatan® (latanoprost) eyedrops	3	1.2
Others	125	50.6
Total	247	

Table 14 below shows the proportion of prescribing errors from different BNF chapters. The top four BNF chapters were those that also accounted for the highest numbers of prescriptions (see **Table 6**).

Table 14: Proportion of prescribing errors from different British National Formulary chapters

British National Formulary Chapter	Frequency	Percentage
Cardiovascular system	41	16.6
Skin	39	15.8
CNS	33	13.4
Infections	29	11.7
Musculoskeletal	28	11.3
Endocrine	15	6.1
Eye	15	6.1
Respiratory system	13	5.3
Gastro-intestinal system	8	3.2
ENT	8	3.2
Immunology and vaccines	6	2.4
Obstetrics and Gynaecology	4	1.6
Nutrition and Blood	5	2.0
Malignant and immunosuppression	3	1.2
Total	247	100

Table 15 shows the drug preparations associated with monitoring errors. It can be seen that simvastatin, warfarin, ramipril and bendroflumethiazide accounted for over 60% of the errors.

Table 15: Drugs associated with monitoring errors

Preparation name	Frequency	Percentage
Simvastatin	10	18.2
Warfarin	9	16.4
Ramipril	8	14.6
Bendroflumethiazide	7	12.7
Furosemide	5	9.1
Azathioprine	2	3.6
Atorvastatin	2	3.6
Perindopril	2	3.6
Candesartan	1	1.8
Amiodarone	1	1.8
Bumetanide	1	1.8
Carbimazole	1	1.8
Valsartan and hydrochlorothiazide (Diovan®)	1	1.8
Levothyroxine	1	1.8
Lisinopril	1	1.8
Losartan Potassium	1	1.8
Methotrexate	1	1.8
Lithium carbonate	1	1.8
Total	55	100.0

Table 16 shows the proportion of monitoring errors coming from different BNF chapters. It can be seen that the vast majority of monitoring errors concern drugs from the cardiovascular chapter.

Table 16: Proportion of monitoring errors from different British National Formulary chapters

British National Formulary chapter	Frequency	Percentage
Cardiovascular system	49	89.1
Endocrine	2	3.6
Malignant and immunosuppression	2	3.6
CNS	1	1.8
Musculoskeletal	1	1.8
Total	55	100.0

Further information is provided below on drug preparations most commonly associated with different types of prescribing error. **Table 17** shows the drugs most commonly associated with incomplete information being given on the prescription. Rather than giving specific dosage instructions, these prescriptions often stated “as directed”, or gave similar non-specific instructions.

Table 17: Drug preparations most commonly associated with information incomplete on the prescription

Preparation name	Frequency	Percentage
Prednisolone	6	8.1
Betamethasone valerate topical preparations	4	5.4
Gabapentin	3	4.1
Sofradex® ear/eye drops	3	4.1
Trimovate® cream	3	4.1
Xalatan® (latanoprost) eyedrops	3	4.1
Bisoprolol Fumarate	2	2.7
Colchicine	2	2.7
Fucidic acid (Fucidin®) cream	2	2.7
Lumigan® (bimatoprost) eye drops	2	2.7
Timolol	2	2.7
Tramadol Hydrochloride	2	2.7
Others	40	54.1
Total	74	100.0

The BNF chapters most commonly associated with information incomplete on the prescription is shown in **Table 18**. It can be seen that skin preparations made up a fifth of this type of error.

Table 18: British National Formulary chapters associated with incomplete information on prescriptions

BNF chapter	Frequency	Percentage
Skin	15	20.3
CNS	14	18.9
Eye	12	16.2
Cardiovascular system	7	9.5
Endocrine	7	9.5
Respiratory system	6	8.1
Infections	4	5.4
ENT	3	4.1
Musculoskeletal	3	4.1
Gastro-intestinal system	2	2.7
Obstetrics and gynaecology	1	1.4
Total	74	100.0

The 44 dose/strength errors involved 35 different drug preparations. Of these, 6 (14%) were associated with oral antimicrobial agents; 4 (9%) with allopurinol (excessive doses in renal impairment); 3 (7%) with paracetamol (incorrect dose in children) and 2 (5%) with rosuvastatin (40mg dose in patients *without* “severe hypercholesterolaemia with high cardiovascular risk under specialist supervision”).

There were just two drug preparations associated with the 26 timing errors. All of these were due to simvastatin not being prescribed ‘to be taken at night’ (in 25 cases the prescription was for simvastatin and in one it was for Inergy®, which is a combination of simvastatin and ezetimide).

The drug preparations associated with frequency errors are shown in **Table 19**.

Table 19: Drug preparations associated with frequency errors

Preparation name	Frequency	Percentage
Fucibet® (fucidic acid and betamethasone cream)	3	15
Aciclovir	2	10
Dalacin T® (clindamycin) topical solution	2	10
Flucloxacillin	2	10
Hydrocortisone	2	10
Clotrimazole with hydrocortisone cream	1	5
Chloramphenicol	1	5
Co-amoxiclav	1	5
Dovobet® (calcitriol and betamethasone topical preparations)	1	5
Elocon® (mometasone) topical preparations	1	5
Fucidin H® (fucidic acid and hydrocortisone) cream	1	5
Lansoprazole	1	5
Morphine sulphate modified release tablets	1	5
Promethazine	1	5
Total	20	100

There were nine drug combinations that were judged to be interaction errors. These included the following:

- Three cases involving aminophylline (two of these were with macrolides and one with ciprofloxacin).
- Two cases involving co-prescription of two non-steroidal anti-inflammatory drugs at the same time.
- One case of a patient receiving co-amilofruse (a potassium sparing diuretic) with valsartan when the patient had a recent history of having potassium levels above the reference range.
- One case of a patient prescribed calcium and a bisphosphonate to be taken at the same time (calcium reduces the absorption of bisphosphonates).

Notable points from analysis of the other types of prescribing error are highlighted below:

- Of the 19 omission errors relating to failure to prescribe concomitant treatment, 16 (84%) of these involved not prescribing an ulcer-healing drug to protect against gastrointestinal bleed in patients taking non-steroidal anti-inflammatory drugs.
- Of the 12 errors associated with prescribing contraindicated drugs, four (33.3%) were for combined oral contraceptive pills where the women concerned had two or more risk factors for thromboembolic disease.
- Of the nine duplication errors, five (55.6%) of these were for influenza vaccine, where records indicated that a patient had received two prescriptions (although there was no clear evidence that any patient had actually received two influenza vaccine injections in the same season).
- Of the three allergy errors, two were associated with penicillin containing products and one was for aciclovir (in each case, there had been clear documentation of previous allergy in the patient's medical record; in none of these cases was there evidence that the patient had been harmed by the prescribing error).
- The single generic/brand name error was associated with carbamazepine being prescribed generically to a patient with grand mal epilepsy.

6.4 Severity assessment of medication errors

The judges assessed 241 different cases, representing a total of 302 prescribing and monitoring errors (since some errors were identical and only one representative case was assessed). The distribution of severity scores was somewhat skewed, with more errors having lower severity scores; descriptive statistics are therefore presented using median and inter-quartile ranges. However we also calculated mean scores where appropriate, to aid comparison with the existing literature.

For the 302 errors, the mean severity score was 3.5, and the median was 3.3 (IQR 2.2, 4.4). The minimum severity score was 0.7; the maximum was 8.6. The 55 monitoring errors had a median score of 3.8; the 247 prescribing errors had a lower median score of 3.0.

Overall, 128 (42.4%) errors had scores of less than 3, and were thus deemed to be minor; 163 (54.0%) had scores of 3 to 7 and were thus moderate; 11 (3.6%) had scores greater than 7 and were thus severe. **Table 20** presents in more detail how the minor, moderate and severe errors were distributed across different types of error.

Table 20: Error types most commonly associated with severe, moderate and minor errors

Error type	Error sub-category	Minor	Moderate	Severe
Monitoring errors	Monitoring not requested	4	29	5
	Monitoring results not available	0	1	4
	Monitoring requested but not done	2	10	0
Prescribing errors	Allergy error	0	1	2
	Information incomplete	41	32	0
	Dose/strength error	17	27	0
	Failure to prescribe concomitant treatment	1	19	0
	Contraindication error	0	12	0
	Interaction error	1	8	0
	Frequency error	14	6	0
	Unnecessary drug	6	6	0
	Incorrect drug	6	4	0
	Inadequate documentation in medical record	1	2	0
	Quantity error	1	2	0
	Formulation error	0	2	0
	Duplication	8	1	0
	Generic/brand name error	0	1	0
	Timing error	26	0	0
		Total	128	163

An illustrative sample of minor and moderate errors, and descriptions of all eleven severe errors, is presented in **Table 21**. Of the eleven severe errors, nine involved warfarin monitoring and two involved prescribing a drug to which the patient had a documented allergy. Of the nine warfarin-monitoring errors, eight occurred in three patients from the same GP practice, where it was routine practice to prescribe warfarin without knowledge of the patient's INR. There was no documented evidence of harm arising from any of these severe errors.

Moderate errors mainly involved monitoring; incomplete information on the prescription; dose/strength errors, and failure to prescribe concomitant treatment (mainly failure to prescribe gastroprotection to older patients receiving regular NSAIDs).

Table 21: An illustrative sample of minor and moderate errors, and all eleven severe errors

Minor errors	Moderate errors	Severe errors
1-year old girl prescribed amoxicillin 125mg/5ml suspension twice during same consultation. One was for 2.5ml TDS ^a for one week, and the other for 5ml ^a for one week.	64-year old patient was prescribed ibuprofen 400mg to be taken one tablet three times daily after a road accident. No concomitant medication was prescribed for gastric protection. Patient also on aspirin for peripheral vascular disease.	62 year old patient with documented allergy to penicillin; prescribed a course of oral flucloxacillin.
Topical betamethasone 0.1% prescribed in adult patient. No directions given relating to frequency of application.	Indometacin 50mg prescribed with dosage instructions 'as directed', with no instructions on frequency or maximum daily intake. Patient diagnosed with alcoholic cirrhosis of the liver.	Aciclovir 200mg prescribed to be taken one tablet five times a day for a widespread coldsore, to a patient coded with a severe allergic reaction to aciclovir.
Betamethasone cream 0.1% prescribed "to be applied sparingly for one week" for a 5 year old child. No frequency of use specified.	Patient was prescribed levothyroxine 25mcg to be taken one tablet a day. Thyroid function tests were requested but not done.	Elderly patients on warfarin. Last documented INR ^c was more than <i>two years</i> previously (n=7 errors).
29 year old patient prescribed co-amoxiclav tablets 21 x 500mg/125mg for sinusitis. Dose and frequency not specified on prescription.	4 year old girl seen in March 2010 with continuous vomiting and some loose stools. Prescribed metoclopramide liquid 5mg/5ml, to be taken as 5ml twice daily. This should be used with caution in children, and recommended dose for 4yr old is 2mg 2-3 times daily.	93 year old patient on warfarin. Last documented INR ^c was more than <i>a year</i> previously. Patient failed to attend three consecutive anticoagulant appointments, but warfarin prescription continued.
Indapamide 1.5mg MR ^b tablets prescribed "as directed". No other dose instructions given on prescription.		76 year old patient on warfarin. Last INR ^c documented more than <i>6 months</i> previously.

^aTDS: three times daily; ^bMR: Modified release; ^cINR: International Normalised Ratio

6.5 Modelling the risks of prescribing or monitoring errors

We used mixed effects logistic regression techniques to model the relationships between the risk of medication error and selected predictor variables and *a priori* confounders. We performed analyses at both the patient level and the prescription level. The outcome measures were binary in nature. For the patient-level models the outcome was defined as patients with one or more prescribing or monitoring errors versus patients with no prescribing or monitoring errors. The outcome for the prescription-level models was similarly defined with the outcome being prescriptions with one or more prescribing or monitoring errors versus prescriptions with no prescribing or monitoring errors.

Initially for all models, the risk of error was be fitted against each predictor variable and *a priori* confounder in several univariate models. A parsimonious model, including the most clinically relevant confounders and predictor variables, was then fitted in a multivariate mixed effects logistic regression model. Odds ratios and 95% confidence intervals for the adjusted risk of error were then reported.

In the patient level models, we included practices in the random effects portion of the model in order to adjust for the clustering effect of patients within practices. Patient and practice characteristics as well as relevant *a priori* confounders were modelled as fixed effects.

In the prescription levels model, we included patients in the random effects portion of the model in order to adjust for the clustering effect of prescriptions within patients. Prescription and practice characteristics as well as relevant *a priori* confounders were modelled as fixed effects. In some models we were unable to adjust for clustering effect by patients because the models would not converge. We have therefore presented the results of two multivariable models, one which does not adjust for clustering by patients, and one that does but adjusts for fewer variables.

The findings from the patient level model are shown in **Table 22**.

Table 22: Patient level model of risks associated with prescribing or monitoring errors

Factor	Univariate models			Multivariable models				
	Odds ratio	95%CI	P value	Odds ratio	95%CI	P value		
sex¹	0.76	0.56	1.02	0.064	0.66	0.48	0.92	0.013
Number of drugs	1.17	1.13	1.20	<0.001	1.16	1.12	1.19	<0.001
Age²								
0-14 years	1.53	0.99	2.35	0.053	1.87	1.19	2.94	0.006
65-74 years	2.69	1.73	4.20	<0.001	1.68	1.04	2.73	0.035
75 years and over	4.26	2.80	6.47	<0.001	1.95	1.19	3.19	0.008
Dispensing practice³	1.05	0.73	1.51	0.781	0.70	0.26	1.88	0.476
Not a training practice⁴	1.33	0.98	1.81	0.065	1.39	0.97	2.01	0.075
Practice size⁵								
<5000 patients	0.83	0.58	1.17	0.281	0.88	0.58	1.33	0.553
>10000 patients	0.74	0.49	1.11	0.147	0.56	0.31	0.99	0.047
Urban or rural practice⁶	1.03	0.74	1.44	0.849	1.06	0.43	2.58	0.905

Baseline categories: ¹Male; ²15-64 years; ³Non dispensing practice; ⁴Training practice; ⁵5000-10000 patients; ⁶Urban practice

There were a number of significant associations from the multivariate analysis of the patient-level model:

- For each additional unique medication item that the patient had received over the course of the 12 month retrospective data collection there was a 16% increased risk of error (odds ratio 1.16, 95%CI 1.12-1.19, P<0.001)
- Women were less likely than men to have a medication error (odds ratio 0.66, 95%CI 0.48-0.92, P=0 .013)
- The following age groups were more likely (than age group 15-64 years) to have a prescribing or monitoring error:
 - 0-14, odds ratio 1.87 (95%CI 1.19-2.94, P=0.006)
 - 65-74, odds ratio 1.68 (95%CI 1.04-2.73, P=0.035)
 - ≥ 75, odds ratio 1.95 (95%CI 1.19-3.19, P=0.008)
- Compared with a list size of 5000-10,000, patients in practices with a list size of > 10,000 had reduced risk of error: odds ratio 0.56 (95%CI 0.31-0.99, P=0.047)

The findings from the prescription level model are shown in **Table 23**. There were a number of significant associations from the multivariate analysis:

- For drugs on the monitoring list, there was an increased risk of error (odds ratio 3.18, 95%CI 2.66-11.49, P <0.001)
- For the following drug groups (compared with gastrointestinal drugs) there was an increased risk of error:
 - Cardiovascular (odds ratio 2.37, 95%CI 1.03-5.45, P=0.042)
 - Infections (odds ratio 2.67, 95%CI 1.17-6.11, P=0.02)
 - Malignant disease and immunosuppression (odds ratios 6.77, 95%CI 1.71-26.84, P=0 .006)
 - Musculoskeletal (odds ratio 6.97 95%CI 3.06-15.88, P <0.001)
 - Eye (odds ratio 4.92, 95%CI 1.12-21.62, P=0 .035)
 - ENT odds ratio 4.6, 95%CI 1.29-16.42, P = 0.019)
 - Skin (odds ratio 5.78, 95%CI 2.04-16.36, P = 0.001)

Table 23: Prescription level model of risks associated with prescribing or monitoring errors

Factor	Univariate models				Multivariable model 1 ^a				Multivariable model 2 ^b			
	Odds ratio	95%CI		P value	Odds ratio	95%CI		P value	Odds ratio	95%CI		P value
On monitoring list	3.57	2.68	4.75	<0.001	3.18	2.05	4.94	<0.001	3.63	2.65	4.98	<0.001
Repeat prescription^c	1.39	1.08	1.79	0.011	1.25	0.91	1.72	0.168	0.98	0.73	1.31	0.903
Formulation^d												
Eye/ear drops	2.01	1.21	3.33	0.007	1.43	0.39	5.23	0.586				
Inhalers	0.41	0.21	0.81	0.01	0.51	0.21	1.27	0.149				
Injections	0.51	0.24	1.10	0.447	0.41	0.06	3.07	0.387				
Liquid oral	0.82	0.49	1.38	0.087	1.08	0.60	1.95	0.794				
Rectal	0.80	0.11	5.95	0.827	1.93	0.24	15.42	0.535				
Topical	0.98	0.70	1.37	0.905	0.66	0.31	1.42	0.287				
Prescriber type^e												
Salaried GP	0.64	0.41	1.00	0.051	0.71	0.46	1.11	0.13	0.76	0.47	1.22	0.258
Locum GP	1.12	0.55	2.27	0.761	1.16	0.60	2.28	0.655	1.23	0.60	2.54	0.576
Training GP	1.34	0.63	2.85	0.441	1.42	0.67	3.01	0.353	1.66	0.74	3.72	0.218
Non-medical prescriber	0.87	0.25	3.06	0.832	1.55	0.47	5.13	0.469	1.09	0.30	3.91	0.898
Other/Unknown	1.78	0.50	6.43	0.376	1.78	0.52	6.14	0.358	1.97	0.54	7.23	0.305

Continued overleaf

Factor	Univariate models				Multivariable model 1 ^a				Multivariable model 2 ^b			
	Odds ratio	95%CI		P value	Odds ratio	95%CI		P value	Odds ratio	95%CI		P value
British National Formulary chapter^f												
Cardiovascular system	5.53	2.66	11.49	<0.001	2.37	1.03	5.45	0.042				
Respiratory system	1.58	0.65	3.84	0.315	2.26	0.83	6.17	0.11				
CNS	2.06	0.94	4.49	0.07	2.09	0.95	4.63	0.068				
Infections	2.37	1.07	5.24	0.034	2.67	1.17	6.11	0.02				
Endocrine	2.87	1.23	6.73	0.015	1.91	0.78	4.72	0.159				
Obs_Gynae	1.09	0.33	3.66	0.887	1.41	0.41	4.80	0.584				
Malignant and immunosuppression	14.00	3.84	51.07	<0.001	6.77	1.71	26.84	0.006				
Nutrition and Blood	1.17	0.35	3.92	0.803	1.22	0.36	4.15	0.752				
Musculoskeletal	6.38	2.87	14.21	<0.001	6.97	3.06	15.88	<0.001				
Eye	6.61	2.74	15.92	<0.001	4.92	1.12	21.62	0.035				
ENT	3.50	1.29	9.50	0.014	4.60	1.29	16.42	0.019				
Skin	3.52	1.63	7.59	0.001	5.78	2.04	16.36	0.001				
Immunology and vaccines	2.18	0.74	6.37	0.155	5.91	0.60	58.00	0.127				
Computer system^g												
EMIS PCS	1.17	0.83	1.64	0.371	1.06	0.79	1.42	0.706	1.13	0.80	1.60	0.501
Isoft Premiere	0.64	0.40	1.00	0.051	0.68	0.46	1.01	0.055	0.64	0.40	1.01	0.058
TPP	1.06	0.68	1.65	0.812	1.05	0.71	1.56	0.803	0.94	0.58	1.52	0.81

^a Model unadjusted for clustering by patient; ^b Model adjusted for clustering by patient but formulation and chapter not included in the model; Baseline categories: c Acute prescriptions; d Solid oral medication (pessaries category omitted); e GP partner; f Gastrointestinal (anaesthesia chapter omitted); g EMIS LV.

6.5 Analysis of omission errors related to failure to prescribe a drug for an existing clinical condition

Following the review of case notes of 1777, the pharmacists identified 15 patients with possible omission errors relating to failure to prescribe a drug for an existing clinical condition. These were cases where there was no documentation to suggest that a decision had been made *not* to prescribe the drug, e.g. due to patient preference or a previous adverse reaction. They were different errors to those associated with failure to prescribe concomitant treatment. Three of the cases were not considered to be errors by the research team. Eleven of the remaining 12 were associated with failure to prescribe cardiovascular drugs:

- Failure to prescribe a statin in patients with >20% 10-year risk of developing cardiovascular disease (n=5)
- Failure to prescribe aspirin in patients with coronary heart disease (n=4)
- Failure to prescribe glyceryl trinitrate spray in a patient with angina who had been prescribed this medicine at a previous general practice (n=1)
- Failure to prescribe warfarin in patient with atrial fibrillation (n=1)

The remaining case involved failure to prescribe metformin to a patient with diabetes mellitus who had received the drug in the past, but had then stopped receiving the medication with no documented reason for this.

6.6 Analysis of data regarding reconciliation of hospital discharge medication

The pharmacists identified 38 patients who had at least one hospital discharge during the 12-month retrospective review of their medical records. Sixteen (42.1%) patients were from Luton, 14 (36.8%) from Nottinghamshire and seven (18.4%) from City and Hackney PCT. One patient did not have a discharge summary in the case notes and was, therefore, excluded from the analysis. Of the remaining 37 patients, 21 were female (56.8%). The median number of medications on each discharge summary was 7 (range 1-15, IQR 5-9) and the total number of medications present in the discharge summaries for all the patients combined was 252. Before hospital admission, the patients were taking a total of 194 medications. Of these, 29 (15%) appeared to be discontinued by the hospitals.

In 36 patients (97%) there was a difference between the medications that the patient was taking before admission and those listed in the discharge summary. In reference to the medication record at the time of hospital discharge, **Table 24** summarises similarities and differences with the medicines patients were taking before hospital admission.

Table 24: Similarities and differences between medications at hospital discharge and those that patients were taking prior to admission

Similarities and differences in medications	Proportion (%)	How many of the changes were highlighted on the discharge communication?
Proportion of drugs on the discharge summary that were prescribed pre-admission and appear to have been continued by the hospital at the same dose	139/252 (55.2%)	Not applicable
Proportion of drugs on the discharge summary that were prescribed pre-admission and appear to have been continued by the hospital at a <i>different</i> dose	26/252 (10.3%)	0
Proportion of drugs on the discharge summary that appear to have been newly prescribed by the hospital	87/252 (34.5%)	7/87 (8%)
Total	252/252 (100%)	7/113 (6%)

In six patients, it was unclear from the case note review when the hospital discharge medications were registered on the patient record. For the remaining patients, the median number of days it took the practices to record on the practice computer the medications the patient was taking at the time of discharge from hospital was less than one day (IQR 0, 4.25; range 0 - 60).

Table 25 provides a summary of the issues/problems that the pharmacists detected in relation to medications in the discharge summaries. Also, as can be inferred from **Table 24**, in 92% (80/87) of cases the discharge communication did not specifically highlight drugs that had been newly prescribed by the hospital. There were no cases where the discharge communications specifically highlighted changes in dose for drugs that patients were taking before admission.

Table 25: Summary of the issues noted in the medications in the discharge summary communication

Issue noted	Proportion of discharge medications where an issue was noted (%)	
Name of drug unclear	1/252	(0.4)
Drug form missing	157/252	(62.3)
Drug form unclear	11/252	(4.4)
Dose missing	2/252	(0.8)
Dose unclear	4/252	(1.6)
Dose instructions missing	0	
Dose instructions unclear	2/252	(0.8)
Suggested duration of use missing	55/252	(21.8)
Suggested duration of use unclear	5/252	(2.0)

When reviewing the case notes of patients, the pharmacists were asked to assess whether there were discrepancies between the hospital discharge communication and those subsequently prescribed to the patient. Discrepancies were found in 16 patients (43.2%).

Of the 87 drugs newly prescribed by the hospital, 21 (24%, median 1 and IQR 1-2) were not continued by the practice. Also, of the 87 drugs newly prescribed by the hospital one was not prescribed subsequently by the practice at the *dose* suggested by the hospital; one was not prescribed subsequently with the *dosage instructions* suggested by the hospital, and one was not prescribed by the practice for the *duration* suggested by the hospital. Thus, of the 87 drugs newly prescribed by the hospital, 24 (28%) were either not continued, or there was some discrepancy between the prescribing advice of the hospital and the subsequent prescription.

Of the 26 drugs that patients were taking before hospital admission, where the hospital had suggested a change in dose, this suggested dose change was not made by the practice in nine (35%) cases.

For the drugs that appear to have been stopped by the hospital, none appeared to have been restarted by the practice within a month of hospital discharge.

Chapter 7: Error producing conditions

Summary

In this chapter, the seven main error-producing conditions perceived to contribute to an increased risk of prescribing errors were described and explored in-depth. Such an exploration enabled a diverse range of conditions within each of these categories to be presented and the perceived challenges experienced by practice staff explained. The main findings presented for each high-level condition were as follows:

The Prescriber - five conditions were found to affect 'The Prescriber', namely their *therapeutic training, drug knowledge and experience, knowledge of the patient, perception of risk, and physical and emotional health*. Undergraduate therapeutic training was felt by many to have been insufficiently taught at University. The "jump" from being a GP trainee to a salaried GP was also perceived to have been quite high. One example, in particular, emphasised not only the importance of hands-on experience with chronic disease patients during VTS training, but also the need for trainees to have experience treating a range of patients at varying stages of their illnesses. Some established GPs admitted becoming '*slightly blasé*' about prescribing for their long-term patients, thus running the risk of overlooking certain things. Prescribers' perception of risk appeared to be influenced by previous experience of a similar situation and the perceived severity of potential adverse effects associated with the drug.

The Patient - *patient characteristics* (including personality, literacy issues, and language barrier) and the *complexity of the individual case* were found to have contributed to prescribing errors. Some particular examples highlighted a tension between the GP's responsibility to improve or maintain their patient's health, and their view on the patient's responsibilities for their own health.

The Team - *poor communication* and *nurses' quasi-autonomous role* within the team were considered to be two key conditions influencing the occurrence of prescribing errors in general practice. The communication between practice colleagues appeared to vary widely, with some feeling isolated whilst others felt very close and supported by their colleagues. Two important factors may explain these different GPs' perspectives, including the length of time the GP had been working in the practice and the frequency of formal / informal meetings within the practice.

Summary Continued

Nurses' *'quasi-autonomous role'* in chronic disease management was felt to be associated with an increased risk of prescribing errors in general practice, particularly because of the need to interrupt GPs to have prescriptions signed when the patient had not been assessed by the GP.

The Working Environment – High workload, time pressures and associated stress were felt to be important factors making error almost inevitable. The failure of appointment systems to cope with patient demand was perceived as a particular source of stress. Distractions and interruptions were common for some GPs and thought to be an important cause of error because of their effects on disrupting prescribers' thought processes.

The Task – We focused on repeat prescribing systems and patient monitoring. Some safety issues were identified in the ordering and processing stage of repeat prescribing, but failure to properly review some patients was probably the most important cause of error. General practices had various systems aimed at ensuring timely blood-test monitoring for patients, but sometimes these broke down. The most important problem identified was in a practice where GPs prescribed warfarin without access to INR results.

The Computer System – There were many positive comments about the role of clinical computer systems in preventing error, but some problems were highlighted including selecting the wrong drug or wrong dosage instructions from pick lists; overriding important drug-drug interaction alerts; unnecessary/inappropriate alerts; the need to maintain an accurate electronic health record, and staff sometimes expecting too much from the computer system.

The Primary Secondary Care Interface - The quality of secondary care correspondence appeared to vary a lot, depending on the hospital and department. The ambiguous wording of hospital letters was also felt to be partly responsible for why some GPs failed to make changes recommended by specialists. GPs recognised the need to update their patients' computer records promptly with hospital information (once received), and individual practices' processes to be in place verifying that these changes have been made. Three important factors appeared to influence GPs' decisions to prescribe medications recommended by specialists, including local guidance, whether the drugs were commonly used in general practice, and whether the GP perceived the harms to outweigh the benefits for the patient.

7.1 Introduction

In our analysis of the causes of prescribing and monitoring errors in general practice, we have identified a number of different error-producing conditions. These have been classified into seven high-level categories: 'the prescriber', 'the patient', 'the team', 'the task', 'the work environment', 'the computer system', and 'the primary/secondary care interface'.

7.2 The Prescriber

Five factors were found to impact on 'The Prescriber', namely their therapeutic training, drug knowledge and experience, knowledge of the patient, perception of risk, and physical and emotional health.

7.2.1 Prescribers' therapeutics training

Many GPs recalled how their therapeutic training at university was poor. One GP in particular felt it had been *"extremely badly taught"* (PR2-GP2) to him as an undergraduate, and admitted feeling a *"little nervous"* about his therapeutic knowledge since. Other GPs' accounts expressed similar views, with one stating how their therapeutics lectures did not occupy *"a huge chunk of [the] syllabus"* (PR3-GP2) and another how *"Ten one hour lectures at 5.30 on a Friday evening didn't a) guarantee interest or b) attendance"*. (PR3-GP1)

All GPs, both at a junior and senior level, agreed that a lot of their therapeutics knowledge had been picked up on the job in rather an 'ad-hoc' way, by talking amongst their peers and eliciting help from both the nursing and pharmacy staff. One GP who reflected on her rotational training (in hospital) spoke overly about her dependence on others to tell her what to prescribe. She explained how she had acted on the advice given to her by nurses, pharmacists and other people, according to what she understood to be *"how things were [done] then"* (PR3-GP2), but emphasised that this 'over dependence' might not have been appropriate. She also felt that she was not formally taught how to prescribe whilst participating in the Vocational Training Scheme (VTS - a specialty training programme for General Practice), but perceived it more to be tied to specific conditions.

"... before you get on the VTS it's very much on the hoof, isn't it?(...) in the old days, you were dependent on being told what to prescribe and dependent on the nurses and the pharmacists and other people, who shouldn't necessarily have been telling you what to do, telling you, double checking that you were doing the right things but that was kind of how things were then, which wasn't correct, don't get me wrong but you were dependent on people. On the VTS I don't think, we had a bit but we didn't have a huge amount, it was more, well you did, it wasn't prescribing so much a chunk

of time on how to prescribe it was more, it was all tied to conditions". (PR3-GP2)

In further analysis of the same interview, this GP's most pressing concern was getting to grips with the management of long term patients with chronic conditions following training. She described how, as a trainee, she only experienced managing patients with chronic conditions up to a certain point, emphasising the short timescale for her training (six months). For her, the "big jump" from being a GP trainee to a salaried GP was quite high and her experience of using a range of different medicines limited.

"And I think also when you go from being (...) a trainee to being salaried it was quite a big jump because when you're a trainee you're only in a practice for six months maximum, well that's what it was like, it's changed now a bit, and so you never got any of the chronic conditions beyond a certain point so even if you diagnosed someone as diabetic you only had them on metformin and that would be it (...). There's a lot of chronic conditions that you didn't actually get to grips with or the medication properly". (PR3-GP2)

This particular example emphasises, not only the importance of hands-on experience with chronic patients during VTS, but also the need for trainees to have experience treating a range of patients at varying stages of their illnesses.

7.2.2 Prescribers' drug knowledge and experience

Our analysis suggests that GPs tended to develop a repertoire of drugs over time that they were comfortable prescribing. In their accounts, GPs explained how such behaviour was usual, reflecting on how it made it "easier to manage the risk" as they became familiar with their side effects. Caution was exercised when using new, unusual or unfamiliar drugs, with one GP recounting how he would have to check the dosage and potential side effects of these drugs before prescribing.

"if we go into esoteric areas then I've either got to sit down and scratch me head and have a think or I'm either going to get the BNF out and look or I'll look online to see what the instructions are regarding the treatments. So for instance, if you're dealing with eczema, so I'm quite familiar with all the steroid verbiage but if I wanted to use one of the new tacrolimus things then I would look it up because I don't use those often enough to remember all the pros and cons in me head and what the dosages are".(PR7-GP3)

This was echoed by a second GP who admitted knowing very little about the drug

Herceptin[®] (trastuzumab) which was prescribed for one of her patients.

“it’s really helpful to have a kind of baseline of drugs you’re familiar with. I think new drugs are a night-mare because I think new drugs or unusual drugs, I had a lass today who’s on Herceptin[®] and I don’t know Herceptin[®] so when she’s talking about potential side effects I don’t even know where to start [looking]”. (PR4-GP2)

In both accounts, GPs appeared to recognise the risk of prescribing certain drugs that they were unfamiliar with, highlighting a need to check their side effects and dosages before prescribing. As far as one GP was concerned, some people were often unwilling to do this, and would *“just go ahead anyway instead of stopping a moment, checking the BNF to see what it says, and then following that advice”*. (PR7-GP2)

Two factors appeared to influence GPs’ prescribing of unfamiliar drugs. Firstly, patients moved between practices, sometimes coming from different parts of the country where there were possibly *“different local preference[s]”*. (PR4-GP2) Some GPs also highlighted how this could be ‘tricky’, with one acknowledging how her practice never uses any drugs that have not *“gone through the formulary PCT process”*. (FG5-GP2) Secondly, several doctors described the difficulties around paediatric prescribing, emphasising how some drugs are not licensed, dosages often need to be calculated based on age and weight, and perceived the paediatric BNF as difficult to navigate their way through.

One GP admitted taking a *“short cut”* for paediatric patients and instead of specifying a specific dosage on the prescription, she just wrote *“as directed”* without calculating the child’s weight. Although admitting that she had previously taken a child’s weight into account whilst prescribing in hospital, she perceived the work environment in general practice had made it difficult for her to do this with various time constraints. Her perception of risk also appeared to be shaped by whether the particular drug could be purchased over the counter, and thus presumably with dosage information included within the patient information leaflet. When examining her account in detail, it is clear that this GP identified a breach in her prescribing process and acknowledged how this could possibly escalate into further problems, with the patient either being over-dosed or under-dosed.

“yes, it’s not ideal and certainly part of the problem there is that, in hospital, I always used to do it on children’s weight, but time constraints there getting the child to put, you know, and then working it out, not having a calculator to hand or looking in the BNF, so sometimes it can be a bit of a short cut just to put ‘as directed’ in this particular case. When it’s actually a drug that can’t be bought over the counter then

it's much more important I think (...) There is the potential for overdose yes, or even equally not giving her enough and then she's still in pain". (PR8-GP1)

This incident illustrates what some implied as an underlying tension between trying to prescribe safely and the pressure of time-constraints, task prioritisation, which will be explored in greater depth later in the chapter.

Prominent in prescribers' accounts was an awareness of how a patient's management changes over time. As far as one GP was concerned, the management of elderly patients had completely changed over the last 30 years; a change he felt was appropriate.

"I think when I first started I don't think we were as aggressive in managing elderly patients, you know, we worked on the basis they'd got to their eighties, they're doing quite well just let's not put them at risk of side effects from these tablets. Their blood pressure's running a bit high, they're fine because if you make it too low they'll probably fall anyway. And I think that's certainly changed in that I feel that we deal with our ninety year old patients probably a lot more aggressively than we did before. Which is fine because we've got a lot of ninety year olds in the practice and they're sparky individuals whose families still want them around so, yes". (PR2-GP3)

Other GPs offer similar evidence of the importance of changes in prescribing policy. One GP admitted struggling with the concept of prescribing beta blockers to patients with heart failure, a concept which in the past was considered inappropriate as it was believed to cause a deterioration in the patient's symptoms.

"if I could have projected myself in a few years time there'd be medications I've not heard of or things I wouldn't dream of doing now which would become normal. It's like giving, I can't remember, I still struggle with giving beta-blockers for heart failure, I mean it's just ingrained in my mind it's a 'No' 'No' but it's a 'Yes Yes' now, you know. So I think you learn so much on the job, you learn so much from consultants' letters, some are better than others and guiding you and saying, "Look this is a new practice" or whatever. "I suggest we do this for such and such a reason". (PR2-GP1)

This particular example emphasises not only the importance of keeping up to date with current evidence, but also the role of secondary care physicians in guiding GP prescribing: *"Sometimes it's from hospital letters that come through and they've managed something and I think "oh right that's how it's being done now". (PR2 – GP3)*

Another GP, who had only recently taken over the management of long-term diabetic patients from a retired colleague, offered an insight into the uncertainties surrounding his decision-making, due to historical differences in prescribing. He described how these patients had been started on gliclazide rather than metformin (which is nowadays considered first line), and he was unsure whether he should be change their existing treatment in line with current guidance.

“I think you do see historical differences in prescribing, so again patients that have been on, diabetic patients, Type 2 diabetics now, it’s more common these days to start with metformin whereas I don’t know, wind the clock back 5 or 10 years gliclazide was very popular and there’s a lot of people are on gliclazide that you see at review that have never been on metformin and their control’s slipping a bit and you think well should I just start again? Restart them on metformin? Should I crack back on the glitazones? So there’s a few historical things”. (PR1-GP1)

Whilst moving beyond the descriptive analysis to further explore the meanings conveyed in these GPs’ accounts, it is important to ascertain a possible linkage between the length of time a GP had been practicing for and their personal clinical judgment. In the narratives above, the first GP (PR2-GP1) had been qualified 23 years, whilst the second (PR1-GP1) had only been qualified 15 months, having taken over from a GP partner approximately seven months prior to being interviewed. Prescribing habits appear to emerge over time and possibly become “*entrenched*” in those practicing for a long time.

“we get entrenched habits and actually it’s changing somebody’s habits and moving them on that’s the difficult bit because what they were doing 10 or 15 years ago was what you did 10 or 15 years ago but isn’t necessarily appropriate now or there are other things you could do before that now. And in some areas we all move on really quickly and in other areas we just stick to those old habits. And it’s difficult to move on”.(PR7-GP2)

These cases also illustrate the point that practice processes need to be in place to highlight drug choices made, for example, “*10 or 15 years ago*” which may not fit with current evidence and guidance, and perhaps need to be changed.

7.2.3 Prescribers’ knowledge of the patient

Most GPs agreed that long-term knowledge of the patient reduced the likelihood of prescribing errors. Many GPs explained how this knowledge allowed them to recognise those “*who are sensible*” and those who they felt they need to be “*more wary of*” (PR1-GP1).

Several doctors described how difficult it was to prescribe for urgent walk-in patients or new patients when “you’ve [got] absolutely no information on them” (PR8-GP1). In their accounts, each GP described how they would resort to a patient’s previous repeat prescription list or possibly rely on their word, which they admitted was somewhat risky. One GP recalled a situation where the patient had incorrectly told him that they had been taking a particular drug. Another GP felt that sometimes patients could do a “circuit of all the doctors for the same thing to get the answer that they want”. (PR7-GP1) As far as he was concerned, not having the information to hand at the time of prescribing or being unable go through the patient’s history before the consultation, made him feel uncomfortable. In the example given below, he felt it was safer not to prescribe for a particular walk-in patient but to ask them to make an appointment to see their regular doctor.

“And a classic example would be somebody who’s got some major condition that instead of making the appointment to follow up with the regular doctor they see, they suddenly come in as an urgent walk-in patient on the day wanting something dealt with and that can sometimes be problematic and sometimes you have to, they might not be acutely ill, they might just have decided to do that and you do have to quietly tell them, ‘Look if you’re coming for this you do need to see the regular person’”.
(PR7-GP1)

Although GPs’ discourses clearly privileged long-term knowledge of patients and the relationship that they had built up over time with them, some GPs admitted becoming “slightly blasé” (PR1-GP1) about prescribing for some long-term patients and possibly ran the risk of overlooking certain things.

“So I think on the one hand that [long-term knowledge of the patient] is a positive, on the other hand, clearly you’ve got the complacency issue that you’ve know[n] someone for so long and things have never been a problem that, you know, you can clearly overlook issues”.(PR2–GP2)

Another GP reflected on how he had possibly overlooked proton pump inhibitor (PPI) cover for one of his long-term patients who developed a gastro intestinal (GI) bleed last year, admitting how if the patient had been new to him, the outcome might have possibly been different.

“I mean knowing a patient more could increase the chances of not looking deeply. I say that because there’s perhaps one of our patients virtually sees me very frequently and then last year had a GI bleed and it made me go back to look at what

had happened before then. And even though we had talked about it at one stage before she was on aspirin and clopidogrel for good reasons and at some stage she was on a PPI cover but I think the PPI got left out and if it were a new patient it would probably be something that I would think about more".(PR14-GP2)

Other doctors' accounts offered similar evidence, with one explaining how *"I would engage my brain more with somebody I didn't know"* (PR4-GP1). This is an important finding as it highlights GPs' awareness of potential inconsistencies in patient management. One might also hypothesise that the existence of practice processes to review the drug management of long-term patients, as previously discussed, might be beneficial in alleviating such problems.

7.2.4 Prescribers' perception of risk

Our study illustrates the argument that the occurrence of prescribing errors may also have been related to how GPs thought about and responded to risk. One GP acknowledged how GPs' perception of risk is subjective, with different GPs perceiving and managing risk differently. He admitted being much more *"laissez faire"* about things than his other GP colleagues, spending far less time worrying about his choices of medication. That said, he was still keen to point out how he regarded his prescribing decisions to be safe.

"GPs tend to be quite good at managing uncertainty, some are, some aren't, and I suppose prescribing risk comes into that whole genre of how you feel about things. And so there'll be some doctors, like X, who's very thorough and really spends a lot of time on these things and there'll be some doctors, like me, at the other end probably who are much more laissez faire about this. Hopefully still safe but less worried about medication in general and more, I suppose, I feel that the day's full in so many other ways that spending 10 minutes thinking about quite whether it should be this one or that one".(PR4-GP1)

At a later point in this interview, the GP was asked at what point he would start to worry about one of his patient who was prescribed valsartan and had a low blood pressure reading.

GP: *If they start falling over.*

Interviewer: *Right so you wouldn't worry about particularly low blood pressure if they're on BP meds?*

GP: *Erm, not unless they start feeling faint, No. I mean that is quite low isn't it to be*

fair but has she got a history, had she fallen recently, do you know?" (PR4-GP1)

In this example, the GP appeared dismissive of concerns regarding his patient's low blood pressure reading. Crucially, what might have determined his decision to intervene in this patient's management was not how low the blood pressure reading was but whether the patient had been feeling faint or had fallen recently.

Two important factors appeared to influence an individual's perception of risk. Firstly, if the GP had previously *"run into trouble"* (PR4-GP1), experiencing a similar situation and made an error that they were aware of. According to one GP, *"it takes an error to actually pull you up sharp"* and, although unpleasant, it makes you realise that *"you do just have to be a little bit careful"*. (PR2-GP3) Risk perception also appeared to be influenced by the perceived severity of potential adverse effects associated with the drug, with one GP drawing a distinction between emollient creams, which he felt were absolutely fine to prescribe with no directions or just 'PRN' on them, and potent steroid creams, which were in his view *"a different story"* (PR3-GP1) and they needed specific directions. In his view, it didn't matter a lot how often one of his patients had been using clotrimazole cream for, but emphasised that *"something of importance"*, like methotrexate, *"would have gone further up my priority radar"* (PR3-GP1). For other GPs, the length of time the patient was going to be on the medication for had a crucial bearing on whether it would be initiated. Acknowledging the existence of a possible drug-drug interaction, one GP took some reassurance from the fact that the patient would only be on an antibiotic for a relatively short time, and how the patient had been informed of the interaction and to contact the GP if she became unwell.

"if there's an interaction then it goes ping, then you think well actually it's only for 6 or 7 days and if you warn the patient, you know, if they were using it for years on end that would be very different but if it's only going to be for a week then you can counsel the patient accordingly and say, "Look there could possibly be a reaction but you're only taking it for 7 days, if you have any worries or any symptoms or whatever, you're not happy about it for goodness sake let me know and we'll stop them".(PR2 – GP1)

7.2.5 Prescriber's physical and emotional health

The prescriber's physical health was another factor found to contribute to prescribing errors. Our analysis shows how tiredness and anxiety may have impacted on some GPs' ability to concentrate. One GP admitted worrying about certain patients who had just left her consulting room, saying *"you're still thinking about that [patient] rather than focusing on the next person that's coming in"*.(PR2-GP3) Another GP pointed out how he had struggled to

find some time recently to do any physical exercise, explaining how he *“used to be able to go to the gym twice a week, I haven’t been to the gym for 2 months now”*.(PR2-GP1) This, in his view, was due to recently taking on more responsibilities at the practice which, he felt, just *“eats away at your time”*.(PR2-GP1)

7.3 The Patient

Our analysis indicates that *patient characteristics* (including personality, literacy issues, and language barriers) and the *complexity of the individual case* contributed to prescribing errors.

7.3.1 Patient characteristics

GPs perceived some patients to be assertive and demanding, and this, they felt, impacted on their prescribing. A deliberative attempt was made by one GP to try and take his patient off the combined oral contraceptive pill, explaining how he did not *“like the idea of it”*.(PR11-GP2) Despite discussing this several times with her and pointing out the risks, he was met with what he perceived to be a certain reluctance, saying *“she’s the kind of patient that knows what she wants and she tells you what she wants”*.(PR11-GP2) This finding was also echoed by a second GP who explained how one of his patients had insisted on being given a large amount of painkillers. He recounted feeling *“very reluctant to give [her] all this”* but admitted that it was *“very difficult and she’s in a lot of pain”*.(PR12-GP2)

Some patients’ lack of ability to read or speak English was also highlighted as a possible cause of errors. One GP recalled how surprised he was at the number of patients he had picked up and said: *“There’s no point writing things down because I can’t read it, Doc”*.(PR6-GP2)

7.3.2 The complexity of the individual clinical case

Other cases in our study offered similar evidence of the importance attached to perceived patient characteristics (including personality, knowledge, intelligence) and the patient’s compliance with their medication regime. These issues were particularly brought to the fore in more complex clinical cases, where patients were on lots of medication and needed to attend outpatient clinics for drug monitoring.

“I would say absolutely 100% the patient personality, knowledge, intelligence, insight are all going to be key factors in maintaining sort of appropriate prescribing and we know that compliance is a massive issue, whatever. So all of those I would say are a given but quite obviously the more complex the clinical case, like in the last one we discussed where you’ve got, you know, all those multiple neurological agents being used, sort of intervention from secondary care, lots of clinics, we’ve identified the fact

that patients don't always attend clinics so that's a major issue as to the responsibility of follow-up".(PR2-GP2)

An exemplar case involved a 93 year old man. This patient was portrayed by the GP as quite a wilful man who had refused, in the past, carers to call to his home, declaring how he “*just want[ed] to be left alone*”.(PR6-GP2) There appeared to be a long history of unease between this GP and his patient, with the GP recalling how he had tried to change him onto a multi-compartment compliance aid (NOMAD®) to improve his medication compliance but the patient had refused. These struggles appeared to acquire particular significance when the patient ended up collapsing and being admitted to hospital.

“I mean the patient's quite a difficult character anyway. I mean he's 93 but he lives alone, he's very much against contacting the surgery or any of the sort of the professionals really, he likes, he just wants to be left alone (...) He's in the past refused carers many a time and I think, I mean he's been highlighted as being a high risk of developing problems really for the last ten years or so. (...) I remember one occasion quite serious concern that he was going to be in danger being left alone at home but he refused to be admitted or refused any intervention.(...) it wasn't until he went into hospital having collapsed or something he came out with a NOMAD® pack that it was only then that, you know, we were happy with the medication that he was taking”.(PR6-GP2)

The GP was also eager to show the patient's lack of compliance, recalling how he had received a letter from the anti-coagulant clinic saying that the patient had missed three of his hospital clinic appointments to get his INR checked and that if he missed a fourth they would suspend him. Despite acknowledging how the patient often was confused with his warfarin dosages and how his eyesight was poor, he continued to prescribe this drug insisting that the colours of the tablets were probably helping him remain compliant.

“I've no doubt he does get confused with the warfarin dosages. And I think it may not be written on it but I think his eyesight isn't that good anyway so there is a bit of concern that can he actually read what dosage he's supposed to be taking. And I think this is where the colours of the tablets probably come in useful”. (PR6-GP2)

A similar situation had also occurred with another one of this GP's patients, emphasising how his “*hands were tied*” when the patient refused to allow him to come to his home. Whilst this GP recognised that he had an obligation to treat these patients, he also reflected on the risks associated with prescribing warfarin for a patient with low compliance and whether

these risks could, in certain situations, outweigh the benefits.

"I remember another patient who had a similar sort of thing and again when he was in a similar sort of position where, you know, we'd ring him up and he'd say actually I don't want you to come round. So, you know, our hands were tied, we can't just impose ourselves on people and say, 'Look, you're not taking your warfarin, what are you doing?' So, you know, this chap although he'd let us in he wasn't always amenable to us just sort of saying "yes I'll do as I'm told" sort of thing.(...) one of the things I looked at to say well what are the risks of not, of stopping the warfarin. I'm trying to think whether that was thought of at any stage because he's over 90 and there is this thing about well is aspirin going to be safer?". (PR6-GP2)

The importance of balancing risk was evident in other accounts, with one GP admitting that he had to "compromise" with the patient in order for her to agree to have regular blood tests done. The patient was presented in his account as a "poor responder" who was a "lot of trouble" to get in and refused to have her lithium monitoring done every three months. The fact that this patient had been stable on lithium for quite a long time, and had agreed to follow instructions if her results were found to be abnormal, solicited just enough leniency from her GP to have her blood tests extended to every six months. He agreed to this, perhaps aware that a more stern approach may have threatened the integrity of their patient-physician relationship.

"I had this discussion with her about how she's not having blood tests being done and she said she refused to have them every 3 months so I compromised with her having them every 6 months, which I thought was better than nothing. (...) we've only now found a first instance of problems with the thyroid. So now we've got that I think we can be much more serious in terms of complying with the recommendations. But up until now I've not felt any reason to push it, she's been on this drug I think for about 20 years. So I felt no reason to say to her, "Well if you're not going to comply with that I'm going to refuse to prescribe the drug". I thought that was a bit far reached". (PR11-GP1)

This finding highlights a tension between the GP's responsibility to improve or maintain the patient's health, and the patient's responsibilities for their own health. GPs expressed foreboding about some patients "who actively change their medication on a regular basis because they think know best" (PR1-GP1) and others who don't take their medication at all. In one particular case, the patient had waited until she was completely out of her combined oral contraceptive pill before requesting a further supply. Unable to carry out all the checks

due to the timing of this request, the GP in question recounted how she felt pressurised into releasing a prescription *“because you don’t want an unplanned pregnancy”*. (PR6-GP4)

7.4 The Team

In this section, we focus on the immediate general practice team (GP, nurse, practice manager, receptionist). *Poor communication* and *nurses’ ‘quasi-autonomous’ role* within the team were considered to be two key factors influencing the occurrence of prescribing errors in general practice.

7.4.1 Poor communication

Several GPs’ accounts highlighted the importance of feeling comfortable within the practice team and sharing any anxieties or worries that they might have about a particular patient with colleagues. Formal and informal ‘coffee’ meetings were described as a *“very useful tool”* (PR2-GP1) to nurture this communication in practices and facilitate discussions about particular issues.

One GP, however, reflected on the isolation he felt whilst working in his practice. According to him, he rarely saw his GP colleagues and reflected on how he had far more contact with his clinical colleagues whilst working in a hospital setting and also was more familiar with their prescribing habits.

“once you’re out of the hospital environment where you’ve got lots of other people around you, it is difficult to know what everyone else is doing because you never see anyone else, we only see our patients. (...) I suppose you do, we do become a bit isolated from others and others’ prescribing habits”. (PR1-GP1)

In contrast, a second GP in another practice offered a different perspective, speaking openly about the special relationship he had with his GP partners, referring to them *“more [as] friends than colleagues”*. (PR2-GP1) He described how attendance at their informal ‘coffee’ meetings were absolutely essential every morning, portraying them as opportunities for gaining answers to any problems that you may have. In his account, he was keen to show the helpfulness of his fellow GPs and appeared reliant on their advice to guide his decision-making.

“We always meet for coffee, it is absolutely sacrosanct that we meet for coffee at twenty to 11, some of us are there sooner than others and it is an extremely, I cannot express how important that session is to, you know, you have a problem and you don’t really know what to do or what medication to use and you just go in there and

you'll have two or three like-minded people and you say, 'What would you do in this situation?' and in a flash all these suggestions, "Yeah, I never thought of that", "Yeah, that's a good idea" and it works fantastically well". (PR2-GP1)

Two important factors may explain these different GPs' perspectives, including the length of time the GP had been working in the practice and the number of formal / informal meetings which had been arranged. Taking the example above, the latter GP (PR2-GP1) had been working as a GP for 23 years, with the majority of his colleagues having worked in the practice for 15 years. However, the former GP (PR1-GP1) had been qualified 14 months, joining the practice approximately 10 months prior to being interviewed. This latter GP (PR2-GP1) also was keen to report how his colleagues had noticed his temporary absence from practice meetings in the past and expressed their concern for his welfare.

"I remember myself once doing that, where I didn't go in there [to meetings] because I was just stressed and I was feeling quite low and one of my partners came out and said, "X, you're not right". (...) loss of [my] sense of humour is the first thing that will go and it was picked up straight away so it's almost like we support each other very well and it's fantastic to have". (PR2-GP1)

This is an important finding, as working in group practices clearly seems to provide an important 'support structure' for some GPs.

7.4.2 Nurses' 'quasi-autonomous' role

GPs from four practices felt that (what one GP termed) nurses' "*quasi-autonomous role in chronic disease management*" (PR3-GP1) was associated with an increased risk of prescribing errors in general practice. These data offered insights into how, and under what circumstances, their role in assessing the patient, generating prescriptions, and obtaining the GPs' signature for those prescriptions, could lead to potential errors. One GP who recognised the importance attached to nurses' input in developing, understanding and following very clear protocols for prescribing, pointed out how he felt a bit uncomfortable with the overall process. In his account, he felt that it had become customary in general practice to sign prescriptions generated by nurses, but questioned the safety of this process when he had not actually seen the patient for himself.

"I suppose nowadays [I find it] a little bit uncomfortable because I'm not actually seeing the patient myself but it's the nature of General Practice, it's the way it's happened for many years. That's not to say it's the right way but, you know, at the moment these particular girls haven't, can't prescribe for themselves. I suppose, I

mean the only alternative is for that patient to be seen by me and I think we decided as a practice that we have very clear protocols that are written down and the nurses understand, they've been written by us in conjunction with the nurses saying this, this and this, if it's all completely straightforward then I'm happy for you to go ahead and do this, and yes I need to sign it".(PR2-GP1)

Both this narrative, and that of other GPs, suggests that trust is a crucial element in the relationship between nurse and GP, and that nurses have to ensure that they have a "good handle on" things and input "a reasonable level of knowledge". (PR1-GP1) Several doctors also described how difficult it was when nurses "loiter outside your door" (PR3-GP1) or "put their head round the corner" (PR2-GP1) and ask them to sign prescriptions. There was a concern amongst these GPs that such interruptions could lead to errors if they did not take sufficient time to stop and look and see what it is that the nurse had prescribed, as "you know, we're responsible if our name's at the bottom, we're responsible". (PR2-GP3) For others, their most pressing concern was how, following these interruptions, they may not have adequate time to properly write up their patients' notes from the previous consultation, highlighting how they might lose track of what they had been entering before they got interrupted. These interruptions acquired particular significance when one GP admitted cutting corners to gain back lost time.

"you get interrupted in-between times, the minute somebody sees your door open they pounce, or sees a patient leave they pounce and you're filling in the notes and suddenly somebody's pounced, then that distracts you from completing the notes properly or completing the task properly because you don't write all the notes in with the patient. And then you're running late so you, I suppose cut corners would be a way of describing it, you try, and then that's when it goes wrong". (PR3-GP1)

In further analysis of the same interview, this GP presented himself as a victim of his own approach in which he would normally meet patients at reception and escort them to his office. As far as he was concerned, this exposed him to a bombardment of requests from nursing staff who would catch him in the corridor and ask him to sign prescriptions. He found the whole process of getting prescriptions signed in his practice to be sub-optimal, exposing the fact that he was asked to sign prescriptions without his glasses, for emphasis.

"I think being caught on the hoof as I'm going out to, I tend to get caught more because I'm one of the doctors that actually walks out to get patients.(...) So I'm out to collect a patient or I'm out at reception to pick up a result or whatever (...) so I'm task focused on doing that, in comes the nurse saying "Can you sign this please?"

(...) if they catch me in the corridor without my glasses I can't see the bloody prescription. No genuinely, I mean that's a fatuous example I have to say but it's a factor, "Hang on a minute, I haven't got my specs, what does it say?"(...) they just say, "Sign here". We, I have significant issues with that". (PR3-GP1)

He also raised concerns about whether or not requested changes to the nurse generated prescriptions were actually completed, saying *"I don't know unless it's been brought back to me whether that's been re-signed". (PR3-GP1)* The responsibility associated with signing these prescriptions appeared to weigh on a few GPs' minds, with some more comfortable with the idea of having independent nurse prescribers who signed their own prescriptions.

"I don't like it because it interrupts me, I don't like it because I'm not sure that it's entirely safe and we're in essence having nurse prescribers acting autonomously when they're not nurse prescribers because they're making a prescribing decision, they're doing everything but the signature really. Aren't they?". (PR3-GP1)

Similar evidence around trust in the relationship between GPs and nurses, and the importance of GPs completing the task in-hand without interruption, reoccurred throughout the dataset. One GP reflected on how arduous the whole process of getting prescriptions signed could be for nurses too, commenting on how they can often spend a lot of time waiting outside the doctor's office to speak to them. He was also keen to point out that some nurses were, perhaps, better than others at prescribing and put this down to experience.

"I have to say from the nursing point of view it's an absolute pain in the neck because they have to wait outside for a doctor until they can rush in and get it signed or whatever, you know, so it wastes their time standing outside the doctor's surgery. (...) there's no doubt there are some nurses who are better than others. (...) And I think that comes with experience". (PR2-GP1)

Findings such as these raise important concerns over the process of signing prescriptions generated by nurses in the practice and the nurses' quasi-autonomous role.

7.5 The Working Environment

In this section, we focus on the workload of GPs and practice staff, and the time pressures they faced. We shall discuss in detail two important conditions that were felt to contribute to this workload: the appointment system and patient demand. We will also discuss the

distractions and interruptions that GPs faced both during and between their patient consultations, and how this may have influenced the occurrence of prescribing errors.

7.5.1 Workload and time pressures

GPs and practice staff regularly experienced periods of high workload, with several explaining how they got “*flooded with messages, you know, left, right and centre*”. (PR6-GP2) One GP disclosed how it would not be unusual to have “*80 to 100 pieces of paper a day to look at*” (PR2-GP2) in a busy practice. Another GP admitted often “*not concentrating on one thing*” but trying to do “*several things at a time*”. (PR4-GP2) The effective completion of these tasks under various time constraints, pressurised GPs with some describing how they have to “*live with a degree of risk*” (PR2-GP2) as there is “*not always a lot of time to think*” (PR4-GP2) or “*deal with the patient properly*”. (PR6-GP2)

“for example, this morning I’ve got all these patients to see and then I’ve got a load of phone calls to make, you’ve got visits to do, then you get a medication query and you’re always in a rush, you’re always stressed, etc, etc. So I don’t think the environment helps at all, I think there’s a lot on GPs’ minds. (...) I think there’s a real risk that things can get overlooked”. (PR6-GP2)

This inherently stressful environment “*rather than ignorance*” (PR13-GP1) or “*a lack of knowledge*” (PR6-GP4) was felt to contribute to errors being made. As one GP explains “*if I’m running an hour late, (...) the first lady didn’t get much of a clinical entry or got a very badly typed one*”. (PR3-GP1)

GPs perceived these mistakes or errors as almost inevitable saying how there is always going to be the “*occasional*” prescription “*that you don’t get exactly right and perhaps you’re not quite as specific as you should be*”. (PR2-GP1) One GP felt that time pressure was the “*biggest potential reason*” for him making a mistake, but hoped that these mistakes did not turn out to be a “*big issue*” or “*anything major*”. (PR2-GP2)

“the critical use of time is for me the biggest single stress factor in General Practice. The fact that there’s so much to do in such a short space of time, that you are almost inevitably going to make some mistake. But now I hope that they are just small mistakes but I don’t think there could be zero mistakes for anyone, honestly, I genuinely don’t”. (PR2-GP2)

Two important conditions were felt to contribute to this stressful working environment; the *appointment system* and *patient demand*.

One GP acknowledged how their patient appointment system was *“not done as well as it could be”* (PR3-GP1) in his large practice and felt that this added to the pressure. He recognised that they had an obligation to offer patients an appointment within a specified period of time, in order *“to satisfy the external issues of access”*, but questioned this necessity when patients often turn up with only *“routine issue[s]”*. (PR3-GP1) Several GPs also felt a lot of pressure from patients who wait in reception and *“demand”* (PR6-GP4) to be seen, or just *“want everything now”*. (PR7-GP2) This created difficulties for those who were already working at maximum capacity:

“So you can offer a planned appointment but that won’t suit, they want to be dealt with that day. And you can’t, it’s difficult to build in the staffing structures to cope with all of that, you know, because we can sometimes have 40 odd patients wanting to be seen by the duty doctor on a duty day in the afternoon, you know, on one afternoon. It just goes on and on and on, people walk in and “Well no, I must be seen.” (PR7-GP2)

All GPs working in one practice were highly critical of their walk-in centre. One GP explained how it *“only takes three [patients] to come in at once (...) for you to know that you’re under pressure”*. (PR14-GP1) As far as his colleague was concerned, the “silly” walk-in centre had increased the likelihood of errors:

“Yes, I think the fact that it is a walk-in centre and the insane business of it and it’s a crazy, crazy system, I think errors are more likely, I think well we all think, we’ve all been forced to work this, we don’t think it’s a good system. I think it’s got a huge potential for errors”. (PR14-GP3)

A third GP in the same practice admitted how *“at the back of your mind you’re thinking I need to deal with the walk-in (...) [and] sometimes it does stop you from looking fully as you would want to”*. (PR14-GP2) Another GP shared a similar view, reflecting on the fact that a high volume of patients (waiting to see her) would increase her stress levels and put her *“more at risk of making errors”*. (PR7-GP2)

“So, for example, a duty day when you know the waiting room is absolutely heaving outside, you know, you do start to become a bit dysfunctional if you’re not careful, so that’s a problem. So if you can keep things under control and manageable levels then

obviously you're going to be a lot safer but that isn't always possible". (PR7-GP2)

Practice staff shortages and the knock-on effects of closing the practice for bank holidays, for example, were also felt by one GP to have a crucial bearing on their workload. One GP admitted that her practice had been particularly poor at planning for these knock-on effects.

"you know after a Bank Holiday everybody wants to be seen so we should clear the decks and make sure everybody can be seen. We don't always do that but I think we could do more of that really. (...) if you've got poorly trained staff or shortage on another level, you know, reception level short staffed or nursing level short staffed, then there's knock on effects on the doctors. Likewise, if the doctors are short staffed, there's knock on effects on everybody else". (PR7-GP2)

7.5.2 Distractions and Interruptions

GPs felt that the potential to be distracted and interrupted by other practice staff and patients was *"enormously high"*. (PR2-GP2) One GP explained how he got interrupted by reception staff, practice nurses, health care assistants *"once or twice [daily], sometimes lots"* but accepted that this was just *"part of the job"*. (PR1-GP1) Other GPs felt more strongly about these unplanned distractions and interruptions as they perceived them as the cause of errors. According to one GP, distractions *"knock us out of our stride"* and things *"go wrong because you're not in that closed zone and giving it your entire attention"*. (PR3-GP1) Even without being interrupted, he admitted that his error rate *"would never be zero"* but it would be *"down lower"*. (PR3-GP1)

Distractions and interruptions caused by practice staff

GPs were interrupted by practice staff both during and after their GP – patient consultations. They insisted that being interrupted during the consultation only happened on occasions for more *"urgent issues"*. (PR3-GP1) Instant computer messages could also flick up on their screen or *"the phone might well go and they [receptionists] say I've got so-and-so to speak to you"*. (PR2-GP2) The majority of interruptions took place in-between patients, however, when practice staff would often be *"hovering outside the door"* (PR3-GP2) waiting to speak to them. As mentioned previously in Section 7.4.2, nurse prescribers would seek a GP's signature for prescriptions they had generated, as part of their 'quasi-autonomous' role. Although one GP did not *"really view it as an interruption, (...) [but] just part of the day really"*

(PR4-GP1), the majority found it “intrusive” (PR2-GP1) and believed it “contribute[d] to errors”. (PR7-GP3)

“I’m really worried that I’ll forget to do something or I’ll forget to write down that I’ve got to refer them because your train of thought’s just gone. And then if you’ve forgotten it and you move on and, you know, that letter will never get done and four weeks later the patient phones up and says “I still haven’t heard from the cardiologist”.” (PR2-GP1)

One GP attempted to sort out this “thorny issue” (PR3-GP1) by raising it at their bi-monthly practice meetings on a number of occasions and sending out specific instructions to staff to keep the number of interruptions down. Despite noticing a temporary improvement, he reflected on how it got “worse again, you know, it creeps back [up]”. (PR3-GP1) He perceived certain practice staff as reluctant to change, explaining that they felt “uncomfortable” leaving a problem “unsorted”. While it is arguable whether this is in fact the case, it raises important concerns around satisfying patient demand.

“we have to say if it’s an urgent situation sure, absolutely, but otherwise, no. Stick it in my tray and I’ll deal with it at the end. But certain staff feel uncomfortable in doing that, they don’t like leaving a problem unsorted with a patient in front of them. They don’t wish to dissatisfy the patient by saying, “Oh the doctor will deal with it at midday”. But one patient’s satisfaction is the patient who’s in front of me’s prescribing error because I’ve got it, you know, because I’ve been distracted and I’ve missed something”. (PR3-GP1)

This GP may have failed to appreciate the persuasive nature of some patients in certain situations as mentioned earlier and their need for “everything now”.

Distractions and interruptions caused by the patient

Our analysis suggests that the patient was also a source of potential distraction for GPs whilst prescribing. Some GPs presented their patients as the talkative type who were often unable to rationalise their particular issues: “you know that Mrs so-and-so is a real whittler”. (PR2–GP3) Several doctors described how difficult it was to concentrate on prescribing when your patients are “sort of nattering in your ear” (PR7-GP1) or “bombarding you with lots of different things”. (PR3-GP2) GPs also showed their tolerance and patience by sometimes asking patients to “just hold that thought”. (PR7-GP2) They also considered trying to get through things quickly so as to “clear the patient out” (PR3-GP1) when you are “pressurised for time”. (PR6-GP4) One GP admitted that it would be very easy to spend “a

lot more than 10 minutes” on one particular consultation if, for example, the patient felt “tired all the time”. (PR6-GP4) In another example, the GP demonstrated how difficult it was to maintain concentration when the patient “comes and presents you with a whole battery of symptomology”. (PR3-GP1) This patient was presented in his account as taking every opportunity to discuss all kinds of issues with him, although it was clear that her recent bereavement lay beyond this GP’s prime area of interest. Although disclosing how hard it was for him to concentrate in this situation, his previous consultations with this patient appeared to enable him to manoeuvre the more recent ones with less difficulty.

“This lady brings an awful lot to the table. And she persistently overruns her consultation. She, how can I put it, she comes up with sort of multiplicity of problems and so trying to fit it all in is very difficult. And it’s often the ‘whilst I’m here’ scenario, ‘oh by the way’ or you get so cluttered up in your 10 minute task with other things (...) all the time, she gives you that feeling ‘Oh God, she’s back again!’ and so what happens is you get distracted and you don’t complete the task because you’re just relieved and you’re 20 minutes late, and you just quickly sort things out”. (PR3-GP1)

In further analysis of the same interview data, this GP makes the argument about extending the time for a patient consultation to potentially 15 minutes, as there is *“so much more in the task now than I ever did before”*. (PR3-GP1)

7.6 The Task

In this section, we focus on two main tasks in general practice: repeat prescribing and patient monitoring. We shall break down the process of repeat prescribing into ‘*Ordering*’, ‘*Processing*’, ‘*Signing*’ and discuss in detail the conditions that we felt contributed to errors in these main stages. We will also discuss the various conditions that influenced the occurrence of errors in monitoring patients.

7.6.1 Repeat prescribing – Ordering stage

Many practices received requests in different ways for repeat prescriptions. They were either hand delivered in person or by a representative, requested over the phone, or submitted by e-mail or through System 1. Staff at the patient’s pharmacy also hand-delivered or faxed

repeat prescription slips through to practices. Some methods were perceived to be safer than others. One GP highlighted how they had as a practice *“stopped receiving requests on the phone because of the potential for medication errors”*. (FG2-GP2) Some practice staff regarded written requests (via e-mail) to be safer and to work *“fantastic[ally]”* well (FG4- Presc Clerk 2). Staff in another practice offered a different perspective, reflecting on the fact that the responsibility was with them to tick the right box (following the information received in the e-mail). As far as one receptionist in this practice was concerned, it was possible to tick the wrong box and give out the wrong medicine if, for example, you have *“aspirin and amitriptyline next to one another”* (FG2-Receptionist 1). Aware of this risk, one GP in this practice explained that System 1 gave patients the responsibility to tick the items they wanted and he encouraged more patients to sign up to, what he perceived to be, a safer system.

“So we’ve been on emails for a few years. The problem with emails, of course, is that they’ve [patients] got to write it and then we’ve [practice staff] got to tick the right box, whereas System 1 does have a choice for them [patients], yes, which we’re trying to get more people to sign up to, where they can actually just tick on their own screen the one they want”. (FG2-GP2)

Another GP also pointed out how pharmacists have requested items in the past on behalf of their patients and ticked *“everything that’s on their repeat”*. (PR6-GP2) He reflected on these actions as inappropriate, explaining how the patient did not actually need some of these requested items.

“So we’ve got two examples right here next to me about how the pharmacy’s just ticked and faxed it to the surgery and our prescription clerk has phoned the patient and [asked] “Have you actually requested these?” and the patient has said “No, I haven’t”. (PR6-GP2)

7.6.2 Repeat prescribing – Processing stage

On receiving a request for a repeat prescription, administrative staff were allowed to issue them in the practices studied if the items had been previously authorised by a GP. For an item(s) that was not included on the patient’s repeat prescription list, then the GP needed to be asked. One GP felt that their practice system of reauthorization was *“fundamentally safe”*, as their prescription clerk was *“pretty good”*. (PR6-GP3) This view was shared by his GP

colleague who explained how they probably have “fewer errors because we have a dedicated Prescribing Clerk who’s very used to dealing with the repeat prescription requests”. (PR6-GP1) Although perceived to be safe, our analysis suggests however that process issues often arose around reauthorisation. One GP recalled how a “few significant events” had occurred around multiple prescriptions for the same patient getting mixed up or separated, but appeared to take some consolation in the fact that it had been a process issue rather than somebody writing “the wrong thing”. (FG2-GP2) In his account, he described how some patients did not have received the items they wanted because their multiple prescriptions got separated.

“some people have said, “I ordered some of these and I got some of those, and I didn’t ask for that but I wanted this”. So a patient would say that and you look back and you try and figure out what’s happened and it’s generally because some things have been reauthorized and some things have been within date and have been printed (...) they haven’t both gone to the Pharmacy at the same time”. (FG2-GP2)

The receptionist’s account similarly showed her awareness of this issue, adding how the prescription “might sit in Reception for a bit because it’s not acknowledged where it’s going” and also explaining how “you can’t catch them all”. (FG2-Receptionist 1)

7.6.3 Repeat prescribing – Signing stage

One GP had a personal strategy of not signing “a prescription unless [he was] in front of a computer”. (PR14-GP2) He felt this was particularly important for repeat prescriptions because you could “just [so easily] issue them”. (PR14-GP2)

“a patient was on a steroid, a topical steroid for psoriasis and was requesting a lot, and one day I just picked it up and thought to myself, hang on a minute why is this happening? So he requested last week and then this week again, and this is like 100 grams per week so that’s a lot. So I put a stop to it and invited him in so that we discussed it”. (PR14-GP2)

Another GP, who also shared this GP’s view, felt it was also important to reply to requests for a repeat prescription on the computer rather than on “little bits of paper”. (PR2-GP3) It was also felt that not having “enough time to look at [repeat] prescriptions before [you] sign them” (PR14-GP3) could lead to errors. In one particular example, one GP explained how

“short courses can become long ones” (PR3-GP1) when you are not giving the task your full attention and replying verbally to the receptionist’s request in the corridor.

“inattention creeps in because they [patient] come in, “Oh, I’m just getting over a knee replacement”, you give them, you know, 2 weeks, 3 weeks whatever of Ibu [Ibuprofen] or any other NSAID and then they come back and they don’t necessarily come back face-to-face, they come to the desk, “Can so-and-so have an extra repeat?” or “They’ve just run out of this”, “Can they have that?”, it goes on. That then somehow ends up in perpetuity because it can get put on repeat”. (PR3-GP1)

Another GP also felt it was *“crucial right at the beginning when you initiate a new medication that the patient understands the instructions and how you want them to take it (...) [because] once it’s on repeat you don’t tend to look at that quite so much” (PR2-GP1)*

7.6.4 Patient monitoring

Patient monitoring appeared to be influenced by a number of conditions including the practice system, the patient, the communication between healthcare settings, and the prescriber.

The practice system and the patient

Some GPs appeared to use the medication review or reauthorisation process as the ‘trigger’ to check if their patients’ monitoring had been done. The frequency of these medication reviews appeared to vary between patients, with one GP explaining how elderly patients would get a six monthly review and *“the younger ones would be 12 monthly”. (PR7-GP2)* A patient’s annual medication review was regarded by another GP as their *“one shot of glory in the year” (PR3-GP1)* to ensure that they were being monitored. Some GPs appeared to be reassured by the fact that, at a particular point in time, the computer would not let the receptionists reissue a repeat prescription *“because it’s run out of steam and you need [a GP] to reauthorise it”. (FG2-GP2)* This was perceived as an opportunity to catch up with the monitoring.

A deliberate attempt was made by one practice to involve the reception staff in their drug monitoring process. They were provided with a list of drugs and allowed to proactively *“book an appointment for a blood pressure and a U&E or whatever” (FG2-Nurse 1)* when the

patient's review date came up. In contrast, a GP in another practice admitted being "*slightly [more] on the ad hoc side*" (FG2–GP2) when it came to monitoring; relying more on the patient turning up.

"we could probably sit down here and think which drugs do we want to actively monitor and we could just run a search on them every month and who's, somebody could just check has everything right happened. And it wouldn't be a huge job but we've never got round to it. So we rely on patients". (FG2–GP2)

His colleague felt that it was the "*absolute bane of everybody's life*" (FG2–GP3) trying to get patients to come in and have their chronic disease bloods done. She explained that some patients "*will come in on time and we don't have to chase them and there are others that don't.*" (FG2–GP3). Patients on warfarin were felt to be "*dreadfully hard*" (PR7–GP2) to keep track of, in particular. One GP admitted becoming quite "*panicky*" (FG6–GP2) when he found out that one of his patients had not attended the warfarin clinic for six months. According to one GP, the source of these issues could be traced back to the general practice system where "*you can be issuing warfarin and have no idea what the patient's INR is and no idea whether they're turning up anywhere, and we're not automatically getting results through and advice that the clinics are giving*". (FG4–GP2) He was keen to point out that one could place trust in this system and mistakenly assume that the patient is regularly attending the clinic for monitoring. The warfarin clinic at one particular hospital site was regarded as "*an absolute nightmare*", with one GP admitting that he "*almost [felt] reluctant to refer*" patients to what he perceived was a "*very poor service*". (PR6–GP2) The results of a recent practice audit helped illustrate how unsafe the system actually was to one GP and how it needed to be changed.

"certainly as we've been going through this audit in recent weeks it just flags up to you how unsafe it is because there are people that aren't obviously being monitored, we have no idea whether they're being monitored or not, and so now they're being flagged up to be chased up to see what's happening. So huge potential for problems. We haven't actually found many that have had adverse effects but that's probably good luck". (FG4–GP2)

Communication between healthcare settings

Although some practices monitored their own patients' INR (International Normalized Ratio) levels and advised them of any dosage changes, others relied on the INR clinic at the

hospital to do this. One GP recognised the importance of not duplicating these activities carried out by the clinic but later revealed how the *“link between the INR clinic and us [just] isn't there”*, with the communication between them being *“a bit off”*. (FG4-GP3) According to her *“the book where the INR is written down, the dose, doesn't get to be seen by us unless they come in for something else [and] then we check it”*. (FG4-GP3) This view was shared by her colleague who felt that the *“system really should be flagged up as a whole area [of] risk”*. (FG4-GP2) Despite this, some GPs appeared to place trust in the system: *“We issue prescriptions but we don't prescribe the dose, we just go by what the [warfarin] clinic tells us to give”*. (PR9-GP1) Another GP felt it was *“usually straightforward”* to just prescribe according to the Yellow Anticoagulant Book which *“states what dose they should be on”*. (FG6-GP3)

The prescriber

Monitoring to some extent *“depends on the GP”* (PR6-GP2) or the individual who responsibility it was.

“So some people monitor everything and other people you'll find things like that slipping through and people have prescriptions for years without, you know, not being seen. But we try”. (PR7-GP2)

Two conditions appeared to influence the responsibility individual prescribers took for monitoring: the number of hours they worked (e.g. whether full-time or part-time) and their role in the practice (e.g. locum or partner). One GP who only worked part-time perceived his colleagues as reluctant to take on the *“absolute responsibility”* of his patients' monitoring in his absence and *“make the decisions that matter”*. (PR6-GP2) He drew a distinction between his GP partners who were *“OK because they realise how important things are”* and some of the junior doctors or locums who were poor at following things through.

“you want to pass on responsibilities for the patient to a particular doctor and because they may only be here for a few months they think well actually why should I take responsibility, make myself extra work etc, etc.”. (PR6-GP2)

In further analysis of the same interview, he offered a way of understanding this perceived reluctance by describing the complexity of some particular patient cases and the high workload involved. Locum doctors and trainees were portrayed as aware of this workload but avoided taking it on.

“So for some people that [are] potentially quite complicated, I think, there’s a real risk that patients get lost to follow-up if their regular doctor isn’t here all the time like I’m not (...) there’s a range of social services [issues for some of them] that (...) can be a lot of work and I dare say sometimes the GP in question says, “Crikey, stay well clear out of this one” sort of thing”. (PR6-GP2)

GPs in other practices offered similar evidence of how locums did not appear to take on the necessary monitoring. One GP highlighted how their familiarity with using the practice computer system was importance because *“if they don’t know the system [then] there could be a problem. We try and get most of them to come beforehand and make sure they know the computer system”. (FG4-GP3)*

“she came for her regular review in June of 2010, unfortunately we had a locum doctor here and he did, the form he did was lipid profile, full blood count, U&Es, he didn’t tick the LFTs. I don’t know why, I can’t explain that”. (PR9-GP1)

7.7 The computer system

There were several accounts of the importance of computing as a method of improving safety, however in this section we address computer-related issues which were mentioned as error producing conditions. The issues can be broadly summarised as problems in first generating a prescription, additional problems related to repeat prescriptions, problems with maintaining an accurate patient record, and issues associated with the computers and software – in practice many of these were interconnected.

7.7.1 Generating the first prescription

A well recognised problem with computerised prescribing systems can be the picking of the wrong product from a list. An example was seen in this extract from a focus group:

*GP: “We’ve had another one with the wrong insulin, it was meant to be a short acting and she was getting the long acting.”
(FG4-GP2)*

The practice nurse commented:

“I always find it’s very difficult with insulin because what you want isn’t always on the choice list, on the pick list it is? And you’ve got to find the right word to start with or you don’t get the right pick list.”

(FG4-Nurse 1)

Sometimes computer hardware or networking problems may have been associated with errors.

“Our problem here is our computers are rubbish. They work really, really slowly so sometimes you can press a button and it can take a long time for that, like if I was to prescribe something for that patient and it was when our computers were running slowly, sometimes it will crash entirely or it takes a long time to come through so we scroll down an option, a pick list, it can pick the wrong thing which is very frustrating.”

(PR3-GP2)

Sometimes medicines were associated with default dose regimes, which might not be appropriate on all occasions.

“Sometimes it automatically gives the dose and the frequency when you don’t particularly want that frequency, like I don’t think it would be a major error or anything but sometimes, doxycycline, it depends what you are prescribing it for. If it’s like a respiratory type thing or sinus it says two now and then one for 8 days, whereas if you are doing it for Chlamydia or PID there’s a hundred twice [a day] so you just, yeah, I think you’ve just got to be a little bit careful.”

(PR8-GP1)

A theme which commonly occurred was that of important alerts being missed. In one case penicillin had been prescribed by a locum for a patient with a documented penicillin allergy. The GP being interviewed tried recreating the prescription, and a red exclamation mark came up with a note that the patient was allergic to penicillin, proving that the system was working correctly.

“The prescriber here, who was doing a locum for a year with us He’s overridden it, hasn’t explained why.” (PR6-GP3)

He goes on to say:

“If you have too many warnings from the computer then that makes you tend to override them, you become a bit more cavalier and that's a danger.”

(PR6-GP3)

There were many other reasons given for alerts being overridden; it could be because the warnings were inappropriate.

“You can have a steroid cream and you get antihypertensives interaction and ‘do you want that?’ And ‘yes I bloody do’.”

(FG2-GP2)

And in some cases there are alerts which can be safety overridden, however important ones can be missed.

“Say for example that you're prescribing ... for someone and they are on amitriptyline 10 mg and I prescribed something that interacted with it that raised the level of amitriptyline slightly, but as he was on only 10 mg it didn't matter. And if there's 3 of those going on then you missed the one that says, the more important one that's in the middle.”

(FG3-GP2)

Even ‘strong’ warnings could be missed.

“Although the information is flagged up you'd be surprised how many doctors, nurses ignore how many warnings come up because if you prescribe something on our system for example it says contra indications for this/that drug, it says strong or you know gives it 3 out of 3, you'd be surprised how many times it says 3 out of 3 and yet the doctors don't actually look at it.”

(PR6-GP2)

Tiredness and workload could also affect vigilance

“But we do reach the point where we do get, if you're tired, or a busy surgery, where you actually stop registering what its saying.”

(PR7-GP2)

7.7.2 Generating repeat prescriptions

The problems of picking from a list, which exist when first generating a prescription, are still present

“It's just ticking boxes so if you've got aspirin and amitriptyline next to one another it's ticking the wrong one.” (FG2 – Receptionist 1)

This surgery had introduced the ordering of repeats by email; however, this had introduced a transcription stage which could be another source of error

“We've been on e-mails for a few years, the problem with e-mails of course is that they've got to write it and then we've got to tick the right box”.
(FG2-GP2)

In one case a doctor had re-prescribed eye drops at the high initial dose, instead of reducing the dose appropriately

“Being honest, I think probably I just hit re-prescribe on that.”
(PR14-GP1)

7.7.3 Maintaining an accurate patient record

All the above causes of error could lead to the patient record being incorrect. There were, however, several other ways in which errors could be introduced. Once the record is incorrect any error is likely to be reproduced by repeat prescribing, or transfer of information to a hospital, for example. Causes of error included putting information into the record of someone with a similar name.

“We had one diabetic lady who was having hypos and when the nurse went back to work out what was going on I think, if I remember rightly, the daughter's insulin was put on the mother's name, they were very similar.”
(FG4-GP2)

Updating the medicines in patient records following discharge from hospital could also lead to problems.

“So if the hospital decides to change somebody’s drugs, if you don’t, at the time you receive the letter, go in there and make the appropriate additions and subtractions then if you see that patient and you don’t know that patient you might not necessarily cotton on to the fact that their medication’s been changed”.

(PR7-GP1)

In that practice the updating of the record under these circumstances was done only by doctors. He explained that the hospital had electronic discharge letters, which were received quickly, but which could lead to problems because they were not on the screen at the same time as the patient record:

“The trouble is you can’t read the letter and make the alterations on the computer at the same time because a) the screens just aren’t big enough and it’s just, you end up having to have the paper copy to update the computer, because it’s just not possible to do”.

(PR7-GP1)

Once a prescribing error had been identified, there was a risk that it would remain in the patient record.

“A chemist may phone and say ‘By the way doctor, do you really mean to say bd?’ and then the doctor will go ‘Oh yes, whoops, sorry’ and that won’t necessarily get documented”.

(PR14-GP3)

Lack of familiarity with the computer system could lead to information being entered but not becoming an effective part of the safety alert system.

“With locums and registrars entering the data accurately is important because someone might present to them and say ‘I’ve got an allergy’, or they think this rash is an allergy to whatever and it’s no good putting it in free text, it’s got to go, it’s got to be coded properly otherwise nobody else can use it in the future”.

(FG4-GP2)

7.7.4 Other issues

It is often difficult to untangle the causes of errors associated with computer systems, as it is not clear whether the problems are to do with the hardware (processing ability, network speed and reliability etc), or the way the software has been locally implemented, or the training of regular and occasional users, or a combination of the above. In an earlier extract the delays in the computer system were seen as a potential cause of picking errors. In the next case, the problem of lack of information for a “walk in” patient is highlighted.

“The only problem with walk in patients is that we don’t always have their acute medication on the screen so then they are telling us what they’re on and we don’t have that sort of safety net ... you’ve got to be a little more careful”.

(PR8-GP1)

GPs and their staff had expectations of the computer system and could overestimate its ability to prevent errors. The following is from an interview with a GP about a prescribing error from his practice which involved a lack of dose instructions for co-amoxiclav.

“I’m surprised you can get through the system without doing that actually. I thought it would have kept going, flashing back to that position saying ‘fill in this box’”.

(PR7-GP2)

7.8 The Primary Secondary Care Interface

7.8.1 Secondary Care Correspondence

The poor timeliness, legibility, content and layout of secondary care correspondence were all felt to increase the risk of prescribing errors in general practice. Our analysis suggests that patients often visited their GPs before this correspondence was received by the practice, thus resulting in many GPs trying to piece together what changes in patient management had been made with little or no information. The quality of secondary care correspondence appeared to vary a lot, depending on the hospital and department, with several GPs in one area raising important concerns about their local ophthalmology department. These GPs, from different practices, described how difficult it was to decipher between medicines which had been stopped intentionally by the hospital clinician and those which they might not have realised that the patient was on when admitted to hospital. One GP felt that she needed to

separate out the correspondence received from this ophthalmology department from that of others, but admitted that this was easy to do when received electronically.

“I think when they’ve been in and out of hospital is a real time of uncertainty because they’ve had things stopped and started, you’ve not got or had anything come through, you don’t know, sometimes they’ve stopped things deliberately, sometimes they just haven’t realised they’re on it, (...) I am very cautious about (...) the ophthalmology letters, I tend to put those to one side and actually have to come to the computer and look at them because it’s quite a common error, area for errors, I think in terms of prescribing. (...) I’ll look at them together which was fine with the old system when we were getting the paper, (...) we’re now getting the electronic mail through and I think that’s not quite as easy”. (PR4-GP2)

Another GP in a different practice also shared this view, describing her uncertainties around whether particular medicines had been stopped, or as another GP put it: “[trying] to work out exactly why three drugs are now no longer on their list”. (FG2-GP4) She explained how she would often phone up patients to seek further details from them on what they were taking, but admitted feeling still a little uncertain even after their conversation.

“Certainly some of the ophthalmology letters (...) are somewhere between ridiculous and useless. They’re just appalling (...) They’re the worst, they don’t say what they’ve stopped, they say medication has been changed and they give you a list. I mean I rarely get one of those without having to phone somebody up and say, ‘What are you taking?’ And even then I’m not sure that it’s right”. (FG3-GP2)

Prominent in GPs’ accounts was the need for any medication changes to be made immediately obvious to them (e.g. they suggested in bold type or in capital letters) or clearly marked at the very onset of the letter and not “buried in lots of other stuff” (FG4-GP2). GPs were usually tasked with the job of looking through the whole list of discharged medicines and deciphering what medication had actually changed. They recounted the difficulties of marrying up a list of drugs in alphabetical order (on their computer system) with those in a random order (on the hospital letter), and the possibility of errors occurring when there is a large volume of information in the hospital letter.

“the biggest problem that we face is in assimilating the information and making a judgment and the more complicated, the more long winded and the more volume, the higher volume and the less time you’ve got to deal with it in a busy working day, I think leads to errors”. (PR2-GP2)

One GP was keen to show the ambiguous wording of a hospital letter he received and admitted failing to pick up on the fact that the hospital clinician was “*sort of suggesting*” that he should prescribe a lower dose of the drug risperidone. He explained how it stated, on the top of the letter, what the patient’s current medication was and how there was no change to medication. However, lower down in the text, he noted how the hospital clinician had discussed the possibility of reducing the dose of risperidone to half with the patient, suggesting that this might be something he would like to consider.

“I’m reading this out, it says “Current medication: PRN risperidone 1 milligram. Change of medication: None”, it says at the top of the page. Within the text of the letter, it says “We discussed the option of using 0.5 milligrams to see if it reduced. Would be grateful if you could kindly issue a repeat as and when required”.” (PR6-GP3)

When this GP’s account is examined in detail, it is clear that he perceived the hospital clinician to be “*thinking aloud*” whilst writing the letter and that this suggestion was something he might like to consider but it was “*not essential*”. (PR6-GP3) He recounted the thoroughness and care he usually takes when reading letters, and felt that the ambiguous wording of this letter was partly responsible for why he had failed to make the change:

“Because on the one hand he says “it might be a good idea to use a lower dose because he was tired afterwards”. On the other hand, he hasn’t made it explicit, in fact he’s actually said “No changes”. So no change was actually made and I have actually, here we are, because when I read letters I do try and put a little comment or two about them on to what I’ve written, ‘Annual review stable, occasional use risperidone if agitated, enjoys work placement’. So that’s what I’ve done, I haven’t highlighted the fact that he suggested he might try a lower dose”. (PR6-GP3)

This example of ambiguity is rich in its potential to offer insight into how and under what circumstances errors may occur. In the example given below, another GP highlights his uncertainty around whether to continue prescribing a medicine (started in hospital) for a patient. After much deliberation, this GP decided not to add the additional medicine to the patient’s repeat prescription list, conscious that they were on quite a large number of medicines already.

“Everybody but everybody comes out on omeprazole, you know, so do you want them to carry on with the PPI or are they only hav[ing] that because of the stress response while they were in hospital? So there are some times when we don’t put on

as a repeat something because they're already on fifteen items and you don't really want them on sixteen". (FG4-GP2)

Both these cases suggest that the wording of hospital correspondence needs to be clear and accurate, with any changes in medication stated explicitly. The reason for these changes, together with the length of time they should be on the additional medication, should also be clearly specified.

Although several GPs recognised the need to update patients' computer records promptly with the information (once received), they also acknowledged how some may "*fall through the net*". (FG4-GP2) Time was considered to be an important factor impacting on whether these records were updated, as one GP highlighted:

"We might get hospital letters and not have enough time to really look at them and think gosh they've changed some, (...) yes, it's mad, it's dangerous". (PR14-GP3)

Another GP in a different practice also explained how some GPs may be more diligent than others at making these changes promptly. One GP also highlighted how if the patient was on a large number of medicines this could increase the chances of overlooking something important.

"And when there's twenty-five drugs on that list, it's just disheartening isn't it? So, of course, you try your best but equally I think that I could probably, I reckon sometimes it slips a bit. [The more complicated the patient] the more dreadful it is, yes". (FG2-GP2)

Another GP offered a different perspective, reflecting on the fact that some GPs' ability to use the practice computer system may be poor. The unclear layout of hospital correspondence, as mentioned previously, was also felt to impact on their ability to make these changes, with the layout of the ophthalmology department's correspondence "*certainly [considered] a risk*" as they had a "*vast array of ticks of various boxes*". (FG3-GP1)

These accounts demonstrate an awareness on the part of the GPs that hospital recommendations need prompt action, whilst also raising important concerns over individual practices' processes of verifying that necessary changes have been made.

7.8.2. Secondary care recommendations

A number of GPs recounted being asked to prescribe unlicensed or specialist drugs without adequate information. Some GPs admitted finding this situation a little "*tricky*" and appeared

reluctant to prescribe these drugs, saying *“you need to be very careful because [if] we’re prescribing, we’re responsible”*.(FG4-GP1) Three important factors appeared to influence GPs’ decisions to prescribe, including local guidance (sometimes referred to as the ‘Red-Amber-Green’ document), whether the drugs were commonly used in general practice, and whether the GP perceived the harms to outweigh the benefits for the patient. One GP admitted feeling *“very de-skilled”* (PR14-GP3) compared to the hospital specialists and would prescribe more than the BNF recommended amount of a drug if requested. In her account, she perceived the prescribing of a higher dose of a drug for epilepsy, for example, to be *“in the patient’s best interests in terms of controlling their fits versus the risks”*. (PR14-GP3) This particular case was not considered an error by the research team, but the following quote shows the GP’s uncertainty:

“I think we feel very de-skilled as compared to the specialists ultimately I would go with their advice even if it was to prescribe more than what the BNF said if it was clear that they knew what they were doing, do you know what I mean? If they said, “We are suggesting that we up his dose to 3.5 which is more than normally is recommended”. So then I would probably just go with it.”. (PR14-GP3)

Chapter 8: Findings from the root cause analyses

Fifteen root cause analyses were undertaken and a brief description of the cases is shown in **Table 26**. It can be seen that a wide range of different types of prescribing and monitoring errors were covered along with two cases that were judged to represent sub-optimal prescribing and one that was subsequently judged to be not an error.

A number of error producing conditions were identified from the root cause analyses. These were mapped onto those identified during the interviews and focus groups with GPs and practice staff. For the purposes of presenting summary findings from the analysis of RCAs we have created a separate category of 'communication' (the issues identified at the primary/secondary care interface fit into this category along with other communication problems) and we have not separately presented the 'computer system' category. **Table 27** summarises the contributing factors in each of the root causes analyses and key points are outlined below, with illustrative RCAs highlighted.

8.1 Prescriber factors

In 12 of the RCA cases, individual factors relating to the prescriber were thought to contribute to errors. These included knowledge and training on the appropriate use of medication (RCAs 1 and 6); drug-drug interactions (RCA 4), and (over)-reliance of decision support systems for alerts of drug interactions and contraindications (RCAs 7 and 8). Failure to carefully check dosages was an issue in some cases (RCAs 13 and 14); failure to carefully check the accuracy and appropriateness of the wording on the prescription before signing it was an issue in others (RCA 10).

8.2 Patient factors

In 12 RCA cases, factors relating to the patient contributed to the occurrence of error. These were commonly related to the complexity of the patient's clinical condition and in several cases may also have been related to the patient having an existing mental health disorder (RCA 2). Furthermore, sometimes errors were related to factors such as the patient being house-bound (RCA 4), or not fully engaging with services, particularly in terms of the need for blood-test monitoring (RCAs 9 and 11).

8.3 Team factors

In 11 RCA cases, it was apparent that team factors, such as lack of coordination of care within the general practice was an issue, and contributed to errors happening. Examples

included the failure to ensure adequate blood test monitoring for patients on high-risk medications (RCAs 3, 9 and 11).

8.4 Communication factors

In 11 RCA cases, communication appeared to be an issue, whether this was between the prescriber and the patient (RCA 10), within the primary health care team (RCA 12), or between primary care and secondary care (RCA 3). Lack of availability of a shared care document stating requirements for monitoring a patient taking azathioprine was an issue in one case (RCA 9).

8.5 Work environment

In ten RCA cases, working conditions were thought to contribute to errors. Problems identified included the heavy workload of GPs with multiple competing demands on their time and specific time pressures in relation to responding to prescription requests. There were also thought to be problems relating to use of locum doctors because of lack of knowledge of patients and inadequate information exchange.

8.6 Task factors

In nine RCA cases, contributing factors were related to the task itself. Examples included failure to undertake rigorous medication reviews (RCA 1); failure to check whether a prescription was safe in terms of cautions (RCA 6) contraindications (RCAs 7 and 8) and drug-drug interactions (RCA 4), and lack of robust systems for helping to ensure timely blood test monitoring (RCAs 9 and 11). In some cases, guidelines and protocols were not easily available; for example, in RCA 10 the general practice did not know that (according to PCT guidance) they were not supposed to be prescribing tacrolimus to a lung transplant patient.

Table 26: Descriptions of potential errors where Root Cause Analysis was undertaken

RCA ^a code	Type of error/problem	Brief description
RCA1	Unnecessary drug	88 year old male prescribed aminophylline 225mg SR tablets one to be taken twice daily since 1993 at the same dose without having a documented clinical indication for it (i.e. asthma/COPD).
RCA2	Unnecessary drug	31 year old male with a history of psychosis was prescribed testosterone decanoate caps 40mg, one daily for impotence. Consultation notes state that Patient has low serum testosterone (5.4nmol/L (normal range 8.4-28.7) and "difficulty with erection". The error judging panel felt that there were more appropriate ways of managing impotence in this case.
RCA3	Monitoring error – result not available	93 year old male prescribed warfarin 1mg tablet "as directed" without the practice having any knowledge of the INR level.
RCA4	Drug-Drug interaction	72 year old male who was regularly taking aminophylline 225mg modified release, two to be taken twice a day, was prescribed antibiotics with potential for serious interaction (erythromycin, clarithromycin, ciprofloxacin) on three separate occasions, on home visits.
RCA5	Omission error – failure to prescribe concomitant medication	78 year old male prescribed aspirin dispersible tablets 75 mg daily, with a history of gastrointestinal bleeding. The error judging panel felt that the patient should have been prescribed an ulcer-healing drug to protect against further gastrointestinal bleeding.
RCA6	Dose/strength error	73 year old male prescribed rosuvastatin 40mg for CHD since an admission in 2003 (where she was swapped from simvastatin 40mg). Patient did not have "severe hypercholesterolaemia" and was not under specialist supervision (BNF advice for 40mg dose). Most recent cholesterol level was 2.7 mmol/L.
RCA7	Contraindication error	82 years old female prescribed allopurinol 300 mg once daily. Patient has an impaired renal function (e-GFR 40mL/min). BNF advises maximum 100 mg daily in renal impairment, increased only if response inadequate. Given impaired renal function and age the error judging panel felt that the GP should have tried reducing the dose to see if control of gout could be maintained.
RCA8	Two contraindication errors and a dose/strength error	77 years old female prescribed simvastatin 80mg once daily and alendronic acid 70mg once weekly. These are contraindicated as the patient has eGFR of 25ml/min (BNF advises that simvastatin doses above 10mg daily should be used with caution if e-GFR <30ml/min, and that alendronic acid should be avoided if e-GFR <35ml/min). In addition, dose of digoxin 250 micrograms once daily puts the patient at unnecessary risk of digoxin toxicity given the age and renal function of the patient.
RCA9	Monitoring error – monitoring not requested	61 year old male prescribed azathioprine 50mg three to be taken daily. Full blood count had not been requested in the previous 10 months.

RCA ^a code	Type of error/problem	Brief description
RCA10	One formulation error One dose/strength error	59 year old male prescribed tacrolimus post lung transplant as generic modified release formulation instead of Prograf®, despite the discharge letter emphasising brand-name prescribing and not to prescribe the modified release formulation. Also, in the GP prescription records, the tacrolimus dose was written ambiguously as “2 in the morning and 1pm”. The discharge letter stated the dose should be “2mg at 8am, and 1mg at 8pm”. The error judging panel felt that for such a critically important drug, the failure to accurately transcribe the dose recommended by the hospital could have put the patient at risk.
RCA11	Monitoring error – monitoring not requested	66 year old female prescribed Priadel®. This is a lithium based medication that requires three monthly monitoring of lithium levels to ensure safe and effective dosing. At the time of data collection, the patient was receiving Priadel® on repeat prescription, but lithium levels had not be requested in the previous 11 months.
RCA12	Suboptimal prescribing - two potential drug interactions; one example of inadequate documentation in the medical record.	29 year old female prescribed fluoxetine 60mg once daily while also taking diclofenac and tramadol. BNF states there is increased risk of CNS toxicity when SSRIs are taken with tramadol, and there is known to be an increased risk of gastrointestinal bleeding when SSRIs are taken with NSAIDs. The medical record was unclear in terms of whether the patient should be taking 40mg or 60mg fluoxetine each day.
RCA13	Dose/strength error	11 year old male prescribed Tamiflu® (oseltamivir) 30mg twice daily for treatment of influenza. This is lower than that recommended for age/weight of patient. Age at the time of oseltamivir prescribing was 11yrs and weight recorded a year previously was >36kg. The suggested dose according to the BNF should have been at least 60mg twice daily.
RCA14	Dose/strength issue - Judged to be sub-optimal prescribing	10 year old male prescribed griseofulvin 125mg twice daily. BNF states that if bodyweight is <50kg then dose should be 10mg/kg daily for dermatophyte infections and 15-20mg/kg daily in tinea capitis. The child has been given a dose appropriate for a child of 24Kg or less. At 10 years old the child is likely to be at least 32kg, which would suggest the need for a dose of at least 320mg once daily, or 160mg twice daily. The panel judged this as suboptimal prescribing as it was felt that the risks of harm to the patient were low.
RCA15	Dose/strength issue – judged to be not an error	40 year old male prescribed levetiracetam tablets 3.5g daily (in divided doses) for epilepsy. BNF states that maximum daily dose is 3g. Patient under specialist supervision and the 3.5g daily dose was recommended by the specialist. The error judging panel felt that this was probably not an error. The case was included as a root cause analysis before the error judging panel had discussed this case.

^a RCA: Root cause analysis

Table 27: Summary of categories associated with different error producing conditions for each root cause analysis

RCA ^a code	Categories associated with different error producing conditions					
	Prescriber factors	Patient Factors	Communication factors	Task factors	Team factors	Work Environment
RCA1		✓	✓	✓		
RCA2	✓	✓			✓	
RCA3	✓	✓	✓		✓	✓
RCA4	✓	✓		✓		
RCA5	✓		✓		✓	
RCA6	✓	✓		✓	✓	✓
RCA7	✓	✓	✓	✓	✓	✓
RCA8	✓	✓	✓	✓	✓	✓
RCA9		✓	✓	✓	✓	✓
RCA10	✓	✓	✓	✓		✓
RCA11	✓	✓	✓	✓	✓	✓
RCA12	✓	✓	✓		✓	✓
RCA13	✓	✓	✓		✓	✓
RCA14	✓		✓	✓	✓	✓
RCA15	N/A ^b	N/A	N/A	N/A	N/A	N/A

^a RCA: Root cause analysis; ^bN/A: not applicable, because RCA15 was judged not to be an error.

Chapter 9: Defences against medication errors in general practice

Summary

Defences against medication errors in general practice have been identified at multiple stages in the medicines management process:

- Issuing new prescriptions
- Supporting patient decision making
- Dispensing prescriptions
- Repeat prescribing
- Monitoring patients
- Amending prescriptions based on outside correspondence
- Processes supporting medicines management.

These defences have been grouped as:

- Personal prescriber strategies
- Practice-wide strategies
- Health Information Technology (HIT) strategies.

Key personal prescriber strategies include:

- Read aloud printed prescriptions to help ensure patient understanding and to allow the prescriber to check the accuracy of the prescription
- Clarify prescribing recommendations made by specialists where these go beyond the GP's comfort zone
- Review newly prescribed medicines within six weeks
- Add medicines to the repeat list only when patients are stable on them
- Confirm important information with patients even when they are well known to the prescriber
- Ensure that prescribers are competent to use all of the important features of e-prescribing and other IT-support systems.

Summary continued

Key practice-wide strategies include:

- Adopt a formulary to increase familiarity with medicines prescribed
- Strongly discourage verbal requests for repeat prescriptions
- Train non-medical staff to manage requests for non-repeat prescriptions and consider using dedicated staff to manage repeat prescriptions, with additional staff trained as back-up
- Highlight repeat prescriptions with queries so they receive more attention when considered for signing off by GPs and other prescribers
- Perform face-to-face medication reviews
- Check INR results before generating repeat prescriptions for warfarin
- Do not delegate responsibility for difficult patients to junior or locum GPs
- Schedule necessary blood tests for one week before medication reviews
- Update prescribing records as soon as possible (within 48 hours) of receiving correspondence from specialists
- Clarify prescribing changes with specialists if correspondence not available
- Build and maintain a strong safety culture based on open, blame-free, communication
- Appoint a prescribing lead for each practice to lead on protocol reviews and best prescribing-practice.

In addition, secondary care strategies include: 1) Ensuring that specialists' correspondence highlights new medicines, changes to medicines and reasons for changes; 2) Ensuring that specialists' requests for unusual medicines state duration, key side effects, and monitoring requirements.

Summary continued

Key health information technology strategies include:

- Code allergies in electronic clinical records
- For high risk medicines: programme robust alerts to highlight risky prescribing; block inappropriate medication request intervals; automatically insert weekly dosage instructions for methotrexate
- Provide on-line access to clinical/medicines information resources, linking directly from clinical computer systems
- Embed an electronic-formulary within the e-prescribing system
- Use the electronic-formulary to guide prescribing to safer alternatives
- Avoid similar drug names being adjacent in pick-lists
- Allow drug interaction alerts with severity gradings and brief descriptions of the problems associated with specific interactions
- For general practices using the EMIS computer system, use 'practice notes' to improve communication and provide an audit trail for unauthorised repeat prescribing requests, errors, and new prescribing information
- Run searches on clinical records system to identify potential prescribing errors, and patients requiring blood-test monitoring
- Programme computer to alert when patients taking warfarin go 12 weeks or longer since their last INR test
- Use screen alerts and repeat prescribing dates to highlight need for monitoring
- Amend e-prescribing records if accepting community pharmacists' interventions
- Familiarise locums with health information technologies available in practices.

9.1 Introduction

This chapter describes the defences against medication errors identified from the focus groups and interviews with individual practitioners. The defences are ordered and grouped according to the medicines management processes which they protect, with a final section detailing the defences which provide overall support to the medicines management process.

Headings for each section within this report are derived from the medicines management processes illustrated in **Figure 5**. Within each section, defences have been grouped according to whether the defence is based on a personal strategy, practice-wide strategy, or a HIT strategy. Summaries of the defences are presented in tables throughout this chapter. Within these tables, some defences are marked with **!**; these are defences in many situations, but based on the interview and focus group data, in certain prescribing scenarios they can also become error producing conditions. Some defences are marked with **★**; these defences were considered desirable by one or more interviewees but, according to data from the interviews, were not being used in any of the practices.

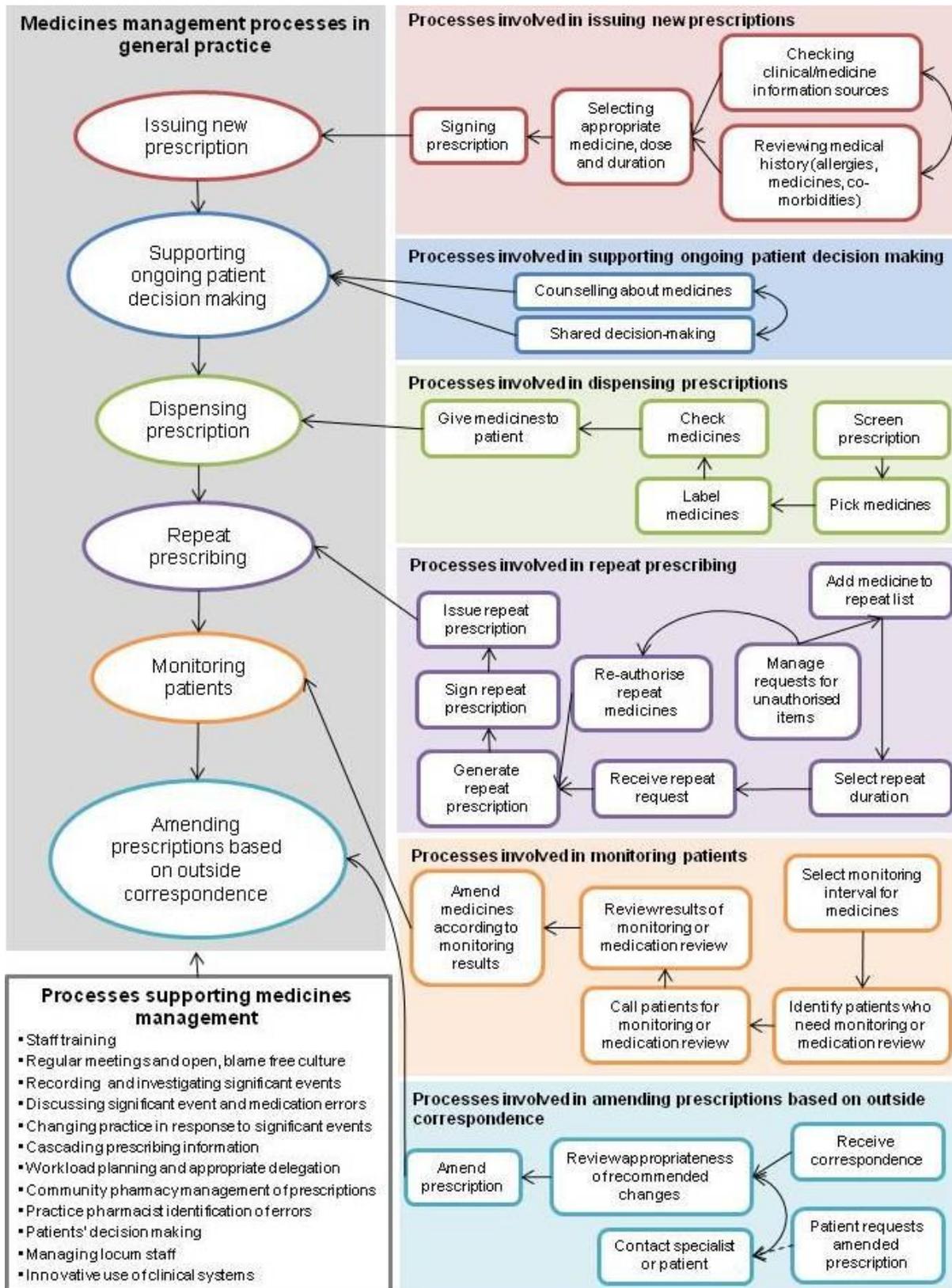


Figure 5: Medicines management processes in general practice derived from interview data

9.2 Issuing new prescriptions

The process of issuing new prescriptions includes many steps where there is potential for error (see **Figure 5**). For each step, defensive strategies were identified and summarised in **Table 28** and described in detail further below.

Table 28: Defensive strategies which can improve the safety of issuing new prescriptions

Medicines management processes	Personal strategies	Practice-wide strategies	IT-based strategies
Reviewing medical history (allergies, medicines, co-morbidities)	<p>Confirm important information with all patients (including well known patients)</p> <p>Ensure competent with supporting features of prescribing system</p>	<p>Contact previous surgery for summary information about new patients</p>	<p>Read-code allergies on prescribing system</p> <p>Summary care record valuable for “walk-in” patients ★</p> <p>Programme robust alerts for high risk medicines</p>
Checking clinical/medicine information resources	<p>Ensure clinical knowledge regularly updated</p> <p>Ensure competent with supporting features of prescribing system</p>	<p>Provide easy access to clinical/medicines information resources</p>	<p>Provide on-line access to clinical/medicines information resources, linking from prescribing system</p>
Selecting appropriate medicine, dose and duration	<p>Where possible, prescribe familiar medicines</p> <p>Pay attention to prescribing system-generated interaction alerts !</p> <p>Refer to prescribing information if unfamiliar with medicine</p>	<p>Adopt formulary to increase familiarity with medicines prescribed</p> <p>Prescribe single strength of high risk medicines !</p> <p>Issue no more than two months of medicine on first prescription</p>	<p>Block inappropriate intervals for high risk medicines</p> <p>Embed formulary in prescribing system</p> <p>Programme ScriptSwitch to give safety advice</p> <p>Automatically insert dosage instructions for high risk medicines !</p> <p>Allow interaction alerts with severity grading and brief descriptions of interaction !</p>
Signing prescription	<p>Read printed prescription to patient to confirm accuracy</p>		

9.2.1 Reviewing patient's medical history

Healthcare professionals stated they believed it was important to refer to patients' medical records even when patients were well known to them. Knowing patients well was also considered to be a further defence against errors. Knowledge of patients' medical and medication histories was felt to be particularly important when access to such information was difficult, such as during home visits, consulting with recently registered patients and walk-in patients, and when clinical information was not properly coded in medical records.

Access to information about patients' medical history was limited during home visits because healthcare professionals did not have access to electronic medical records. This resulted in patients being prescribed medicines they were allergic to, and increased the likelihood of other inappropriate prescribing. This lack of information can be partially overcome by printing out a summary of the patient's medical record.

"We did a significant event meeting on a person that was prescribed amoxicillin on a home visit a few years ago and that was because it was a hand written prescription and the computer had obviously told us that they were allergic to penicillin so as a result of that we now print off the patient summary to take on a visit because obviously now that with computers we don't take notes that we were kind of going a little bit with the repeat prescription maybe but not with anything else so that was a solution." [FG3-GP2]

Knowledge of patients' allergies was considered particularly important and the need to properly code allergies in electronic medical records (rather than enter as free-text) was highlighted. The need to train locum doctors, GP registrars, and staff responsible for summarising patients' records, in how to code allergies was also emphasised. In addition, to avoid allergies and adverse reactions becoming lost in medical records, 'Practice 12' added this information as *"alert[s] so when the patient comes in, you call the patient in, [the computer] alerts you"* [PR12-GP2].

Patients who had recently registered with the practice, especially those with repeat prescriptions, were also noted to be a problem. These patients could request repeat prescriptions before their records had been transferred to their new practice. These patients were always expected to consult a GP before having their prescriptions issued. In addition, reception staff could *"get in touch with the surgery previous and ask them to send us over [a summary] of their previous medication as a safeguard that they can take their medications"* [FG6-Snr Recep 1].

A similar problem was identified for “walk-in” patients (patients who were not registered at the surgery) where GPs had to rely on patients’ recollections of their medical and medication history; this was considered unsatisfactory. GPs seeing “walk-in” patients at ‘Practice 8’ believed that the “[summary] care record would be ideal” because GPs would then know “if [patients are] allergic to anything or whether they’ve had an interaction or problem before.” They also hoped that “the computer (...) will flag up and I think that will prevent errors...” [PR8-GP1].

9.2.2 Checking clinical and medicines information resources

GPs referred to the importance of checking clinical and medicines information when making prescribing decisions, although there were differences in the types of information they accessed. The majority of interviewees referred to the British National Formulary (BNF) if they were unfamiliar with a medicine. Some GPs used the paper-based BNF.

“I tend to use just the good old-fashioned paper BNF. I get my glasses out. I don’t know why, that’s how I’m used to doing it and it just feels familiar and I do use the BNF a lot.” [PR14-GP3]

Others preferred the online version (linked directly from the electronic prescribing system) because of the ease and speed of access.

“GP: I mean I think that, you know, often, I mean with the EMIS system and we’re going EMIS web shortly that, when I went on a training thing it was actually quite helpful that you could click and you’d be straight into the appropriate bit of the BNF which I would find really helpful because I use the BNF all the time.

Interviewer: *So more quickly than in ...*

GP: Oh much more, much more. You actually prescribe the drug and then there’s a little icon and it goes Chapter 14, .72 and it’s actually got the page there for you to read about the drugs which is helpful. Because sometimes if I’m not sure, I mean I’m old enough and experienced enough to quite happily pick up the BNF in front of the patient and say I’m just checking for whatever reason if I’m not certain so to have it on the screen as quickly as that would be great.” [PR2-GP1]

Other clinical information systems of particular note included EMIS Mentor (a clinical decision support system which linked from the practice computer system), clinical knowledge summaries, patient.co.uk, and local and national policies.

“But in terms of clinical information I use loads of different places. There is, I use Mentor a lot. It’s on EMIS. Again because it keeps a record of what I have been looking at so I can make notes of what I’ve looked at as well.” [PR14-GP2]

“Well, yes I do use clinical knowledge for some reason. I think patient.co.uk is very good. I like that, not just for patients, for me, because there are the ones with the little apple on, so they’re very good.” [PR4-GP2]

Web-based resources which were linked directly from the prescribing system (and therefore easily accessible) were particularly valued.

“What I don’t want to do, what works well for us is having an intranet where everything is very available. So we have a hyperlink, so for example the new guidelines you’ve just sent out about preferred prescribing, we’ve downloaded that on to our computer and we’ve hyperlinked it so if we want to look up a preferred prescribing list it’s there. It’s not practical in a 10 minute consultation to have to go through lots of hoops and jumps to get to something. But of course the problem is you need it central so it can be updated easily. If everybody’s got their own individual thing it quickly gets out of date so you almost need a central resource, that’s almost like a click away, that I think would be fantastic, to be able just to say ‘Yes, that’s what it is’, this is where your prescribing information is, that would be fantastic but having to be password protected and get into it, and go into this, that makes it tricky and it makes it less usable and if it’s not usable it doesn’t get used. So it doesn’t matter how fantastic the information is if it’s not easily accessible.” [PR4-GP2]

Not all prescribers had the skills to benefit from the HIT available to support them.

“Interviewer: I mean with regards to the EMIS system I’ve been told there is a medical information

GP: I never use it, I don’t know how to use it. Sad but true!” [PR14-GP3]

It seems reasonable to conclude that, in order to make the best use of the electronic information resources available, prescribers should undertake training in how to use the electronic prescribing and medical record systems, including their additional features.

9.2.3 Selecting appropriate medicine, dose and duration

A number of strategies were identified which increased the likelihood of selecting the appropriate medicine, dose and duration for a prescription. These ranged from personal

strategies such as prescribing from a restricted list of familiar medicines, to practice- or cluster-wide adoption of a formulary, and incorporating information technology strategies to reduce the risk of selecting the wrong drug.

Some prescribers found the interaction alerts generated by the electronic prescribing systems to be very useful, considering themselves *“lucky [to have] the backup of the default for alert messages and systems software that will assist you.”* [PR2-GP2] These alerts were considered particularly useful for GP registrars because *“they’ll take heed of every single interaction it says and come and mention it to you, and you can go through it”* [FG4-GP3]. Frequent alerts were, however, also thought to cause alert fatigue which increased the risk of important alerts being missed.

“...you get so many of them and when you’re prescribing for complex patients well I know all these things interact but, you know, there’s very few choices left and so you start to block out those because you see them so often.”[FG4-GP2]

Another prescriber used the interaction alerts to determine which drugs from a particular class would be safest to combine with another drug (as an alternative to referring to the appropriate clinical information source). This practice was not, however, considered safe by all prescribers. In contrast, some prescribers felt that interaction alerts should not be relied upon; instead they should be used in conjunction with clinical skills and information from other sources because they required clinical interpretation. It was also felt that interactions alerts may *“give a false sense of security”* [PR6-GP4] because prescribers might assume that they would be alerted to all potential problems.

Prescribers found it *“useful”* [FG1-GP3] to have graded alerts (e.g. red alert, level one, level two, level three) which indicated the potential severity of interactions. A summary of the interaction, and the ability to switch off the less severe interaction alerts on a per-prescriber basis, were also considered helpful. In addition to the system-specific interaction alerts, an additional software called ScriptSwitch® (mainly used to highlight more cost-effective prescribing) could also be programmed to highlight *“safety advice”* [FG4-GP2].

National or regional strategies, such as prescribing single strengths of high risk medicines such as methotrexate or warfarin were considered *“a good step forward in”* [FG4-GP2] reducing the risk of prescribing the wrong dose of these medicines. However, risks were also noted if patients moved from a region which did not adhere to this practice. Patients who were accustomed to taking multiple strengths could be confused by administration instructions provided in areas which prescribed a single strength of warfarin. These

instructions do not routinely contain the strength of tablet to be administered; for example *“take one on a Monday, none on Tuesday, three on a Wednesday”* [FG3-Nurse1].

Formularies were considered useful for ensuring that prescribers were familiar with a restricted list of medicines and GP1 from ‘Practice 1’ stated that the formulary had resulted in *“slight changes”* to his prescribing behaviour. Prescribing from a restricted list of familiar drugs was perceived to *“make errors less likely (...) because you just look at them and go that’s not right”* [PR4-GP2]. Formularies could also be dictated by stock availability; this was a particular feature noted in the dispensing practices, but it seems reasonable to assume that this could also apply to surgeries with a close link to a community pharmacy. Some prescribers felt that cluster-wide formularies would be useful to control prescribing costs and ensure consistency in prescribing across practices. Electronic formularies were considered particularly useful, especially if they were embedded into the electronic prescribing system. ‘Practice 2’ had *“a system where certain drugs [were] above a dotted line”* and this indicated the practices *“preferred prescribing list”* [PR2-GP3]. This allowed preferred choices to be highlighted and the medicines with similar names to be separated which, in turn, helped avoid wrong-drug selection errors.

If formularies required prescribers to switch between screens they were less likely to be used by some individuals, however, others became accustomed to switching between screens and didn’t feel that this affected the formularies’ usability.

“What’s crazy is that there is a – of – formulary but I don’t tend to use it very much because I’m peripatetic and I’m in a different room every day I don’t have it saved as a favourite on my desktop in every single room, I’ve never systematically managed to do that. (...) So ideally that’s what I would do but I don’t.” [PR14-GP3]

Robust IT-based safety strategies for high risk medicines were welcomed by prescribers. Those of particular note prevented overdoses of methotrexate. Strategies included preventing the prescription of methotrexate at intervals less than weekly and automatically inserting the dosage instructions for methotrexate. This strategy could be of particular benefit where specific instructions are required such as topical steroids. Where medicines have more than one indication and dosage schedule, however, automatically inserting dosage instructions was thought to increase the risk of prescribing errors. Therefore, this strategy should be used with caution.

“I mean, yes, sometimes it automatically gives the dose and the frequency when you don’t particularly want that frequency, like I don’t think it would be a major error or

anything but sometimes doxycycline it depends what you're prescribing it for. If it's like a respiratory type thing or sinus it says 'Two now and then one for 8 days' whereas if you're doing it for Chlamydia or PID there's a hundred, twice those so you just, yeah, I think you've just got to be a little bit careful." [PR8 GP1]

Some prescribers also felt that new prescriptions should be issued as 'acute' prescriptions only and not put straight onto repeat. This helped ensure that patients were adequately reviewed in terms of efficacy, adverse effects and that necessary monitoring was carried out before medicines were re-issued or stopped. Duration of first prescriptions varied between one to two months depending on the surgery and type of medication.

One GP also noted the importance of linking a prescription to the indication at the time of prescribing. This was felt to be particularly helpful for future medication reviews.

9.2.4 Signing prescriptions

Once the prescribing decision had been made and the appropriate medicine, dose and duration selected on the e-prescribing system, many prescribers did not re-check the paper prescription when they signed it. Some prescribers assumed that the paper prescription was accurate once the details were entered on the computer because *"you know what it sounds like, once you've done it, once you've made a decision you just go on, there's so many other things to get right"* [FG1-GP1]. Despite this, some prescribers were aware that patients had received the wrong prescription in the past.

"I have on one or two occasions there's been something on the printer that I've not taken off and picked it up and signed it and given it to the patient" [PR1-GP1]

Our highlighting of a prescribing error which could have been identified by checking the final paper prescription was sufficient to encourage one GP *"...to double check before [he] re-issue[s]"* [PR14-GP1] prescriptions.

A small number of prescribers, however, had strategies of varying robustness to ensure that the paper prescription was correct. The most robust strategy involved reading every prescription out loud to the patient, especially those with more than one item. This allowed the GP to check the accuracy of the prescription and provide patient counselling in a time efficient manner. Alternative strategies included, counting the number of items on a script to ensure it matched the intended number of items.

“What I do with patients is I read [the prescription] out to them, what it is, after it’s been printed out. It’s come out of the printer, I’ve got the bit of paper, I read out to them what it is, how they take it so that they’re clear how to take it (...) You’re doing two things by doing that, a) you’re checking for yourself and b) you’re checking the patient understands it.” [FG2-GP1]

9.3 Supporting ongoing patient decision-making

Once a prescription was issued to a patient, the patient decided whether or not to take the medicine, how to take it, and whether or not to attend for subsequent monitoring visits. A number of personal strategies were identified which could support patients in making these decisions. These included providing patients with adequate information, helping them remember to take their medicines, or by facilitating an open discussion about patients’ concerns regarding the management of their medicines (further below.

Table 29). These defensive strategies are discussed in more detail further below.

Table 29: Defensive strategies which may help improve safety by supporting patient decision making

Medicines management processes	Personal strategies
Provide information about medicines	Give both verbal and written instructions to the patient Supply medicines in multi-compartment compliance aids (MCAs) for confused patients ! Counsel patients about side effects Read aloud printed prescription to patient to confirm understanding
Use shared-decision making within consultations	Use shared-decision making in consultations with appropriate patients to achieve agreement on medicine taking and monitoring

9.3.1 Provide information about medicines to patients or carers

Informing patients about the potential side effects of their medicines and what to do if they occur was felt to be important. This practice was perceived to encourage patients to seek advice if side effects did occur, and therefore improve the safety of medicines management.

“Well it’s good practice anyway to advise patients on possible side effects and the need for them to be monitored, maybe to be seen every 6 weeks or 2 weeks or sent for blood, we’ll do that anyway, monitoring them, patient advice on side effects.” [FG6-GP2]

Another GP, however, did not “*spend an awful lot of time [counselling patients] because they all go home and avidly read the bit of paper in the box*” [FG2-GP3]. She perceived the majority of her patients to be a “*...well-read professional (...) group of people in a higher social class, (...) Guardian readers*” [FG2-GP3] who would contact the practice if they thought there was a problem. In contrast, one GP felt it was his personal responsibility to “*make it perfectly clear as to how I want [the patients] to take it*” [PR2-GP1].

As described above, one GP facilitated patient counselling by reading “*through [the paper prescription] on the desk, pointing to it as I go through*” [PR3-GP2]. This provided an opportunity for patients to ask for further clarification if they were unsure.

Providing both written and verbal instructions to patients was felt to be important. A nurse highlighted how one of the GPs would “*write on the blank side of the prescription a lot of instructions often, (...) if they need to be seen for a blood test in two weeks because of the commencement of a drug*” [FG2-Nurse1]. This was considered particularly useful if the main carer was not present or there was a language barrier.

“...a lot of things are said verbally and explained verbally or sometimes I write a little note so the family member I can then say, ‘Oh can you give this to your daughter’ because you know sometimes the daughter accompanies and she couldn’t this time so can you show it to your daughter and then she will tell you.” [PR6-GP4]

This GP also experienced difficulties with language barriers when translators were hard to access “*and you may not have a receptionist who could speak*” [PR6-GP4]. This was sometimes overcome by “*phon[ing] the pharmacy and specifically direct[ing] to the specific pharmacist who you know that person can speak their own language. It is a problem*” [PR6-GP4].

Some prescribing situations required changes to prescriptions without face-to-face contact with the patient. Increasing the cost effectiveness of prescribing in general practice can be achieved by ‘batch changing’ prescriptions (where more than one patient’s records are changed in a single process). Where many patients were involved it was felt impractical to have face-to-face consultations with all of them. Instead, patients who may be easily confused by the change were identified for face-to-face consultations in order to mitigate the risks of batch changes to prescriptions.

The number of patients treated in a day can be increased by telephone consultations; however, these were perceived by some to reduce the safety of prescribing. One GP

recalled an instance where, during a telephone consultation, he had advised a carer to increase the amount of amisulpiride suspension given to a patient based on his record of the strength of preparation prescribed. The patient had, however, been supplied a different strength by the community pharmacy. The carer noted the discrepancy between the verbal instruction and the product supplied *“and thankfully they rang back and said, ‘I don’t think we’re talking about the same thing’”* [FG4-GP2]. This example highlights the important defensive role played by patients and carers, and the importance of good communication and record keeping between community pharmacy and general practice.

Some patients can be confused by their medicines, or forget to take them. One practice believed that dispensing medicines in MCAs helped these patients take their medicines as prescribed. There were, however, some difficulties associated with using MCAs.

Medicines such as analgesics, which needed to be taken ‘when required’, caused a dilemma. One GP highlighted that *“in your old and confused patients is it safer just to say, ‘Look, let’s put three lots in’. Just do it three times a day because that’s less harmful potentially than you taking twelve thinking you’ve only had two today. That’s the problem, so it’s not perfect”* [FG3-GP1]. In addition, some medicines also became chemically unstable when exposed to light or moisture in the atmosphere which, in turn, meant that they had to be dispensed separately. The patients most likely to benefit from MCAs were also felt to be those who needed their medication regimens altering on a regular basis. This could mean lots of wasted medicines if MCAs were filled monthly.

“By the time they need a dosette they are by definition unstable.” [FG3-GP1]

9.3.2 Use shared-decision making in appropriate consultations

One GP found that using shared-decision making in consultations, where the risks and benefits of prescribing or monitoring medicines were discussed and patients’ views obtained, was helpful for improving safe medicines management. This GP noted that a patient who was receiving six-monthly monitoring for lithium would not have attended any monitoring appointments had he not engaged in shared-decision making with her and reached an agreement on a monitoring interval that was acceptable to both parties.

Other GPs also stopped short of a truly concordant approach to consultations, instead using extensive explanation and discussion to convince patients that their prescribing decision was the best course of action.

“Well there are times of course when the patient will refuse to take additional, you know, they’ll say I don’t want to take two new tablets, I just want one thing to sort this out, and then, you know, it is quite hard to have to sit down and talk through with them the reasons why you do it. But I generally find those patients when you explain the reason why and say it’s only while you’re taking this other tablet that you have to take both, they’re usually OK with it. So I wouldn’t think that’s a big factor, I’d like to think that most of us are quite willing to sort of have that discussion with the patient if they’re resistant to the idea.” [PR6-GP1]

9.4 Dispensing medication

In one of the focus groups, staff from a dispensing practice spoke about the process of dispensing medicines in general practice. These data are supplemented with comments made by a community pharmacist who participated in different focus group. Practice wide and IT-based defensive strategies at the points of screening, picking, labelling and accuracy checking medicines are summarised in **Table 30** and discussed in more detail further below.

9.4.1 Screen prescriptions

In community pharmacy, all prescriptions are screened by a pharmacist who can identify certain types of prescribing error such as overdoses or drug-drug interactions. Community pharmacists are also supported by computerised interaction alerts. This safety barrier is not present in dispensing practices, where prescriptions are dispensed by trained dispensers. In ‘Practice 1’, the loss of this safety barrier was felt to be mitigated by using well trained dispensary staff (NVQ level two). The dispensary staff were:

“usually pretty good at picking up something that doesn’t look quite right and certainly simple slip-ups like instead of prescribing 28 tablets you hit ‘two’ and they ring up and say, ‘Did you really want Mrs Bloggs to have two amoxicillin rather than whatever’, so they’re very good at that.” [PR1-GP1]. This GP “hadn’t really thought about losing that filter [pharmacist screening], until now.” This made him feel “uncomfortable” although he was “fairly confident in what [he] prescribe[d]” [PR1-GP1].

Table 30: Defensive strategies which can improve the safety of dispensing medicines

Medicines management processes	Practice-wide strategies	IT-based strategies
Screen prescription	Use well trained dispensary staff	
Pick medicines	Keep remainder of split packs in original boxes	Barcode dispensing !
Label medicines		Electronic transfer of prescriptions !
Check medicines		Barcode dispensing !

9.4.2 Picking and labelling medicines

The dispensing practice used a barcode dispensing machine (Dispens-IT®) to improve the safety of dispensing. Prescriptions were transferred electronically to the dispensary. The dispensers then electronically transferred the prescriptions to the Dispens-IT machine, before picking the required medicines and scanning the barcodes to ensure they matched the prescription. If the correct medicine had been selected, a label was automatically generated. The dispenser then stuck the label to the medicine packaging. Dispensing error records showed that this system of work had reduced the numbers of dispensing errors identified within the practice. A number of problems were, however, highlighted by the dispensers:

- The first time a product was purchased, the details had to be manually entered into the Dispens-IT system. If this information was entered incorrectly, the wrong medicine may be selected.
- The barcode scanner did not recognise the quantity in a packet; therefore, wrong quantity errors would not be identified.
- The Dispens-IT system did not recognise all of the abbreviated directions used by the GPs. Dispensers sometimes needed to manually amend instructions to ensure that patients could understand the medicine labels. If dispensers misinterpreted the abbreviations, patients would receive the wrong instructions.

The GPs in the dispensing practice were unaware of these limitations to the Dispens-IT system, particularly the issue with abbreviated directions.

“Dispenser 3: [Dispens-IT] doesn’t help at all because if on the system we’re on, if they put ‘mdu’ it says ‘mdu’ on it which the patient hasn’t got a clue what ‘mdu’ means and ‘1 om’ on omeprazole would come up ‘1 om’. You’ve then got to go back into the computer and put them, the reference that it will recognise...‘take in the

morning' but then put that in. The EMIS system we use doesn't recognise all of the abbreviations that the doctor uses.(...) We have to change the computer to what it will recognise, 'as directed' (...)

GP 2: *You could set your doctors to change.*" [FG1]

9.4.3 Check medicines

After all the items were picked and labelled, they were bagged. When a patient collected their medicines a dispenser checked the items before giving the completed prescription to the patient. This second manual check acted as an accuracy check on the prescription and further reduced the risk of dispensing errors reaching the patient. In addition, prescriptions for controlled drugs were also accuracy checked by a GP before being given to the patient.

9.5 Repeat prescribing

Repeat prescribing allows general practices to issue medications to patients without the need for a consultation. This can save time for practices and for patients. There are, however, risks in terms of propagating prescribing errors or missing adverse events. For this reason, repeat prescribing must be carefully managed to ensure safe medicines management. Participants in the focus groups and interviews identified a broad range of defensive strategies to maintain the safety of repeat prescribing. These are summarised in **Table 31** and described in more detail further below.

9.5.1 Add medicines to repeat list

According to data from the interviews and focus groups, responsibility for adding prescriptions to the repeat list lay with the GPs in all the practices in the study. If patients requested items which were not on the repeat list, these requests were referred to the GPs. The GPs only added medications that the patients were stable on to the repeat lists; one GP defined "*stable*" as "*routine patients who are not to be monitored for 2 or 3 months (...) and they don't need to see anyone for 3 to 6 months*" [FG5-GP2]

Table 31: Defensive strategies which can improve the safety of repeat prescribing

Medicines management processes	Personal strategies	Practice-wide strategies	IT-based strategies
Add medicine to repeat list	Use caution when adding medicines to repeat list Only add medicines to the repeat list when patients are stable on them	Only allow GPs to add medicines to repeat list	
Select repeat duration		Issue one to two months supply on each prescription Authorise repeats for 3 to 6 months for patients with chronic diseases	
Receive repeat request from patient or carer		Do not accept verbal requests for repeat prescriptions (unless housebound patients)	Patients request repeats via online tick-list system or in writing via email
Manage requests for unauthorised items		Train non-medical staff to manage requests for non-repeat prescriptions Dedicated staff to manage repeat prescriptions, with additional staff trained as back-up ! Highlight repeat prescriptions with queries so they receive more attention Dedicated staff member to review unauthorised repeat requests ★	Use EMIS practice notes to communicate with GPs about unauthorised repeat requests
Re-authorise repeat medicines		Perform face to face medication reviews after 6 months Proactively identify patients approaching end of repeat authorisation !	Use computerised templates to help manage chronic disease patients !
Generate repeat prescriptions		Only generate prescriptions for medicines currently authorised on repeat list Staff responsible for generating repeat prescriptions check whether monitoring is due Check yellow book before generating repeat prescriptions for warfarin	
Sign repeat prescriptions	Sign repeat prescriptions in small batches For chronic disease patients, check: blood results, progression, date since last review, and repeat interval before signing repeat prescription	Only allow GPs to sign repeat prescriptions	
Issue repeat prescriptions		Document which pharmacy patients prefer prescriptions to be sent to Do not issue repeat prescriptions using postal service Maintain a record of where prescriptions have been sent to	

Restricting the repeat list to “*stable*” medicines ensured that patients were regularly reviewed until the GPs were confident that patients were responding well to the medicines (i.e. the medicines were effective and not causing undue adverse effects). Also, being cautious about adding medicines to the repeat list reduced medicine waste and helped avoid patients titrating doses of medicine by increasing the number of tablets they took (this was thought to increase the risk of confusion and therefore overdose). Additionally, one GP was very cautious about adding prescriptions to the repeat list to avoid patients getting more medication than they needed.

9.5.2 Selecting repeat duration

In all practices, medicines on the repeat list were authorised for a limited period of time and/or number of issues. This limit was set by the authorising GP. The duration depended on the medicine and age of the patient. High risk medicines such as lithium were given relatively short repeat intervals of two months by some GPs to ensure that appropriate monitoring was done (and the results regularly reviewed). Most other medicines for chronic conditions were authorised for six months, except one practice where patients were reviewed every two to three months. The duration of individual prescriptions varied from one month (in one practice which was perceived to have a very strong focus on medicines safety) to two months for most prescriptions and up to three months for oral contraceptives. Chronic disease templates were also used to limit the number and duration of prescriptions which could be issued.

9.5.3 Receiving repeat requests from patients or carers

In all practices, once medicines were on the repeat list, patients were able to request further supplies without seeing their GP. Written requests for medicines were considered to have less “*potential for medication errors*” [FG2-GP2] than telephone requests because there was less risk of practice staff misunderstanding the request. In all practices, verbal requests for repeat prescriptions were strongly discouraged because of the risk of selecting the wrong medicine from the tick list. An exception was made for elderly and house bound patients where it would be difficult for them to request repeat prescriptions in other ways. Written requests could be submitted via a tick list, a written list, email, or fax. The safest method of requesting repeat prescriptions was considered to be via the online request linked to the e-prescribing system.

“...the problem with emails of course is that they’ve got to write it and then we’ve got to tick the right box whereas SystemOne does have a (...) choice for them yes, which

we're trying to get more people to sign up to where they can actually just tick on their own screen the one they want." [FG4-GP2]

Repeat prescription requests were also received from pharmacies and nursing homes. Nursing home requests arrived in large batches which would allow practices to plan their staffing around this additional workload. Requests from some pharmacies had raised concerns in one practice, because they had:

"picked up [some] in the last couple of weeks where the pharmacist has literally just ticked everything that's on their repeat and it may be a sheet that the pharmacist has had from an old prescription request and the pharmacist hasn't checked with the patient what he actually needs" [PR6-GP2].

In response, they had extended the prescription clerk's role to *"phone the patients and [ask] have you actually requested these"* [PR6-GP2]. This GP felt that *"there's no reason why we can't extend [the prescription clerk's role] to say something like warfarin."* [PR6-GP2].

9.5.4 Managing requests for unauthorised items

All requests for repeat items were screened by either reception staff or dispensing staff (depending on the practice) to check whether they were currently authorised for repeat prescribing. Unauthorised prescription requests included requesting prescriptions too soon (suggesting overuse of medicines), not frequently enough (suggesting underuse), medicines not included on the repeat list, medicines started in hospital, or medicines which had past their review date. All staff who managed repeat requests received informal training on how to manage repeat requests (this involved shadowing an experienced member of staff and then being supervised for a period of time).

One GP managed all requests for unauthorised items in his practice; in the remaining practices, requests were sent to the GP responsible for the patient. Requests for unauthorised items were highlighted in different ways. In some practices, requests were highlighted with either a coloured disc or a note attached to the request. In one practice, EMIS practice notes were used to communicate unauthorised requests to GPs. This had two benefits: there was a clear audit trail linked to the patients' record for each unauthorised request and, because EMIS practice notes were linked to the patients' record, GPs were:

"more likely to go into the notes and see what it is. You know, when they last had it and whether or not. (...) I mean that was why that was done but because it's on there

you're also more likely I think to pull their history up so that you get a clearer idea than just scribbling 'yes' on this bit of paper that then goes back" [PR2-GP3].

In one of the dispensing practices, the repeat prescribing system was managed by the dispensary staff. The dispensers were given extensive responsibility for managing unauthorised repeat prescription requests and described a number of "grey" areas where they believed they might be allowed to issue unauthorised requests, these included items started in hospital, requested by district nurses or community matrons, or where directions had been changed in earlier consultations. For patients who requested items started in hospital, which were not yet entered on their repeat list, the dispensers checked whether the practice had received a letter. If there was no letter, patients were asked to bring their medicines to the surgery. It was unclear whether the dispensers then changed the prescription record, or passed the information onto the GP. If patients requested a change to the directions on their repeat medicines, dispensers checked the medical record for a written record of the change. If a change was found, the prescription record was amended and the printed prescription was sent to the GP (with an explanatory note attached) for signing. At this stage, the GP could decide whether the change in prescription was acceptable. In some cases district nurses or the community matron would request sip feeds or dressings. The dispensers believed they were able to authorise these requests, without asking the GPs. The GPs were, however, unaware of this practice and did not agree with it:

"Dispenser 3: Yes. There's a little grey around dressings, sip feeds that sort of thing when the district nurses will come in or community matron and ask for things. It's still a little bit grey. (...)

GP2: Well actually for nurses requesting sip feeds you shouldn't just do them for nurses you need to go through a doctor, so we're trying to keep those down." [FG1]

GPs used a series of quality judgements when deciding whether to issue an unauthorised prescription request. These were based on the perceived risk of the medicine, knowledge of the patient and their motivations for making the request, frequency of use, potential for abuse, and whether the GP was comfortable to issue the medicine without seeing the patient.

Some GPs admitted that requests for unauthorised prescriptions were onerous to deal with, but it was important to deal with them appropriately. One GP suggested that it would be helpful to have a member of staff *"with a bit more time behind a desk, with a bit more thinking time"* [FG2-GP2] dedicated to reviewing unauthorised prescription requests.

Another GP felt that it created an additional workload when medicines authorised for repeat prescribing went past their authorisation date or duration. When patients put in prescription requests, and some items were no longer authorised, prescriptions would be separated from those for authorised medicines. This resulted in reception staff receiving queries from patients who had not got all the medicines they had expected.

9.5.5 Re-authorising repeat medicines

Once the authorised duration of repeat prescribing or number of prescriptions had expired, all practices had a system for re-authorising prescriptions. Some practices allowed prescription clerks to authorise one extra prescription to ensure that patients did not run out of medicines. The prescription was sent to the GP for signing with a form attached highlighting the need for a medication review. In other practices, no further prescriptions could be issued by the prescription clerk until the GP had reviewed the patient. In one practice, this system caused disruption because prescription requests from individual patients got separated and patients did not receive their full medication supplies at the same time. To counter this problem, two GPs:

“proactively try and search ahead of who’s about to run out and we authorise their drugs so that it’s more streamlined within reception and less likely to have a few that are printed off and a few that aren’t because they’ve run out and then you’re trying to match up” [FG2-GP2].

This particular GP then performed a technical review of the items and re-authorised the prescriptions. This ensured that patients were less likely to experience supply problems because their repeat prescription had expired. This GP did not, however, have face to face or telephone consultations with the patients and was therefore less able to identify adherence problems or adverse effects from the medicines. He was aware that technical reviews were not as thorough as face to face medication reviews, but believed that technical reviews were a better use of the resources available to him.

In one practice the role of the prescription clerk in re-authorising repeat prescriptions was extended. In another practice, the GPs were considering extending this role. In both cases, in addition to issuing authorised prescriptions, the prescription clerks were expected to check that monitoring had been undertaken.

9.5.6 Generating repeat prescriptions

Responsibility for generating repeat prescriptions within the surgeries lay with support staff, such as prescription clerks or dispensers. These staff collected the prescription requests

and ascertained which requests were on the repeat prescription list and in date. The support staff were authorised to issue these prescriptions.

Some practices had dedicated members of support staff, other practices assigned responsibility for generating repeat prescriptions to the reception staff on a rota basis. One GP thought they *“probably [had] fewer errors because [they] have a dedicated Prescribing Clerk who’s very used to dealing with the repeat prescription requests”* [PR6-GP1]. This was confirmed by the practice manager who thought:

“it makes a difference having dedicated prescription clerks. I mean we do have quite a few members of the team that can in a, you know, crisis situation let’s say could, can do prescriptions but having people that are dedicated like [Prescription Clerk 2 and Prescription Clerk 2’s] backup, they know the patients more, they know the medications more...” [FG4-Prac Manager1].

The GP, however, felt that problems could arise when the dedicated prescription clerk was absent, even though they had another trained member of staff as back-up.

In one practice, in addition to generating repeat prescription, the dispensary staff also checked whether monitoring had been done (the computer system reminded them when monitoring was due). In another practice, prescriptions for warfarin were only generated after the yellow warfarin book had been checked by the reception staff.

9.5.7 Signing repeat prescriptions

In all practices, once the repeat prescriptions were generated, they were sent to the GPs to be signed. Systems for managing how prescriptions were signed differed between practices and individual GPs. In ‘Practice 14’, GP2 had *“a policy of not signing a prescription unless I’m in front of a computer and looking through, especially with repeat prescriptions because patients request them and then we just issue them”* [PR14-GP2]. In contrast, GP3 in ‘Practice 14’ felt that *“...people just haven’t got enough time to look at prescriptions before they sign them and they’re repeats...”* [PR14-GP3]. This sentiment was echoed by GP2 in ‘Practice 2’ who felt that it was not possible to check all repeats carefully every time they were signed. In another practice, one GP was responsible for signing repeat prescriptions; he signed them in small batches between patients or in the gaps created when patients did not attend appointments. This helped him *“concentrate on them individually”* [FG5-GP2]. Another practice differentiated between routine repeat prescriptions, and those with queries. Authorised prescriptions were put in a box and GPs *“grab a handful and sign”* [PR4-GP2]

when they have a chance. Unauthorised prescriptions were “*put into individual doctor’s boxes*” [PR4-GP2] which highlighted that they needed careful consideration.

9.5.8 Issuing repeat prescriptions

Once the repeat prescription has been signed it must be transferred to a pharmacy for dispensing. Most practices reported a system for issuing prescriptions to patients. Some practices documented which pharmacy patients preferred their prescriptions to be sent to (this allowed patients to collect the dispensed prescription direct from the pharmacy). One practice had a policy of not posting prescriptions back to patients because “*whatever the reasons are sometimes [patients] don’t get their prescriptions posted back in time. So that either they’ve run out of it, don’t have medication or various things happen or the post doesn’t get there at all and we get so much of hassle with it...*” [FG5-GP2]. This practice aimed to produce repeat prescriptions within 24 hours of receiving requests. Other practices were also concerned about prescriptions going missing. To counter this one practice recorded the destination of prescriptions issued, including uncollected, faxed, and posted prescriptions, prescriptions collected by pharmacy staff and prescriptions for Ritalin so that they “*know basically where each one’s gone*” [FG4-Prac Manager 1].

9.6 Monitoring patients

Monitoring is important for patients who have been recently started on medicines, such as statins, and for all patients who are on repeat prescriptions. Monitoring involves reviewing the effectiveness of medicines through medication reviews in addition to performing tests and reviewing results. Participants in the focus groups and interviews identified a broad range of defensive strategies to maintain the safety of monitoring. These are summarised in **Table 32** and described in more detail further below.

9.6.1 Select monitoring interval

Monitoring intervals varied depending on whether it was for a new medicine or a chronic disease. In general, most GPs aimed to review patients four weeks after starting a new medicine. One GP reviewed patients two weeks after starting diclofenac, and another reviewed patients with hypercholesterolaemia or hypertension after four to six weeks.

Patients with stable chronic diseases were reviewed six monthly in most practices, but in one practice the GPs preferred to see their patients monthly. In other practices patients aged over 75 years with chronic diseases were seen every two months.

9.6.2 Identify patients who need monitoring or medication review

All practices had systems in place to identify patients who needed monitoring or a medication review. Systems varied between practices. In 'Practice 4', GP2 authorised *"meds for the appropriate amount of time, so if I want to see them in three months for anti-depressants I would give them a three month review date I wouldn't just let it go on."* In one practice, when repeat prescriptions expired, the dispenser's saw *"a red highlighted date"* [FG1-Dispenser 3] alerting to the need for monitoring. The dispenser's were expected to *"check before they print [methotrexate prescriptions] that [patients] have had the blood test done"* [FG1-GP2].

In another practice patients were recalled for review after two or three prescriptions had been issued. Practice receptionists were also responsible for identifying patients needing monitoring. In one practice the receptionists had *"a list of chronic disease management and what is required, to a six month and a twelve month review, which is in reception and the review date of the medication corresponds with that so when the review date for medication comes up [the receptionists] know that they've got to book an appointment for a blood pressure and a U&E or whatever. And the receptionists do that and then, yes."* [FG2-Nurse1] In another practice, the dispensers were responsible for highlighting patients that needed monitoring. They were reminded by a *"big message on the message screen at the bottom of the repeat prescribing there's a message, when the next one is due"* [FG1-Dispenser1].

In other practices reminders for monitoring were not linked to the repeat prescribing system. Instead, screen alerts were used to remind practice staff that monitoring was due. This was useful when multiple healthcare professionals were caring for a patient because they would all be alerted to the need for monitoring. In one practice the GP entered a date when monitoring was next due and the computer raised an alert when that date was reached. Screen alerts were also used to highlight the need for three monthly monitoring with methotrexate and warfarin. Similarly, another practice ran a chronic disease clinic where the practice nurse used reminders to alert to the need for monitoring. Disease management templates, where the date of the last test was recorded, were also used to highlight the need for monitoring. However, relying on chronic disease clinics or lists to identify patients requiring monitoring means that patients that don't meet the criteria for these chronic diseases may fall through the net.

"GP1: He would not have fulfilled the criteria to come to our regular Long Term Condition clinics. However having said that I normally do an annual audit on folk on

non-steroidals and look at their renal function so that does get done and I personally do that audit every year.

Interviewer: *Do you do that on all the patients or just on...*

GP1: *Yes we do it on them all. And he hasn't had his renal function checked for some time and I would agree that we probably do need to tighten that up.*" [PR7]

Audits of the prescribing system can help to identify patients needing monitoring although, as the above example shows, patients can still be overlooked. Likewise, audits of prescribing systems were not able to identify patients who were underusing their medicines. Despite this, audits can be useful for creating patient registers to ensure that monitoring is completed. In training practices, these audits were usually completed by GP registrars as part of their training.

Screen alerts were used in one practice to remind staff of the need for a medication review. However, if the alert was not put on the patient's record, the review would be missed. One practice linked medication review dates to the month of the patient's birthday and six months later. This ensured that medication reviews were spread evenly across the year, and not linked to a chronic disease list.

Some GPs believed that patients should also take some responsibility for being monitored. If patients were reluctant to attend monitoring appointments then GPs could encourage them by insisting that patients attend an appointment to get their prescription, rather than continue to collect repeat prescriptions.

9.6.3 Call patient for monitoring or medication review

All practices had systems in place to encourage patients to attend monitoring. In practices where monitoring was linked to the repeat prescribing interval, patients were encouraged to attend appointments by alerting to the need for monitoring on the repeat prescription form, reducing the duration of supply on each prescription and writing to patients if they did not attend, and then taking the medicine off the repeat list if they still did not attend. Finally, in worst case scenarios, GPs would refuse to supply medicines until patients had their monitoring completed.

GP1: *...the message goes there on the side of their repeat prescriptions saying 'You are due to have a medication review please make an appointment in the next few*

weeks'. So then on the computer if they don't do that then that goes down as another failed time and then is it 2 or 3 strikes?

Dispenser 3: *Well then we send them a letter that says you need to come in or else and then if the worst comes to the worst...*

GP1: *And then you've got, if they don't respond you drop it down to weeklies."*
[FG1]

In one practice, when GPs started new prescriptions which required monitoring, patients' were given a blood test form and told when to return for monitoring. This, however, relied on patients understanding and recalling the instruction. In one case where a patient was started on a diuretic, the patient had their blood tested on the day the prescription was supplied, rather than two weeks later. This led to the test results being misinterpreted:

"...I normally tend to give people a U&E form when I start them on a diuretic and say 'You need to have this done in two weeks time' and then there was lots of miscommunication between the hospital at that point as well with his anti-coagulation so I think it was sorting that out and sorting out his abnormal LFTs and his liver ultrasound and stuff like that and so whether he took it straight to the desk and got bled the same day, which might have happened if he was seen on the 12th and he had his bloods done on the 12th but how he didn't get another one after that."[PR3-GP2]

One GP noted that, following a period of leave, some of the more challenging patients she had passed on to more junior members of staff had not been sorted out. She felt that in future she would only transfer care for complex or challenging patients to senior GPs who would be able to take full responsibility for their management.

9.6.4 Medication reviews

Medication reviews were considered to be particularly problematic in a number of practices. Patients often didn't understand their importance and they were slotted onto the end of appointments because patients would finish the consultation with *"by the way can you do my review?"* [PR3-GP1] GPs did not feel they could refuse to supply the medication, so instead they performed a lower standard of review to ensure continuity of supply. This meant that problems were missed. This problem was particularly exacerbated in complex patients where problems were thought to be even more likely to be missed:

“GP: And I probably, for the medication review, it’s interesting isn’t it because when you do the medication review in the 10 minutes if she comes and presents you with a whole battery of symptomology and says, ‘Oh by the way can you do my review?’ And you’re 9 minutes 59 seconds or in her case 19 59 seconds, what do you do? You can say clear off,...

***Interviewer:** So she comes for her medication review but it’s filled up with other issues.*

***GP:** It’s filled up with other clutter. If you tell her to clear off and come back but also the way we run the system we actually don’t, we don’t issue prescriptions for people who go overdue on their review so you’re left backed into a corner to do a review quickly, and probably inadequately as you’ve seen.” [PR3-GP1].*

As noted earlier, one GP partially solved this problem by proactively identifying patients whose repeat prescriptions were due to run out. He did not, however, perform face-to-face medication reviews. Instead, he performed a technical review with the patient’s medical record only. Although useful for identifying overdue monitoring, he was unlikely to identify wrong instructions on medicines, underuse or adverse effects. The GP, however, perceived this method to be a better use of his time and allowed him to plan his medication reviews into quiet periods in the surgery and perform them on a rolling basis. This GP did not seem to value medication reviews highly. He believed that it was important to get prescriptions right the first time because medication reviews were not effective at identifying all prescribing problems. He also did not feel it was possible to use double appointments to review complex patients:

“Yes I would love to be able to say we’ll make a 20 minute appointment, give me more time to actually go through this thing but we just cannot physically do that, it would just be impossible. And we’ve talked about this as a practice because there were certain parts of the practice where some people do take double appointments and we’re saying, ‘I’m sorry guys, I know you’ve got complex patients, we’ve all got complex patients but, you know, this is how we all do it. And this is how we should all do it’. Can’t fill up a morning surgery with double appointments just because you’ve got to do medication reviews.” [Pr2-GP1]

In some practices the responsibility for medication reviews was split between practitioners. In one practice a healthcare assistant had a face to face discussion with the patient about their medicines. The GP then reviewed the healthcare assistant’s notes with the test results.

This process, whereby tests were conducted a week before the medication review, was considered desirable by another GP. In another practice, patients were reviewed by disease and therefore did not receive a holistic review. If some of the patient's medicines were not reviewed, then the patient had a further appointment with their GP to complete their review. This was considered inefficient for both the patient and the practice. Similarly, where patients were reviewed according to disease templates, medicines could be missed if they were not included on the template:

“GP1: Or they'd come in for a blood pressure and then they'd come in and our Health Care Assistant or the nurses would then send it through to us for a medication review, so this is your information, do the review.

GP2: So they may have had a face-to-face check with somebody, one of the team and that there'll have been a conversation about are your tablets all right and the bloods will have been taken and then we'll get a message saying the medication review's done and we'll look at the blood pressure, we'll look at the results, we'll look at the dialogue...” [FG3].

One GP felt very strongly that medication reviews should only be undertaken by an 'autonomous practitioner' who could take full responsibility for the patients' care:

“So I don't think, this is a personal view and it is shared by some of my partners which is why we are moving to change it and potentially reconfigure our workforce, that actually nurses who are not the full autonomous practitioner are the right way of doing it because for the very reasons we've just identified in terms of monitoring, they don't know what they don't know, their lack of knowledge of the monitoring, their lack of knowledge of counselling when starting patients on medications potentially and the initial monitoring, so for instance short term Us and Es or even 3 monthly LFTs, they're not aware of that. And we're caught on the hoof, you know, we're given a problem, no time to solve it, it's a quick signature and they slip through the net.” [PR3-GP1].

Some GPs used a combination of telephone and face-to-face appointments to increase the efficiency of their medication reviews. One GP reviewed each patient's medication list annually and then called the patient for a telephone or face-to-face review if he identified a problem. This, however, does not allow patients to raise their own problems so is not an ideal system for medication review. Another GP performed “*partial medication reviews*” [PR4-GP2] each time he saw a patient, and updated their review date based on this. This,

however, did not allow for a comprehensive medication review therefore problems may have been missed.

9.6.5 Review results of monitoring

Once monitoring has been completed it is essential to have robust systems in place to ensure that test results are reviewed. Some practices noted that this was a particular problem with warfarin where the GPs take responsibility for prescribing warfarin, but are not involved in dosing or monitoring patients. In some practices, international normalised ratio (INR) records were incomplete. 'Practice 12' addressed this by asking to see the yellow warfarin book before issuing a repeat prescription. Another practice ensured that monitoring was undertaken by having three monthly reminders on patients' records. However, because of the incomplete INR records, they were not always able to review the results. Incomplete records were the result of poor communication between anticoagulation clinics and practices. The INR monitoring system relied on patients attending anticoagulation clinics and practices were only informed about attendance after a patient had missed an appointment:

“Our system now tells you it's 12 weeks since an INR was done, it didn't up until very recently and as it's all set up at the moment you can be issuing warfarin and have no idea what the patient's INR is and no idea whether they're turning up anywhere and we're not automatically getting results through and advice that the clinics are giving. The patients get them, when they get their yellow book but the way we're set up at the moment we don't see that and we need to consider changing our system.” [FG4-GP2].

It is clear from these data that improvements to the reporting of INR results in general practice are needed.

Table 32: Defensive strategies which can improve the safety of patient monitoring

Medicines management processes	Personal strategies	Practice-wide strategies	IT-based strategies
Select monitoring interval	Review patients on new medicines after 2 to 6 weeks	Monitor renal function at least annually for patients taking medicines which affect renal function Face-to-face review with chronic disease patients at least every 6 months!	
Identify patients who need monitoring	When prescribing high risk medicines, document need for increased monitoring in patients' notes		Search clinical records system to identify patients Programme computer alert when patients 12 weeks post last INR test Use screen alerts and repeat prescribing dates to remind about monitoring
Call patient for monitoring		Senior GPs should retain responsibility for complex or otherwise challenging patients	
Review results of monitoring		Check yellow book before generating repeat prescriptions for warfarin Schedule tests one week before medication review	
Amend medicines according to monitoring results	Titrate medicine doses according to patient response		

9.6.6 Amend medicines according to monitoring results

Once the test results have been reviewed, it is important to adjust medication accordingly. One GP felt very strongly that titrating medication was poorly performed in general practice:

“GP: Yes. You know, like with anything. Even blood pressure medications, with asthma you know you can increase the puffs, you can decrease the puffs so a lot of people forget, all GPs they don't stress on titration is not in their world, titration is a

new word for them. Only Pharmacists will know titration rates. They're very, very poor. (...) But I'm very conscious about it, titration. That's why patients don't get better. You see, patient's blood pressure is there OK? Not getting better, you have to look at increasing the doses, adding of more, of multiple bloods, you just keep them and oh not getting better, but you have to look at it, having to increase to the maximum dose. You know like they're happy to, same thing all the blood should be maximum doses, I'm talking about maximum doses. So titration is very poor with a lot of doctors but I must say it. Titration is, when you start medicine you must be able to increase and decrease it or stabilise it. Depends upon the response you get from the patient. (...) Fundamental otherwise there's no pharmacology, without titration there's no pharmacology. It's not a life-long one dose. (...) It's not training, it's a fundamental, when you're at medical school you ought to learn titration. You're a Pharmacist, you learnt Pharmacy. Titration but we forgot. When they actually come into practice they forget. They forget they need to titrate the medication, they forget.” [PR12-GP2]

9.7 Amending prescriptions based on outside correspondence

A final stage in the medicines management process is updating prescription records based on outside correspondence. Such correspondence could come from specialist consultant clinics, hospital discharge summaries, or out of hours consultations with GPs or Accident and Emergency (A&E). Effective management of this correspondence is essential for the safe management of patient's medicines. Strategies to improve the safety of managing outside correspondence are summarised in **Table 33** and described in more detail further below.

9.7.1 Receive correspondence

Practices reported receiving correspondence in both paper and electronic formats. Electronic or type-written letters were considered more legible and easier to understand than handwritten correspondence. Handwritten discharge letters had caused particular problems:

“The positive thing is [the discharge summary] is now typed, we used to have lots of problems with legibility a few years ago.” [FG4-GP3]

Electronic letters were useful because they could be incorporated straight into the patient's electronic medical record; however, paper copies of letters were preferred by GPs because they were easier to view in conjunction with the electronic medical record:

“Well the turnaround time for hospital letters has improved greatly, certainly for admissions of late and they come by and large electronically.” [PR7-GP1]

If letters were received in paper format, they were scanned into the computer and then passed onto the GPs for review. This could lead to a delay in the GPs receiving the letters. If letters were received in electronic format, some GPs preferred to wait for the paper copy or print their own to avoid having to switch between screens (which made identifying important details more difficult):

“The trouble is you can’t read the letter and make the alterations on the computer at the same time because a) the screens aren’t big enough and it’s just you end up having to have the paper copy to update the computer because it’s just not possible to do.” [PR7-GP1]

9.7.2 Review appropriateness of recommended changes

Once correspondence was received, in all practices, GPs were responsible for reviewing the letters and identifying the recommended changes made. GPs noted that the layout of letters could make identifying changes more difficult. One GP suggested that letters should begin by highlighting new medicines, changes to medicines and reasons for changes. Instead, some letters lost these important details in long narratives:

“GP3: But if they realized what would make our life a bit easier, you know, what other changes that they made, something I said earlier and what needs to continue, just one line or a couple of lines would be very helpful. It’s usually up to us to look through the list and decipher what bits have changed

GP2: And that crucial bit of information is actually buried in lots of other stuff and it actually needs to jump out at you so that everybody sees it, the most important bit first...” [FG4].

Once medicine changes were identified, GPs needed to decide whether they agreed with the recommended changes. Many GPs stated that they would query recommendations where they perceived the harms to outweigh the benefits, or where they were uncomfortable with the changes. In contrast, one GP stated that he was happy to make the suggested changes if they were within the consultant’s specialist area. If he was unfamiliar with the medicine, then he would have a *“quick look in the BNF”* [PR1-GP1].

One GP also felt that when hospital consultants recommended starting unusual medicines, they should specify how long to continue the medicine for, important side effects to monitor for, which tests to undertake and how often:

“What sometimes happens, mostly unlicensed drugs when the consultant starts it, we don’t get the proper information because as we believe we have to take over the care, we’ll be prescribing those drugs in the future so as to how long do we continue, what side effects to look, what blood tests to follow up, those are the information still we lack at times, as the consultant’s letter follows after several days and sometimes it doesn’t. So that is still an issue” [FG4, GP1].

Table 33: Defensive strategies which can improve the safety of amending prescriptions based on outside correspondence

Medicines management processes	Personal strategy	Practice-wide or hospital-based strategies	IT-based strategies
Receive correspondence			Send letters electronically ! Scan paper letters for electronic clinical records ! Avoid handwritten correspondence
Review appropriateness of recommended changes	Refuse to prescribe if risks outweigh benefits Give careful thought to, and take personal responsibility for, changes to prescriptions	Assign one GP to review and annotate correspondence ! Distribute correspondence to GP responsible for patient Correspondence should highlight new medicines, changes to medicines and reasons for changes Requests for unusual medicines should state duration, key side effects, and monitoring requirements	
Patient requests amended prescription before correspondence arrives		Clarify prescribing change with specialist or medication packaging if correspondence not available Counsel patients about medicines if they are confused by changes	
Contact specialist or patient	Clarify changes with specialist if prescriber uncomfortable with prescribing decisions		
Amend prescription		Update prescribing records as soon as possible, and within 48 hours of receiving correspondence Prescription clerk/dispenser make annotated changes on computer	

9.7.3 Patient requests amended prescription before correspondence arrives

Sometimes patients request new prescriptions before the GPs have received the correspondence detailing the recommended changes. In this situation, all practices would require confirmation of the recommended changes before a new prescription would be issued. How this information was obtained varied. In some cases reception staff would ring the hospital to confirm the changes or request a faxed copy of the letter. In other cases reception staff would ask the patients to bring in the new medicines (with the packaging) to verify the changes.

In some cases patients would be confused by the changes to their medication. In this situation, one GP would invite the patients to bring their medicines to an appointment where they could talk through the changes.

9.7.4 Amend prescription

Once GPs have accepted the recommended changes, the patient's prescription record needs to be updated. In some practices, GPs made changes to the prescription records whilst they reviewed the letters. In other practices, the GPs annotated the letters with the required changes and the staff responsible for repeat prescribing made the changes on the prescription record on their behalf. In one practice one GP was responsible for reviewing correspondence. Sometimes this GP reviewed the letters whilst the practice manager made the changes on the prescribing system. In another practice, the GPs tried to update the prescription record on the day the letter arrived, but if that was not possible, then within 48 hours of receipt.

9.8 Processes supporting medicines management

Within each practice were a range of processes which supported the safety of medicines management by creating a safe culture of work. These processes help to address communication issues and knowledge gaps which are important contributors to medication errors. Defensive strategies which improve the contribution of significant event reporting to medicines safety are summarised in **Table 34**. Other processes which support the safety of medicines management are summarised in **Table 35** and described in more detail further below.

Table 34: Defensive strategies which can improve the contribution of significant event reporting to medication safety

Medicines management processes	Practice-wide strategies	IT-based strategies
Regular meetings and open, blame free communication	<p>Maintain a good safety culture based on open, blame-free, communication</p> <p>Regular multidisciplinary meetings to facilitate practice-wide discussion</p> <p>Informal discussions during “coffee-breaks”</p>	
Recording, investigating and reporting significant events	<p>Include medication errors in significant event reports</p> <p>Record significant events on a standard form or in a book</p> <p>Perform root cause analyses for serious events</p> <p>Report significant events to designated staff member or committee</p> <p>Report major significant events to PCT</p>	<p>EMIS practice notes used to communicate prescribing errors to originator</p>
Discussing significant events	<p>Discuss significant events at regular multidisciplinary practice meetings</p> <p>Have a mechanism for cascading learning to staff not present at significant event meetings ★</p>	
Changing practice in response to significant events	<p>Re-audit changes in practice to ensure efficacy ★</p>	

Table 35: Defensive strategies which can improve the safety of processes which support medicines management

Medicines management processes	Personal strategies	Practice-wide strategies	IT-based strategies
Staff training		Mandatory staff training Debrief with GP registrars Senior practice staff demonstrate open communication throughout day-to-day work Clinical meetings and audit presentations useful for informal training	
Cascading prescribing information		Appoint prescribing lead for practice to lead on protocol reviews and best-practice for prescribing Discuss guidelines at clinical meetings Prescribing information should highlight key messages, supported by evidence at bottom of document Do not hold meetings with “drug reps”, obtain prescribing information from PCT pharmacists instead Attend cluster/PCT wide meetings Review NPSA guidance at clinical meetings	Practice notes used to alert to new prescribing information
Workload planning and appropriate delegation		Longer appointment slots allow more time to see complex patients ! Alter clinic appointments and staffing levels for known busy periods ★ Avoid handing over complex cases to junior or locum staff	Use screen reminders to pass on important monitoring information
Community pharmacy management of prescriptions	Phone community pharmacist to check doses of unfamiliar paediatric medicines	Develop close-working relationship with local community pharmacy	Amend electronic prescribing record if accepting community pharmacist’s intervention on prescription Give community pharmacists access to patients’ electronic clinical records ★
Practice pharmacists	Face to face contact to maintain better relationships		Audit electronic clinical records to identify errors in practice patients Use the e-formulary to guide prescribing to safer alternatives and avoid similar drug names being adjacent in pick-lists
Patients’ decision making		Patients can act as a defence against errors	
Managing locum staff		Use same locum agency to ensure familiarity with practice systems Provide induction and locum pack	Familiarise locum with clinical record and e-prescribing systems
Innovative use of clinical systems			EMIS practice notes allow patient-specific messages to be communicated without interrupting consultations

9.8.1 Regular meetings and open, blame free communication

All practices held regular multidisciplinary meetings which varied in frequency from weekly to monthly to quarterly. These meetings facilitated practice-wide discussion of important issues. Some practices had additional meetings for different staff members which fed into each other e.g. clinical meetings, reception meetings, and practice meetings. Discussions about individual patients were rarely included in these meetings, instead these were held informally during coffee breaks. 'Practice 12', however, included presentations about complex patients in their clinical meetings. These were felt to be educational to all members of staff. Staff in most practices also felt able to discuss problems informally, although one GP felt isolated and unable to discuss his prescribing problems. GPs in one practice noted that *"because of this silly walk-in system not everybody is comfortable because one person's got to be doing the walk-in."* [PR15-GP3]. This meant that the GP seeing walk-in patients could not participate fully in the staff meetings.

One GP commented that prescribing meetings no longer took place at a Primary Care Trust (PCT) level. These meetings were also not taking place at a GP-cluster level. The GP felt this had affected the dissemination of prescribing information. Another practice reported that they received all their prescribing information from the PCT pharmacists because they no longer saw pharmaceutical representatives.

Most practices reported having a blame free culture where staff felt able to talk freely about problems. In one practice this was encouraged by the senior staff raising their problems within meetings in order to demonstrate to new and junior staff that this was a good thing to do:

"...new people coming into the team to start with are very quiet and listen to what everybody else has to say and they're seeing that the senior partner brings something that he's been involved in and something that one of the nurses brings and actually then they get the confidence actually, well you know all these people are sharing their stuff so I'll start and come out with some. It takes a while but they get the idea that all of us can be involved in something somewhere along the line and it's good to share that." [FG4-GP2]

9.8.2 Reporting, investigating and recording significant events

All but one of the practices recorded significant events and included medication errors within this reporting system. The exception was a practice where the GPs preferred to discuss

clinical prescribing errors informally over coffee, rather than feed these issues into the significant event reporting:

“If somebody’s written the wrong thing we would tend to be informal and perhaps have a chat over coffee about, ‘I saw this, you probably didn’t mean it, what do you think?’” [FG2-GP2]

In one practice all events were reported to the senior GP, who would then report up to the PCT if the event was serious. Most, however, practices did not routinely report significant events to the PCT. One exception was a practice where the PCT required the practices to submit a certain number of significant event reports in order to earn Quality and Outcome Framework (QOF) points. This practice reported that the PCT had said their significant events *“weren’t really significant. I said, ‘Well they are to us, so we’ll do it’.”* [FG4-Prac Manager1].

Few of the practices were aware of the National Reporting and Learning System (NRLS), and some confused the reporting system with the yellow card reporting system for adverse events. However, one practice had reported one significant event to the NRLS. This practice had a book that they routinely recorded all significant events in. Other practices used a standard form for reporting.

One practice, where GPs were not always able to attend practice meetings, sent *“...each other practice notes on EMIS about what errors they’ve noticed...”* [PR14-GP3]. This was considered to be *“...mostly (...) a very OK kind of a way...”* [PR14-GP3] to communicate errors to each other. Other practices said that, if an event was serious enough, it would be investigated using root cause analysis.

9.8.3 Discussing significant events

In most practices, significant events were discussed in regular multidisciplinary meetings. These discussions were considered to have educational value in most practices. In one practice, the branch surgeries discussed significant events independently, and the results of these discussions were then reported at the GP partners’ meeting. This final presentation at the GP partners’ meeting was viewed as a *“bit tedious”* [FG1-GP2]. In another practice, it was noted that there was no mechanism for cascading learning points from the significant event meetings. Individual significant event reports could be emailed to staff, but learning was impaired if you weren’t engaged in the meeting. This was a particular problem where one GP had to be on duty to see walk-in patients during these meetings.

“It depends who’s there is one thing because increasingly the practices are open longer and not everyone is there at meetings and what have you and so we minute them and circulate the minutes but it’s often you learn it better if you’re there don’t you or if you’ve been involved personally. So we would, if there was a significant event report we might send it round as a notification which flicks up on everyone’s desktop for people to have a look at and think about. But we’ve got no formal system really” [FG2-GP2].

The frequency of significant event discussions varied between practices from weekly to six-monthly. One GP reported that his practice should have quarterly significant event meetings, but these had not been held for a while. Another GP felt that there should be more discussion about significant events between practices within each ‘cluster’ of general practices.

9.8.4 Changing practice in response to significant events

Most practices demonstrated that they changed practice systems of working in response to discussions about medication-related significant events (see **Table 36** for examples). One GP, however, noted that they did not close the audit loop by checking that the new systems of work had improved the safety of medicines management.

Table 36: Examples of changes to practice systems of working in response to medication-related significant events

Practice/area	Significant event	Change in practice
Area 1	500 Piriton prescribed in error	Problem related to computerised drug dictionary – increased vigilance advised
Area 1	Problem with repeat prescriptions going missing	Tracking system introduced to record who collected repeat prescriptions
Practice 2	Requests for changes to repeat prescriptions noted on pieces of paper, or in a book, which were subsequently lost	Requests for changes to repeat prescriptions sent to GPs as EMIS practice notes linked to an individual patient’s record
Practice 12	Patient receiving warfarin from practice but not attending anticoagulation clinic	Yellow books checked before issuing prescriptions for warfarin
Practice 13	Confusion over patients with same names	Date of birth checked, in addition to patient’s name

9.8.5 Staff training

Staff training was considered important in most practices. In one practice, however, they received no training about medication errors; instead staff were expected to “...get

[them]selves there..." [FG6-GP2]. In some practices training was perceived to involve more than just attending training sessions. In one practice, the clinical meetings were designed to act as educational sessions for all practice staff:

"What we do is normally, we have our clinical meetings regularly then we have review and all the staff in the clinic they can listen what we're saying so if they listen they can understand and we are doing so many audits in the clinical areas and prescribing and we present the audit results and discuss them during the clinical meetings. So that's education for the clinicians and the management staff as well." [FG5-GP2]

Training was particularly aimed at new staff and locums to ensure they were aware of the systems of work within the practice. Training could include shadowing existing staff members, familiarisation with the computer system and reading induction packs. In addition, in a teaching practice, GP registrars were *"debriefed after every surgery"* [FG3-GP1]. This was *"helpful"* to the senior GPs as well because *"if you're up-to-date for other people you have to be up-to-date for yourself and, you know, registrars have sometimes got a better idea of what's current in hospital than we have so they can sometimes be very useful"* [FG3-GP1]. Also, computerised interaction alerts were considered to be a useful learning tool for GP registrars because *"they'll take heed of every single interaction it says and come and mention it to you, and you can go through it"* [FG4-GP3].

One GP felt that there was *"never...any off the record, anonymised sort of error discussion with any professional colleagues"* [PR2-GP2]. He felt such openness was essential for developing an open culture about error:

"...the culture should be well they do occur, let's have a look why they occur and we know it's never going to be zero but goodness me let's make sure we don't make these big bloopers that actually hurt people." [PR2-GP2].

This GP felt very strongly that *"some postgraduate sort of learning and analysis would be a huge advancement"* [PR2-GP2]. Another GP had previously found the cluster-wide meetings helpful but now felt that *"the [cluster] events where you potentially can disseminate good care. I think the problem is in effect where they're becoming business meetings and the educational component is being shunted to the sides."* [PR4-GP2].

No practices talked about formal training in using computer systems; instead, training for locum GPs involved *"familiarising"* themselves with the computer system. There were also

clear examples where prescribers were not able to get the best support from the computer systems they used because they did not know how to use some features:

“Interviewer: I mean with regards to the EMIS system I’ve been told there is a medical information

GP3: I never use it, I don’t know how to use it (...) Sad but true!” [PR14-GP3]

9.8.6 Cascading prescribing information

Most practices had a process for cascading prescribing information. Systems ranged from informal discussions during coffee breaks, to formal discussions at clinical meetings or email cascades. Email cascades were considered problematic because of time restrictions and the volume of *“irrelevant”* emails that were received. Some of the GPs found the public media, such as Radio 4 or the Daily Mail were more helpful for giving them *“a heads up as to what horrors are waiting that morning... that’s going to be a subject for discussion during your surgery”* [FG3-GP1]. Another practice felt that, although you could easily miss email alerts, important messages were sent lots of times and in different ways, so you generally saw them.

One practice routinely reviewed National Institute for Health and Clinical Excellence (NICE) guidance in their clinical meetings, but with a focus on *“cost-effectiveness”* rather than *“safety”*, which was considered to be *“down to the clinician”* [PR6-GP4]. This practice also has a *“prescribing lead”* GP who reviews *“protocols as well as cost-effectiveness and how to prescribe efficiently, [and] safely”* [PR6-GP4]. Another practice, which had no prescribing lead, found it more difficult to keep abreast of new developments. He felt that *“prescribing could be a lot more important clinically than some of the other dross we have to trawl through on a daily basis. But it’s having the time to do it.”* [PR1-GP1].

One practice relied on *“Community Pharmacy and PCT Pharmacists”* for prescribing information because they *“don’t see (...) any pharmaceutical reps and things”* [FG3-GP1]. This practice was cautious about starting *“anything too new”* and this meant they had not *“been caught out with many things (...) and (...) didn’t really get hammered with...”* [FG3-GP1] needing to change lots of prescriptions when new drugs were withdrawn from the market such as COX-II inhibitors.

One GP felt that it would be helpful if prescribing information was more *“practical, you know, and it’s lovely to be evidence referenced but I like that to be at the bottom where, I really*

want a points system of do this, and this is why.” [PR4-GP2]. Another GP reported that his practice used EMIS practice notes to alert each other to prescribing issues, although, these were focussed on cost-effectiveness, rather than safety:

“We tend, I mean we have a, you probably have seen the computer system encompassing messages, so if anyone comes across any issues around this drug is out of market, or is more costly or whatever you tend to send a message round to all the doctors.” [PR6-GP4]

9.8.7 Workload planning and appropriate delegation

This section draws together workload related themes, some of which have been described earlier. Some of the increased workloads in general practice were predictable, but one GP felt they could adjust their staffing levels better to compensate for known busy periods:

“There are some things you can plan for and anticipate demand and probably we could do more of that, so like you know after a Bank Holiday everybody wants to be seen so we should clear the decks and make sure everybody can be seen. We don’t always do that but I think we could do more of that really.” [PR7-GP2]

Similarly, longer appointment slots could be used to see complex patients, but one GP felt this system was *“physically...impossible”* and that you *“can’t fill up a morning surgery with double appointments just because you’ve got to do medication reviews”* [PR2-GP1]

Some GPs also had reservations about passing on complex patients to junior or locum staff. One practice felt so strongly about this that they would process all the nursing home prescriptions before the lead GP went on holiday so that this responsibility was not delegated to a locum:

“Practice Manager: *We always try to do the batch of nursing home prescriptions before they go so that then...*

GP2: *...nursing home is taken out.*

Practice Manager: *We don’t ask the locum to do that.” [FG5]*

This issue was also noted by a part-time GP who found that if he handed over complex patients to locum or more junior salaried GPs they did not want to *“take responsibility, make [themselves] extra work etc, etc.”* [PR6-GP2]. This GP believed that there was *“a real risk*

that patients get lost to follow-up if their regular doctor isn't here all the time.” [PR6-GP2]. His solution was to hand over patients to “the partners...because they realise how important things are” whereas she thought “some of the junior doctors or locums I think they're a little bit, they can be a little bit slack” [PR6-GP2]. This GP also used screen messages to remind himself to monitor patients, but he found when he returned to work, he would be bombarded by messages where GPs had delegated tasks back to him.

9.8.8 Community pharmacy management of prescriptions

Community pharmacists were generally viewed as “quite good” [FG4-GP2] and many GPs were happy to take their advice, and seek their advice in some cases. GPs were even more likely to listen to community pharmacists' advice if they had a close working relationship with them. Such a relationship was improved by face to face contact.

“GP: Well the other thing that I would say that I think would be that we've had the community pharmacist come in to us and sometimes look at our prescribing and I think that has helped us in a way as well.

Interviewer: OK and would that also generally improve your working relationship?

GP: Yes. Our local pharmacist here, like the one on the same street and then if there are things that they're not quite sure they easily call us and I think they know me by name now, on a first name basis, so he calls me and I call him sometimes and say, 'Oh this is what's going on.'” [PR14-GP2]

This relationship was, however, less likely when there were multiple pharmacies in one area:

“...in one of our branch surgeries we've got a very close working relationship with the pharmacist who's constantly helping us with cost-effectiveness and who's not compliant with their medication and things like that and, you know, that helps so much but the main surgery don't have that because people are dissipated round different pharmacists. So there's advantages and disadvantages.” [FG4-GP2]

Within the prescribing errors reviewed in the interviews, there were opportunities for community pharmacists to have intervened (i.e. they should have had sufficient information to know a prescription was in error), but if they had intervened with the prescriptions, their interventions would not be routinely documented on the patient's medical record. This could lead to errors being propagated to subsequent prescriptions.

“Yes so you mean a chemist may phone and say, ‘By the way doctor do you really mean to say bd?’ and then the doctor will go, ‘Oh yes, whoops, sorry’ and that won’t necessarily get documented as that conversation. I mean sometimes it will and sometimes it won’t, it depends how busy and also just how obsessed that doctor is about paying attention to documenting details.” [PR14-GP3]

One GP felt that the safety of role community pharmacists would be further improved if they were able to access clinical records, especially where the pharmacy was based within the practice building. The practice had considered making such access available but there were concerns about confidentiality which they were unable to overcome:

“We raised it in a practice meeting and the feeling of the meeting was that’s probably going to be difficult for patients to accept.(...) So the only way that I could see was to make somebody an honorary member of staff but again that was uncharted territory. We asked at the PCT level and nobody was doing that.” [FG4-GP2]

9.8.9 Practice pharmacists’ role in medication safety

Two practices specified that they had input from a practice pharmacist, but only one pharmacist was interviewed as part of this study. The remaining practices did not feel that the PCT pharmacists’ had a particular role in medication safety:

“Well there is monitoring of what we do, we have an attached PCT advisor, there’s obviously an annual PCT visit. We’ve got the Newcastle data. There’s a lot of involvement in broad use of prescriptions groups and classes particularly with costs, the PCT’s more concerned about costs I think than they are about individual errors.” [PR2-GP2].

The Practice pharmacist believed *“that’s part of my job isn’t it, to find problems around prescribing”* [FG2-PCT Pharm1] and cited many instances where she had helped improve the safety of prescribing within her practice. This pharmacist reviewed patients in nursing homes and highlighted patients who were overdue for monitoring. She felt there were two approaches to medication safety from a practice pharmacists’ perspective: *“do it actively for the future or you can look at what’s happened in the past and usually you find the problem and then you audit it and fix it and then try and put a process in place for the future, which happens quite a lot”* [FG2-PCT Pharm1]. One approach was to identify problems in individual patients and then audit practice records to determine whether other patients were also affected:

“...if you came across a couple of patients not prescribed calcium and vitamin D but are on a bisphosphonate then you kind of go OK, who else is this not happening for so we’ll fix the problem and then ensure that everybody’s aware it was a problem and it tends not to happen again.” [FG2-PCT Pharm1]

This pharmacist used the electronic formulary embedded within the e-prescribing system to improve the safety of prescribing:

“...with choosing prescribing for me its formularies are great because it makes it really easy to choose the correct drugs that you’re supposed to be using and it makes it less easy to choose those that aren’t in frequent use so even if there’s a way of, if I put things on the formulary only those on the formulary come above the picking list line so if you go below the line you know you’re looking for something less frequently used. Anything above the picking list line should be something that you frequently and commonly use therefore like you’re saying you would have enough knowledge and you’re not going to select the drugs that are 30 milligrams instead of 35 because it’s not going to be easy to find.” [FG2-PCT Pharm1]

Another practice had had a positive experience of working with their practice pharmacist to improve patient safety. In this case, the pharmacist had performed a “*serious drug incidents audit*” [FG4-GP3] which had identified two incidents. This practice also noted how the “*face to face*” contact with the PCT pharmacist had created a “*better relationship*” which helped the practice to ask the pharmacist “*more general things*” [FG4-Prac Manager1].

9.8.10 Patients’ decision making

Throughout the interviews there were a number of examples where patients or carers had identified errors and therefore acted as a defence. GP1 in ‘Practice 1’ recalled how sometimes he gave the wrong prescription to patients:

“Mostly but I have on one or two occasions there’s been something on the printer that I’ve not taken off and picked it up and signed it and given it to the patient and the patient goes, ‘That’s not me’. (Laughs) Sorry, yes, yours is the next one. So occasionally that does get done” [PR1-GP1].

In another example, the carer identified that they were being asked to alter the dose of a different strength of medicine during a telephone consultation:

“We’ve also had somebody where the patient was having amisulpiride and I thought she was having 25 milligrams in 5 mls and her behaviour had deteriorated and as a short term fix we were adjusting that and I said ‘Oh well I can do this many mls’. And then they rang back and said, ‘Well actually our bottle says 100 milligrams in 1 ml’. And I said, ‘Well I prescribed 25 milligrams in 5 mls’. So they received something different from the pharmacy from what I prescribed, so we fed back through to the pharmacy about that and we did have a report back from them. So you think you’re giving the right advice and actually somebody’s got something different in front of them and thankfully they rang back and said, ‘I don’t think we’re talking about the same thing’” [FG4-GP2].

9.8.11 Managing locum staff

Practices which used locum GPs to cover staff absences had a number of strategies to maintain the safety of patient care. One practice always used the same locum agency to ensure that the GPs were familiar with the systems of work within the practice. Whilst another practice provided locums with an induction to the practice to allow them to familiarise themselves with the clinical record and e-prescribing system as well as a locum pack containing details of the practice protocols.

9.8.12 Innovative use of clinical systems

A number of practices had begun to use EMIS practice notes in innovative ways to improve communication across the practice. This had many benefits, including maintaining an audit trail for unauthorised repeat prescription requests, avoiding interrupting consultations with queries about patients, disseminating important prescribing data, and advising prescribers when they had made errors.

Chapter 10: Discussion

10.1 Summary of main findings

From a 12-month retrospective review of the records of a 2% random sample of patients from 15 general practices in England, prescribing or monitoring errors were detected in around one in 20 prescriptions; around one in eight patients were exposed to a prescribing or monitoring error. The vast majority of these errors were of mild to moderate severity. The following factors were associated with increased risk of prescribing or monitoring errors: male gender, age less than 15 years or greater than 64 years, prescription of additional medications, and being prescribed preparations in the following therapeutic areas: cardiovascular, infections, malignant disease and immunosuppression, musculoskeletal, eye, ENT and skin. Prescribing or monitoring errors were not associated with the grade of GP or whether prescriptions were issued as acute or repeat items.

On the basis of interviews with prescribers, focus groups with general practice staff and root cause analyses, a number of important error producing conditions, and defences against error, were identified. Error producing conditions were associated with a wide variety of factors concerning the prescriber (therapeutic training, therapeutic knowledge and experience, knowledge of the patient, perception of risk, and physical and emotional health); the patient (including personality, engagement with health services, literacy and language issues); the team (including communication problems, interruptions, and the 'quasi-autonomous' role of nurses); the working environment (high workload, time pressures and associated stress); the task (problems relating to repeat prescribing systems and inadequate blood-test monitoring); the computer (errors in selecting from pick lists, overriding alerts, failure to maintain accurate electronic records), and the primary-secondary care interface (significant problems were highlighted concerning correspondence about medications particularly at the time of hospital discharge).

A wide range of defences against error were identified as being deployed in relation to the multiple stages of the medicines management process. These defences include strategies that can be used by individual prescribers, practice wide strategies, and the effective use of health information technology.

10.2 Discussion of the methods used in the study

This is one of the largest and most comprehensive studies to be undertaken aimed at identifying the prevalence, nature and causes of prescribing and monitoring errors in general practices. One of the major strengths is the multifaceted nature of the study which allows for triangulation of the findings. Below we highlight some of the strengths and limitations of the different components of the study.

10.2.1 Systematic reviews

We updated two systematic reviews^{23, 24} using standard rigorous approaches. These updated reviews did not identify many new publications, reinforcing the importance of the current GMC-funded study.

10.2.2 Sampling

The 15 general practices recruited to the study were reasonably representative of English general practices in terms of list size (number of patients per practice), number of GPs per practice, age profile and points achieved in the Quality and Outcomes Framework (QOF). Compared with overall figures for England, the recruited practices were more deprived.

Our sampling strategy allowed us to cover a range of locations (inner-city, urban, suburban and rural) and have both GP training practices and dispensing practices. It is possible that the recruited practices had relatively high levels of interest in prescribing compared with other practices, and a greater openness to external scrutiny of potential prescribing errors.

We sampled the 34 face-to-face interview participants based on the errors that we had identified. The sample was extremely varied in terms of gender, location of undergraduate medical education, and length of experience in general practice. The majority of participants were GP partners with only four being salaried GPs, and one a nurse prescriber. The interviews did not directly cover the views of locum GPs and GPs in training.

The sampling for the six focus groups was very successful in terms of recruiting a wide variety of primary healthcare staff in each of the groups.

10.2.3 Investigating the prevalence and nature of prescribing and monitoring errors

Our study of the prevalence and nature of prescribing and monitoring errors used retrospective case note review, which is recognised as one of the most practical methods for obtaining information on errors²⁹. It is particularly useful in highly computerised general

practices, such as those used in our study, as information is easily available to help judge whether an error may have taken place. For example, full details of virtually all prescriptions are available along with demographic details, consultation records, details of morbidities and previous adverse reactions, laboratory test results, and correspondence from hospitals. Other methods for investigating the prevalence and nature of prescribing and monitoring errors are available including real-time collection of information (this is a highly labour-intensive activity, and potentially invasive for practitioners), examination of prescriptions only (this potentially misses out all the information available in the patient's clinical record), or database studies²⁹. Each method has strengths and limitations and may pick up different types of error. Nevertheless, a study comparing four methods of detecting prescribing errors in the hospital setting suggests that retrospective record review captures the highest proportion of clinically important errors³⁰. Our study has focused on errors associated with prescribing and blood test monitoring. With more resources it would have been helpful to have investigated errors associated with other aspects of medicines management in primary care, as Barber et al were able to do in their recent study of medication errors in care homes in the England⁶.

As mentioned in the introductory chapter (Chapter 1), the prevalence of prescribing errors can vary between studies depending on the definitions of error that are used. As explained in Chapter 2 we used a definition that is practitioner derived, clinically relevant, has been validated, and has been used in several other studies^{11,21}.

We obtained a random sample of patients from each practice and this meant that any problems with sampling bias were avoided.

The pharmacists who collected data for our study all had clinical experience and were provided with training. Nevertheless, it is possible that the pharmacists varied in their ability to detect potential prescribing and monitoring errors. The processes we used for collecting data seemed to work well.

The pharmacists were asked to identify omission errors related to failure to prescribe a drug for an existing clinical condition. This was separate from their investigation of prescriptions issued to patients, and so the task may not have received their full attention. Only 11 omission errors were identified, and we suspect that this under represents the true scale of the problem.

The use of a panel to judge whether the problems identified by the pharmacists fitted with our error definitions meant that we were able to provide consistency in the classification of errors. We have provided detailed information on the judgements that we have made (see **Appendix 7**).

We put considerable effort into ensuring that data entry was correct by employing a pharmacist to check every data entry item and to make changes where necessary. We had a statistician (SA) as a member of the project team and she undertook the statistical analysis for the study investigating the prevalence and nature of prescribing and monitoring errors.

We used a previously validated method involving a panel of judges for assessing the severity of prescribing and monitoring errors^{26, 27}, and this worked satisfactorily using data from primary care.

10.2.4 Investigating how general practices incorporate medicines information from hospital discharge correspondence

Our investigation of medicines reconciliation issues for patients discharged from hospital worked well in identifying and quantifying potential issues. The sample was not particularly large, however (38 patients), and this may limit the generalisability of any conclusions that can be drawn from the findings.

10.2.5 Investigating the causes of prescribing and monitoring errors and informal and formal safeguards to protect patients against potential harm

In keeping with previous research undertaken in secondary care^{31, 32} we have successfully used Reason's Accident Causation Model⁹ to guide the analysis, although we deliberately focused on error producing conditions rather than unsafe acts by individuals. Partly this was out of necessity, because the time-lag between the errors identified and the interviews meant that it was often difficult for the prescriber to comment in detail on unsafe acts such as slips and lapses. More importantly, however, it was because we felt that the identification of error producing conditions offered the greatest potential for generating solutions to the problems.

The face-to-face interviews and focus groups generated rich data, and the use of N-Vivo software enabled us to map the large amounts of qualitative data to the themes that emerged from the analysis. Originally, we had planned to analyse the interviews and focus groups separately, but it turned out that both sources of data were valuable in terms of

exploring the causes of error and defences aimed at preventing error. The focus groups were particularly helpful in allowing us to witness interactions between members of the primary health care teams. In general, these interactions were lively, respectful, and sufficiently challenging at times, to give us a sense that practices had a culture that allowed for open discussion of issues concerning medication error.

We recognise that the data obtained from the interviews and focus groups represent the accounts of healthcare professionals and that these do not necessarily accord with their behaviour. In general, respondents seemed open in their discussions, and this is evident from many of the quotes we have provided in this report. Understandably, however, there were times when respondents appeared defensive and not willing to divulge information. An example of this was a relatively new GP partner who clearly had concerns about some of the prescribing of his predecessor, but was not keen to expand on these concerns.

10.2.6 Root cause analyses

We managed to obtain useful data from the root cause analyses and these were helpful in triangulating with the findings from other parts of our study. Having said this, the pharmacists varied in their levels of confidence in conducting root cause analyses and as a result we have presented only summary data in this report.

10.3 Discussion of the findings in relation to the objectives of the study

10.3.1 Updating systematic reviews

As mentioned earlier, the updated systematic reviews did not identify many new publications. A study of the prevalence, causes and potential harm associated with medication errors in care homes for older people is relevant to the current study because it used similar methods for assessing errors, and it reported a particularly high prevalence of errors in an elderly population with multiple morbidity⁶. While the prescribing error rate by opportunity for error was 8.3%, almost four in ten care home residents had one or more prescribing errors. There were monitoring errors in over one in six medications that required blood test monitoring.

In contrast to our earlier systematic review²⁴, our updated review did not show benefit from pharmacist interventions aimed at reducing medication related morbidity or hospital admissions. Pharmacist interventions have nevertheless been shown to be effective in other

aspects of patient care such as using medication review to reduce drug-related problems for patients on repeat medication³³.

10.3.2 The prevalence and nature of prescribing and monitoring errors

The prevalence of prescriptions with prescribing or monitoring errors found in our study was 4.9% with fairly tight 95% confidence intervals of 4.4% - 5.4%. Around one in eight of the population studied were exposed to a prescribing or monitoring error during the 12 month data collection period. Given that we had a sample of practices and patients that was reasonably representative of England, we believe that these figures give a reasonable estimate of the likely prevalence of prescribing and monitoring errors across the country. It is reassuring that the vast majority of the errors were judged to be of only minor or moderate severity, with one in 550 prescriptions being associated with a severe error.

The prevalence of prescribing or monitoring errors was particularly high in certain groups of patients: it was 38% in patients aged 75 years and older receiving at least one medication; 30.1% in patients of any age receiving 5 or more medications, and 46.5% in patients receiving ten or more medications. While it is expected that patients receiving more medications would have a higher prevalence of error, our multivariable analysis showed that there was an additional 16% increased risk for each medication received, over and above the risk associated with each item independently. Overall, these findings suggest that greater attention needs to be paid to the elderly and those on multiple medications to prevent (or detect and correct) errors. Creating more time for thorough prescription reviews would be one way of addressing this problem.

We identified a wide range of types of error associated with different drugs and drug groups. There were, however, some patterns to the errors detected, and several of these would be amenable to audits to detect and correct problems. Examples include:

- Identifying high-risk drugs (such as oral corticosteroids) with non-specific dosage instructions, and correcting these
- Identifying older people taking non-steroidal anti-inflammatory drugs to check whether the prescription is necessary and that they are receiving ulcer-healing drugs to protect against gastrointestinal bleed
- Identifying prescriptions for simvastatin to ensure that these state that the drug should be taken at night

- Identifying patients taking medications that require blood test monitoring to ensure that monitoring is taking place at appropriate intervals; this is particularly important for high risk drugs such as immunosuppressants and warfarin.

We have recently shown that a pharmacist-led intervention was effective at reducing the prevalence of errors in general practices that had been detected through searches of GP clinical computer systems³⁴. This approach, which involved pharmacists working with general practices to correct the errors identified and improve safety systems, would be suitable for tackling some of the errors identified in the current study.

Some of the most serious errors detected in our study related to prescribing medications that patients had a recorded allergy to. Practices need to ensure that allergy alerts are activated for all patients with previous history of allergy; effective systems are needed to ensure that prescribers are aware of a history of allergy when seeing patients outside the practice.

In addition, serious errors were detected for patients who were prescribed warfarin by GPs without access to the results of blood-test monitoring; in one case this led to a 93 year-old man continuing to receive warfarin when he had not attended the (separate) anticoagulation clinic for blood-test monitoring on three occasions, and did not have an INR result in his GP records within the previous 12 months. Almost all of the errors relating to warfarin came from one general practice and this highlights the importance of ensuring that all practices have robust procedures in place for the prescribing and monitoring of warfarin.

Given the paucity of research into the prevalence and nature of prescribing and monitoring errors in general practice, it is difficult to compare the findings from our study with other literature. The recent study by Barber et al⁶ involving care homes is probably the most comparable although it was based on a high-risk elderly population, while the current study covered a random sample across the whole population. There were some similarities in terms of types of error, with incomplete information on the prescription being the commonest category of error in both studies.

There were some similarities between the approach taken to identifying errors in our study and that used by Dornan et al in their GMC-funded study of the prevalence of prescribing errors in hospitals³². Potential errors were detected by pharmacists and a validation panel was used to judge whether each report represented a 'genuine prescribing error'. The severity of errors was also considered. The study from Dornan et al differed from ours in that the data were collected very close to the time of the prescribing act, the majority of

prescribers were junior doctors, and the setting was secondary care. Dornan et al found prevalence of 8.4 errors per 100 medication orders³². Dornan et al had four categories of seriousness: Minor, significant, serious and potentially fatal³². While these do not map directly onto the categories that we used - mild, moderate and severe - it is interesting that in both studies over 90% of errors were in the two lower severity categories.

10.3.3 Factors associated with prescribing and monitoring errors

Our study found some important associations with prescribing and monitoring errors at the patient and prescription level.

The finding that older people were at high risk of prescribing and monitoring errors is not surprising, and in keeping with other studies⁶. Nevertheless, this highlights the importance of developing better strategies for avoiding errors in older people, particularly in terms of judicious use of medicines and thorough prescription reviews.

The finding that those aged up to 14 years are at higher risk of receiving an error is in keeping with longstanding concerns about prescribing to children in the community³⁵. Our study has highlighted particular problems relating to incorrect drug doses in children, and the accompanying qualitative work has shown that some GPs do not feel they have the time to properly check doses in relation to a child's weight. In addition, the prescription of topical corticosteroids with non-specific instructions was another common problem picked up on children's prescriptions. These issues need to be addressed to help protect children against the risk of adverse events associated with overuse of oral and topical preparations.

The finding that men seemed to be at higher risk of prescribing and monitoring errors than women is surprising, as the literature suggests women are at increased risk of adverse drug events³⁶. Nevertheless, while adverse drug events are associated with prescribing and monitoring errors, they are not synonymous and so it is possible that men and women differ in their susceptibility to each. This finding needs further exploration.

The finding that larger practices (with a list size of over 10,000 patients) were associated with a reduced risk of error needs to be treated with some caution given the low numbers of practices and the upper 95% confidence interval being close to 1. The literature gives conflicting findings in relation to the influence of practice size on quality and safety in general practice. Nevertheless, in a stratified sample of 60 English general practices, diabetes care was better in larger practices³⁷. Also, in a secondary analysis of data from 271 general

practices in the Netherlands, composite scores of 8 process measures of medication safety were higher in practices with more than two GPs³⁸.

The finding that the risk of error is increased three-fold for the prescription of drugs requiring blood test monitoring is not surprising given the increased opportunity for error with these drugs. Nevertheless, this does highlight the importance of practices ensuring that rigorous processes are in place for patients to receive appropriate monitoring, particularly as the most common underlying reason for error was failure to request monitoring.

The finding that, compared with gastrointestinal drugs, several drug groups had substantially increased risk of error is of considerable importance. The more than six-fold increased risk for musculoskeletal drugs and drugs used for malignant disease and immunosuppression suggest that these groups of drugs need to be targeted in error reduction strategies. As mentioned earlier, the major problem with musculoskeletal drugs relates to high risk prescribing of NSAIDs. The finding in relation to drugs used for malignant disease and immunosuppression needs to be treated with some caution because of the low numbers of prescriptions for these drugs and the wide 95% confidence intervals. Nevertheless, errors were detected in relation to incorrect formulations, dosage instructions, and inadequate monitoring. For such high risk drugs it is essential that robust processes are in place if prescribing and monitoring is to be undertaken in general practices.

It is worth mentioning some of the factors that were not associated with differences in the prevalence of prescribing and monitoring errors. Grade (or type) of GP did not emerge as a significant factor, although the clear majority of prescribers were GP partners. Also, there was no difference between acute and repeat prescriptions in risk of error. This is an interesting finding given concerns that have been raised about repeat prescribing³³. It suggests that problems detected on repeat prescriptions may not be strongly related to the fact that they are repeats, but instead to the global problem of prescribing errors in general practices. Nevertheless, if repeat prescribing systems - with robust medication review - were more effective, one might expect lower error rates for drugs on repeat.

10.3.4 Incorporation of information from hospital discharge prescriptions

Although we had only a small sample of cases involving medicines reconciliation at hospital discharge the findings are potentially important because they back up previous research³⁹ highlighting the major risks to patients at the interface between primary and secondary care. Explanations for some of the difficulties that GPs face when dealing with hospital discharge

medications were highlighted in our qualitative studies, and some thoughtful solutions were proposed. In particular, GPs highlighted the need for the wording of hospital correspondence to be clear and accurate with any medication changes clearly highlighted.

10.3.5 The causes of prescribing and monitoring errors

Our qualitative studies have generated a wealth of useful information on error producing conditions associated with prescribing and monitoring errors. Some key issues are discussed below.

Training and continuing education for GPs

GPs commented on the lack of formal training and ongoing education with respect to therapeutics and safe prescribing. It would seem that there is relatively little emphasis on these topics in vocational training schemes and newly qualified GPs struggle to make the transition to becoming a partner or salaried GP because of the need to take increasing responsibility for patients with long-term conditions and complex medication needs.

Our study would suggest there is a need for increased emphasis on therapeutics and safe prescribing as part of GP training. Management of prescribing for complex patients needs to be included in this. If the length of GP training in the UK were to be extended, this would allow for more time to address safe and effective prescribing and medicines management.

There is also clearly scope for paying greater attention to safe prescribing and medicines management in continuing professional development for GPs. Options include educational packages addressing key safety concerns, the use of audits to identify and correct errors and the continued use of significant event auditing. Encouraging GPs to focus on improving safety systems within their practices would also be valuable.

Knowing the patient, and the problem of medication review

While some GPs suggested that knowing their patients well was helpful in terms of medication safety, others commented on the risk of becoming blasé and not properly reviewing patients to check the safety and appropriateness of their medications. This was evident when, as part of our study, we detected patterns of hazardous prescribing that had been going on for many years on repeat prescription without apparent challenge. GPs noted the difficulties of conducting thorough medication reviews in some of their regular complex patients given that this was normally done as part of a consultation, and simply dealing with the patient's agenda often took well over 10 minutes. In these cases, there may be benefits

to having extended consultations for high-risk patients, or an independent health professional to review the patients' repeat medications at appropriate intervals.

Dealing with challenging patients

When we discussed a number of prescribing and monitoring errors with GPs, they commented on the difficulties of dealing with patients who had strong views on what medicine they wished to receive (even if it was contraindicated), or who did not engage well with blood-test monitoring. GPs often sought a compromise with these patients in a concordant manner, but often were left feeling discomfort about hazardous prescribing or monitoring failures. The discomfort GPs feel in this sort of situation has been highlighted previously in the literature⁴⁰. Nevertheless, while respecting patients choices is important⁴¹ some GPs need help with developing strategies to resist pressure to prescribe where the risks of harm are particularly high.

GPs' perceptions of risk

Most of the GPs involved in the interviews and focus groups showed high levels of awareness of risks associated with prescribing. These appear to have developed with experience in general practice and were sometimes associated with previously "run[ning] into trouble". There was one GP who recognised that he was at the 'laissez-faire' end of the spectrum when it came to being worried about prescribing, and although he expressed the hope that he was 'still safe', his expressed reliance on patients to report adverse effects of drugs, rather than trying to detect potential problems early, gave some cause for concern. Similarly, as highlighted above, we had concerns where GPs did not take responsibility for a situation where they were prescribing warfarin without any information on the patients' INR.

GPs clearly vary in their perceptions of risks associated with the use of medicines and it is important that high-risk attitudes are identified and challenged. This might be a role for general practice teams or for primary care organisations.

Team factors

Although we came across many good examples of effective team working in relation to medication safety, there were also perceived to be some problems in relation to the role of nurses, interruptions and in some cases professional isolation. GPs expressed concern about what one called nurses' 'quasi-autonomous role' in terms of assessing patients, issuing prescriptions and then expecting GPs to sign these without seeing the patient. Our study did pick up a small number of errors associated with this practice, but it was not one of the highest risks that we identified. Nevertheless, if nurses are to issue prescriptions based

on their own clinical assessment practices it would seem most sensible (and in line with current legislation) for them to be qualified as non-medical prescribers⁴²

Interruptions were also an issue identified by some GPs, and they talked about this in emotive language using words like being 'pounced' upon. One of the major concerns here is that GPs' thought processes can be disrupted by an interruption, meaning that they might make a mistake or fail to record something, with potential adverse consequences for patients. We did not come across specific examples of errors caused by interruptions, but this was probably because of the time-lag between errors and the interviews. It would seem sensible for practices to develop strategies to minimise the frequency of prescribers being interrupted during their clinical work.

Workload

High workload, time pressures and associated stress were perceived to make errors almost inevitable by some of the GPs in our study. The main problem seemed to be limited time in consultations and the fact that dealing with prescribing issues (including prescription review) is often squeezed into the last part of the consultation. A solution to this would be to increase consultation length, particularly for complex patients. However, in the context of current workload in general practices, several interviewees felt this would not be feasible. Therefore, attention does need to be paid to adjusting GP workload to levels that allow sufficient time for safe prescribing and medicines management. One option would be to increase the size of the GP workforce. Another would be to train more non-medical prescribers, particularly pharmacists who might be well placed to deal with complex medication regimes.

Information technology

It was clear from our study that GPs valued the safety features of their clinical computer systems, but some safety concerns were identified that have been highlighted in previous studies⁴³⁻⁴⁵ There is a need for computer system suppliers and drug database manufacturers to address some of these issues (such as improving design to reduce the risks of prescribers making mistakes when choosing from pick-lists, and increasing the availability of alerts for contraindicated prescribing and the need for blood-test monitoring). There is also an important need to ensure that general practices are able to make best use of the existing features of their clinical computer systems (e.g. by ensuring that important information (such as drug allergies) is reliably and accurately coded on the system; by attending to hazard

alerts, and by using existing call and recall systems to help ensure that patient received blood-test monitoring).

Other studies exploring the causes of prescribing and monitoring errors

We are not aware of many other studies that have explored in depth the causes of prescribing and monitoring errors in general practices. Gaal et al undertook a qualitative study involving 22 GPs and seven practice nurses in the Netherlands⁴⁶. Practitioners were interviewed about their perceptions of patient safety. Medication safety was seen to be the most important item and the following were highlighted to be of particular importance: repeat prescribing, the use of computerised medication monitoring systems, and dealing with polypharmacy. In their study, practice nurses were seen to play an important role and GPs relied heavily on their knowledge and skills.

10.3.6 Informal and formal safeguards to protect patients against potential harm from prescribing and monitoring errors

Our study has identified a large number of informal and formal safeguards to protect patients against potential harm from prescribing and monitoring errors. These defensive strategies are applied at all stages in the medicines management process, including those processes which support medicines management.

The defensive strategies can be divided into three main categories: personal strategies which individual prescribers can choose to adopt; those that would be most effective if adopted at practice-level; and those which utilise the features of electronic prescribing systems or other forms of information technology. These defensive strategies have been summarised in tables throughout Chapter 9.

Our analysis has raised a number of important issues in relation to defences against prescribing and monitoring errors in UK general practice. For example, there is great variation in the use of defensive strategies within individual general practices, and between general practices. At present, many practices do not have a unified approach to reducing the risk of prescribing and monitoring errors. This is despite many practices having open cultures for discussing errors in a blame free environment where learning from significant events is common. In one practice, there appeared to be a 'business-oriented' approach to running the practice whereby processes were focussed on time efficiency, not prescribing safety. In contrast, another practice appeared to be highly focussed on medicines safety. Given the large number of medication safety strategies identified in our study, it would seem

sensible to consider these in further detail with the aim of sharing best practice. This might result in a wide range of information and practical tips being available so that practices can select from these to suit their needs, and the needs of their patients.

As might be expected, when there is limited sharing of defensive strategies within and between practices there is no unified approach to reducing the risk of error between practices at a cluster or regional level. This may be because there is little opportunity to share learning at a cluster or regional level. The data presented in Chapter 9 has highlighted examples of good practice in terms of error defences. Dissemination of these data through inter- and intra-practice training is essential to ensure the spread of best practice.

Research identifying interventions which can reduce medication errors in general practice has, to date, focussed on pharmacist-led interventions, educational interventions, and interventions to reduce the risk of falls²⁴. Previous research exploring the underlying causes of medication errors in general practice has identified prescribers, pharmacists, and computer systems as potential defences, but has not explored in detail how processes of work could act as defences against medication errors⁴⁷. In contrast, our study highlights the importance of processes of work for maintaining medicines safety in general practice.

Research has highlighted the importance of pharmacists in preventing medication errors in the hospital setting^{31, 32} and the recent PINCER trial has shown the benefits of pharmacist intervention to reduce prescribing error rates in general practices³⁴. Our current study, however, has highlighted a relative lack of involvement by community and practice pharmacists in preventing medication errors in general practices. At present, community pharmacists are largely restricted to a reactive role in which they usually respond only when patients present a prescription. Their ability to respond as an error defence is also limited by lack of access to clinical information about patients. Practice pharmacists are currently more focussed on cost-effective prescribing than medicines safety. As noted earlier, pharmacists have a potentially important role to play in medication review in primary care^{33, 34} and our study would suggest that there is considerable scope for this role to develop, particularly in relation to the management of complex patients on multiple medicines.

10.3.7 Systems that are used, or could be used, to report prescribing errors in general practice

All but one of the practices involved in the study recorded significant events and included medication errors within this reporting system. The exception was a practice where the GPs preferred to discuss clinical prescribing errors over coffee. There was, however, little evidence of errors being fed back to the local primary care organisation (PCT) and we identified only one case of a practice reporting to the National Reporting and Learning System (NRLS) (<http://www.nrls.npsa.nhs.uk/>), with many practices not having heard of the system, and some confusing it with the Yellow Card reporting scheme for adverse drug reactions.

These findings echo those of a Dutch study where GPs and nurses reviewed safety incidents only within their own practices⁴⁶. When asked, some primary care workers said that they would be prepared to engage with an external incident reporting system, but most did not see the benefits.

It would seem, therefore, that GPs see the value of reporting significant medication-related events within their own practices, but may need convincing of the value of reporting these events more widely. Greater publicity for the NRLS would be helpful, particularly if accompanied by a clear rationale for the benefits of reports from primary care.

10.3.8 What might be unique to general practice culture that might have an impact on prescribing error rates and incident reporting?

We identified a number of positive aspects of general practice culture that might be conducive to minimising prescribing error rates and encouraging incident reporting. In contrast, we also identified some concerns. These are discussed further below in relation to the dimensions of patient safety culture identified in the Manchester Patient Safety Framework (MaPSaF)⁴⁸.

Overall commitment to quality

In the accounts given in the interviews and focus groups, the majority of practitioners seemed committed to delivering high-quality care for patients.

Priority given to patient safety

While there were a small number of exceptions, most of the participants in the interviews and focus groups expressed a high priority for patient safety.

Perceptions of the causes of patient safety incidents and their identification

All of the practices involved in the study undertook analyses of prescribing safety incidents and seemed prepared to investigate the underlying causes of these.

Investigating patient safety incidents

All but one of the practices involved in the study used significant event auditing to investigate prescribing safety incidents. More detailed investigations, such as root cause analyses, appeared to be rare.

Organisational learning following a patient safety incident

We identified a number of instances where, as a result of discussions around a significant prescribing safety event, practices made changes to policies and procedures in order to try and prevent that event from occurring again in the future. Having said this, it is likely that there were many other cases where prescribing safety incidents were discussed without any definitive actions being taken.

Communication about safety issues

The clear majority of practices reported having an open blame-free culture for communicating prescribing safety issues, and this seemed to be backed up by the interactions we witnessed in the focus groups. In some practices, communication was augmented by very strong personal relationships that had built up over years and by informal discussions over coffee or lunch. One GP, however, reflected on the isolation he felt whilst working in his practice; this would not have been helpful in terms of allowing for open communication over safety issues. We did not come across many examples of practices describing the use of written communication to convey information and policies regarding prescribing safety.

Personnel management and safety issues

There was relatively little discussion of personnel management and safety issues. It was striking how, in some practices, the GPs struggled to enforce safety policies such as reducing the amounts of interruptions they had during their clinical work.

Staff education and training about safety issues

Apart from the use of significant event audits meetings, which many practices opened up to all staff, education and training about safety issues was considered important in most practices, particularly for new staff. In some cases there was a strong expectation of staff picking things up 'on the job', and this echoes the findings from a recent ethnographic study

of repeat prescribing in general practices⁴⁹. Some practices had mechanisms for ensuring that locum doctors were trained in the use of the clinical computer system and informed of practice prescribing policies. It was noted that GP registrars (GPs in training) had debriefing after every surgery which gave the opportunity for discussing prescribing safety issues including how to deal with computerised interaction alerts. While many practices recognised the importance of being able to use all the important prescribing safety features of their practice computer systems, there was no discussion of formal training in the use of these systems. Instead, staff were expected to 'familiarise' themselves with the computer system without formal training.

Team working around safety issues

There was not a strong sense of team-working around prescribing safety issues, apart from the use of significant event auditing. Instead, responsibility for prescribing safety seemed very much located in the individual prescriber. All practices had procedures for repeat prescribing and blood test monitoring, but there was not a strong sense of working as a team to ensure patient safety (even though teamwork was clearly used in these aspects of medicines management, as has been demonstrated by Swinglehurst et al in relation to repeat prescribing⁴⁹).

10.4 Recommendations arising from the PRACTICE Study

A number of recommendations have emerged from this study for reducing the prevalence of prescribing errors in general practice and these are outlined below.

A number of recommendations have emerged from this study for reducing the prevalence of prescribing errors in general practice and these are outlined below.

1) GP training

Many of the types of error identified in the PRACTICE Study could have been prevented with better training in safe prescribing in general practice. We recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. We recommend that discussions focus on ways of strengthening training in, and assessment of, safe prescribing and medicines management. Options include:

- Reviewing the RCGP curriculum to give greater prominence to therapeutic knowledge, and the skills and attitudes needed for safe prescribing
- Development of an educational package to enable GPs in training to assess the safety of their prescribing (e.g. by structured examination of, and reflection on, a sample of their prescription items)
- Development of an educational package to help GPs in training (and established GPs) to improve their knowledge and skills in undertaking structured medication reviews with the aim of identifying and correcting important prescribing and monitoring errors
- Making available within the RCGP Trainee ePortfolio a facility to enable GP associates in training to record educational activities, audits, and reflections specifically relating to prescribing
- Including in the RCGP membership examination, assessments of prescribing competence, such as the ability to write error-free prescriptions and to detect, and correct, errors when undertaking simulated medication reviews
- Additional educational support for newly qualified GPs to help them make the transition to providing on-going medicines management for patients with complex long-term conditions.

2) Continuing professional development for GPs

Many of the types of error identified in the PRACTiCe Study could have been prevented with greater attention to safe prescribing in the continuing professional development of GPs. Some of the recommendations made above for GP training may be relevant to established GPs. In addition, we recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. We recommend that discussions centre on the following options for continuing professional development:

- Development of an educational package highlighting key learning points from the PRACTiCe Study to support reflection and, where appropriate, for use in identifying GPs' personal development needs

- Development of strategies to support GPs in dealing appropriately with high-risk prescribing scenarios (balancing risks, benefits, patient requests and the need to avoid error)
- Development of strategies to help GPs make best use of information technology to support safe prescribing
- Development of strategies for improving prescribing safety systems in general practices.

3) Clinical governance

Many of the types of problem identified in the PRACTiCe Study could have been identified and corrected using appropriate clinical governance procedures, particularly in relation to hazardous prescribing and failure to undertake timely blood test monitoring for certain drugs. We recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. We recommend that discussions centre on promoting the following clinical governance methods to identify, correct and report prescribing errors:

- Conducting audits using prescribing safety indicators⁵⁰ and correcting problems identified using evidence-based approaches (such as support from pharmacists, as demonstrated in the PINCER trial³⁴)
- Conducting significant event audits
- Reporting adverse prescribing events (and near misses) through the National Reporting and Learning System

4) Effective use of clinical computer systems

General practice clinical computer systems contain a number of features aimed at improving the safety of prescribing. As noted above, we recommend that general practices develop strategies to ensure that they make best use of the safety features that are already present on their systems.

In addition, we recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems

regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. We recommend that discussions centre on whether improvements can be made in the following areas:

- The training of GPs and practice staff so that they are able to make best use of prescribing safety features
- The use of pre-specified “order sentences” to encourage prescribers to provide appropriate dosage instructions
- Context-specific dosage guidance taking account of patient factors such as age and renal function
- Alerts to the most common and important examples of hazardous prescribing (in addition to drug-drug interaction alerts which are present on all GP clinical computer systems in the UK)
- Alerts to the need for blood test monitoring for certain drugs

5) Improving safety systems

General practices vary in the systems they use to support safe medicines management within the practice and at interfaces in health care (such as community pharmacy, community nursing, care homes and secondary care). We recommend that the GMC discuss the outcomes of this research with those organisations with a remit for quality assurance (including other professional and systems regulators), patient safety and the provision of medical education and training. Where appropriate, this would include the RCGP and General Pharmaceutical Council. Specifically, we recommend that discussions focus on the following proposals:

- General practices review the procedures they have in place for repeat prescribing, medication monitoring, medication reviews and communication at interfaces in health care to help ensure that these are as safe as possible in the context of high workload and multiple competing demands on staff
- Primary care organisations, general practices, community pharmacies and acute trusts take account of recommendations for managing patients’ medicines after discharge from hospital, such as those issued in England by the Care Quality Commission³⁹

- General practices review the procedures they have in place for minimising interruptions to clinical staff
- Further research is commissioned to establish the organisational policies, procedures and practices that help to ensure safe medicines management in primary care.

10.6 Conclusion

Prescribing or monitoring errors occurred in one in 20 prescription items and most of these were judged to be of mild to moderate severity; one in 550 prescription items contained a severe error. The risks of error were higher in young people, the elderly, males and those on multiple medications. Several groups of drugs were associated with higher risks of error including those requiring blood test monitoring, and those used for musculoskeletal problems and malignant disease/immunosuppression. A wide range of different types of error were identified with a wide range of underlying causes. The general practices involved in the study identified a large number of strategies for minimising the risks of error. As a result of this study a number of recommendations have been made in relation to GP training, continuing professional development, clinical governance, the effective use of clinical computers, and improving systems to support safe medicines management.

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Appendices

Appendix 1: Practice Information Sheet



Practice Information Sheet

The PRACTICE Study ***"Investigating the prevalence and causes of prescribing errors in general practice"***

Invitation to take part

You are being invited to take part in the above study, however before you decide to take part, it is important to understand why this research and what it involves. The information sheet provides you with a brief explanation of what will happen during the study and will provide you information on all aspects that the study will cover. Please take the time to read the information provided and feel free to ask questions and discuss it with other practice members. Please take your time and decide whether or not you would like to be a part of this study.

Thank you for taking the time to read this leaflet.

What is the Purpose of the study?

The main aim of this study is to estimate the prevalence and nature of prescribing errors in general practice.

Why has my practice been chosen?

Your practice has been chosen because your Primary Care Trust (PCT) has agreed to take part in the study. We have contacted all general practices in your PCT in order to try to obtain a sample of practices that are representative of practice characteristics nationally.

Does my practice have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time, and without giving a reason. If you decide not to take part, or to withdraw from the study at a future date, this will not affect the standard of care you receive.

What will happen if we decide to take part?

If your practice is selected to take part in this study a pharmacist who is employed by your local PCT will examine the medical records of a 2% random sample of your patients. The pharmacist will treat all data confidentially. This means that:

- they will not talk to anyone about you
- they will not write patients' or staff names down on any form that they use for collecting information
- they will not take any information out of the practice that would allow anyone to know that you have been involved in the study, or to identify any of your staff or patients

Information will be collected from your patient medical records about the types and nature of prescribing errors identified. Information will be recorded from around one year ago (this is one year before the study starts in your general practice) until the time that the pharmacist visits the practice to look at your records. If a clinically important prescribing error is identified by the pharmacist, a relevant GP will be asked if they would be willing to participate in an interview to explore the reasons to why the error happened. GPs will be given separate information about these interviews, which will take place only if they individually consent to participate. If a serious prescribing error is identified by the pharmacist, particularly if this results in patient harm, this will be fed

back to the relevant GP and reported through the routine incident reporting system of the trust as per local incident reporting procedures.

What are the possible disadvantages or risks of taking part?

If you decide to take part, the practice will need to find the space (and access to the practice computer system) for the pharmacist to undertake reviews of clinical records. In addition, members of the practice will need to be willing to consider taking part in interviews and (for a small number of staff) a focus group.

What are the possible benefits of taking part?

Allowing a PCT pharmacist to examine medical records in your practice will help the research team estimate the prevalence of prescribing errors, and understand the nature of these errors. Interviews with members of practice staff will help in the understanding of why errors occur. In turn, this will help in the development of strategies for preventing errors in the future. Taking part in the study will be a potential benefit to your practice because it is likely to increase understanding of medication errors and their causes. There are also likely to be benefits to patients because if pharmacist pickup clinically important errors, and these are then corrected, patient harm may be avoided.

The research team recognise the time commitment involved in taking part in the study and will reimburse the practice up to £500 to cover the costs of involvement in the study.

Will the practices' participation in the study remain confidential?

All information which is collected about the practice during the course of the research will remain confidential, and no participant details will be collected.

What do I have to do?

Complete and return the enclosed reply slip, in the postage paid envelope provided, indicating whether you wish to take part in this study.

If your practice is selected you will be asked to confirm in writing that the practice is willing to take part in the study.

What will happen to the results of this study?

The results of the study will be published in medical journals and will be presented at conferences. There is no possibility that any individual person or doctor's surgery could be identified in any report or article that is published.

Who is organising and funding this research?

The research is organised by the Division of Primary Care, University of Nottingham in collaboration with the schools of Pharmacy in universities of Hertfordshire and Reading as well as the London School of Pharmacy, University of London.

The research is funded by the General Medical Council. The official name for the study is the "PRACtICE study".

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nottingham REC 1 Research Ethics Committee.

Contact for further information

If you wish to ask any questions about this study before deciding to take part, please contact one of the following people, who would be pleased to help you:

PRACTICE study Co-ordinator:

Dr Maisoon Ghaleb, School of Pharmacy, University of Hertfordshire, College Lane Campus, Hatfield AL10 9AB.

Tel: 01707 285087; Fax: 01707 284506, e-mail: m.ghaleb@herts.ac.uk

Chief Investigator:

Professor Tony Avery, Head of Division of Primary Care, School of Community Health Sciences, University of Nottingham Medical School, Nottingham, NG7 2UH.

Tel 0115 8230209; Fax: 0115 8230214; email: tony.avery@nottingham.ac.uk

If you agree to take part in this study, you will be given a copy of the Practice Information Sheet and practice letter of approval to keep.

Thank you for considering taking part in this study

Appendix 2: Form used for collecting demographic and prescription data on patients.

FORM 1: Prescribing Record Sheet

Database Unique ID No.

Instructions: Please use one sheet per patient (use extra sheets if more than 15 prescriptions) and record any possible prescribing or monitoring errors.

Initials of pharmacist doing review: _____	Date: _____
Practice ID code: _____ (assigned by research team)	
Patient ID code: _____ (for internal use by practice)	
Patient information:	
Age _____ Years/months (indicate as appropriate)	Sex: Male / Female (please circle)
Months registered with practice during the 12-month data collection period: _____	

If no prescriptions for this patient, tick here and move on to the next patient.

In the table below please record summary data on the prescriptions for this patient over the last 12 months (record data in relation to the latest prescription if a drug (at a particular dose) has been prescribed more than once during the year).

If you pick up any potential errors, please fill in **Form 2** for each of these errors.

If you pick up any omission errors relating to failure to prescribe for an existing condition, please fill in **Form 3**.

If the patient has had any correspondence from secondary care regarding medicines at hospital discharge during the previous 12 months, please fill in **Form 4**.

If you pick up any examples of prescribers identifying errors and correcting these please record this in **Form 2** or for errors not identified by this study, fill in **Form 5**.

Rx ¹ No.	Drug name/dose/form ²	Is this drug on the drug monitoring list (Y/N)	Acute (A) or Repeat (R) ³	GP type ⁴	No. of possible Rx error(s) ⁵	No. of possible monitoring error (s)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

¹: Rx = prescription; ²: Name of drug/preparation as it appears in the patient record; ³: Record "A" for acute prescription and "R" for repeat prescription; ⁴: Record GP type (1=GP partner; 2=Salaried GP; 3=Locum GP; 4=GP in training; 5=F2 doctor; 6=Other doctor; 7=Non-medical prescriber; 8=Other; 9=Unknown); ⁵: if no error, please put zero (0).

If this patient has more than 15 prescriptions, please tick here and do an extra Form 1

The PRACTICE Study (Final version 13.0: 30 July 2010)

Appendix 3: Form used for collecting detailed information on potential medication errors.

FORM 2: Details of possible prescribing and monitoring errors

Database Unique ID No.

For the possible errors identified on Form 1, please provide further details below and overleaf (use additional sheets as required)

ONE FORM PER POSSIBLE ERROR

Initials of pharmacist doing review: _____	Date: _____
Practice ID code: _____ (assigned by research team)	
Patient ID code: _____ (for internal use by practice)	
Patient information:	
Age _____ Years/months (indicate as appropriate)	Sex: Male / Female (please circle)

Rx No. from Form 1¹	
Drug name & formulation²	
Strength	
Dosage instructions	
Quantity	
Initials of prescriber	
Error code³	

¹ Please use the appropriate prescription number from Form 1; ²: Name of drug/preparation as it appears in the patient record; ³: please use the following error codes:

Prescribing errors

- 1 Unnecessary drug
- 2 Incorrect drug
- 3 Duplication
- 4 Allergy error
- 5 Contraindication error
- 6 Interaction error

- 7 Dose/strength error
- 8 Formulation error
- 9 Frequency error
- 10 Timing error
- 11 Information incomplete
- 12 Generic/brand name error
- 13 Omission error relating to failure to prescribe concomitant medication

Monitoring errors

- 21 Monitoring not requested
- 22 Requested but not done
- 23 Results not available
- 24 Results not acted upon

Appendix 4: Form used for collecting data on potential omission errors related to not prescribing for an existing condition

FORM 3: Omission errors relating to failure to prescribe for an existing clinical condition

Database Unique ID No.

Please note that this form is for recording medications that, after careful examination of the patients' records, you think **should** have been prescribed because of an **existing condition**, e.g. aspirin, ACE inhibitor, beta-blocker and/or statin post-MI.

Note: use forms 1 and 2 to record possible omission errors relating to failure to prescribe necessary concomitant therapy in relation to patients' existing medicines, e.g. failure to prescribe a PPI to a patient taking NSAIDs when they are at high risk of a GI bleed.

Initials of pharmacist doing review: _____	Date: _____
Practice ID code: _____ (assigned by research team)	
Patient ID code: _____ (for internal use by practice)	
Patient information:	
Age _____ Years/months (indicate as appropriate)	Sex: Male / Female (please circle)

Please describe the possible omission error(s) in this patient.

1) Clinical condition(s) for which you believe medication should have been prescribed:

.....

.....

.....

2) Medicine(s) that you believe should have been prescribed:

.....

3) Please provide an explanation for why you think this was an omission error:

.....

.....

.....

.....

4) Having thoroughly reviewed the patient's records is there anything to suggest that the medicine you think should have been prescribed may not be indicated, e.g. due to previous ADR, expressed patient preference, caution or contraindication?

Yes / No/ Uncertain (Please circle as applicable)
If 'Yes' or 'uncertain' please give details below.

Appendix 5: Form used for information on medicines reconciliation for patients with a hospital discharge communication.

FORM 4: Reconciliation of hospital discharge prescriptions

Database Unique ID No.

Initials of pharmacist doing review: _____	Date: _____
Practice ID code: _____ (assigned by research team)	
Patient ID code: _____ (for internal use by practice)	
Patient information:	
Age _____ Years/months (indicate as appropriate)	Sex: Male / Female (please circle)
Months registered with practice during the data collection period: _____	

For the last hospital discharge within the 12-month period, please record the following information (n.b. do not include day case admissions or short-stay admissions where no changes made to medication).

1) Was a summary of discharge medication available?

Yes / No (please circle as appropriate). If 'No', please go to question 14.

2) Was there more than one summary of discharge medication available from the same hospital admission (e.g. an immediate communication followed by a letter)?

a) Yes / No (please circle as appropriate).

If 'Yes' please select the first of these for answering the following questions, but note in the comments sections if there were any discrepancies between the communications, e.g. if one version contained different, or more detailed, information.

b) How many medications were present on the discharge communication?

3) Were there any differences between the medications that the patient was taking before admission and those listed in the discharge communication?

Yes / No (please circle as appropriate). If 'Yes', go to question 4, if 'No' go to question 5.

4) With reference to the medication record of the patient immediately *before* the admission:

Question	Number	How many of the changes were highlighted on the discharge communication?
a) How many drugs that were clearly being prescribed pre-admission* appear to have been continued by the hospital at the same dose?		Not applicable
b) How many drugs that were clearly being prescribed pre-admission* appear to have been continued by the hospital at a <i>different</i> dose?		
c) How many drugs on the discharge summary appear to have been newly prescribed by the hospital?		
d) Add up 3a, 3b and 3c to check this equals the figure given in Question 2:		Not applicable
e) How many drugs that were clearly being prescribed pre-admission* appear to have been <i>discontinued</i> by the hospital?		

*Please use your judgement in deciding whether or not a patient was clearly being prescribed a drug pre-admission, e.g. recent acute prescription or regularly requested repeat prescription. In case of uncertainty, please note this below.

Comments (where applicable):

.....

.....

.....

The PRACTICE Study (Final version 13.0: 30 July 2010)

FORM 4: Reconciliation of hospital discharge prescriptions

Database Unique ID No.

5) For how many of the medications on the discharge summary was the following noted:

Issue	Number of medications where issue noted (put 0 if none)	Comments
Name of drug unclear		
Drug form missing		
Drug form unclear		
Dose missing		
Dose unclear		
Dose instructions missing		
Dose instructions unclear		
Suggested duration of use missing		
Suggested duration of use unclear		
A change in dose of a drug that the patient was taking on admission not explicitly highlighted		
A drug newly prescribed by the hospital not explicitly highlighted		

6) How soon after the date of hospital discharge was the medication summary logged as being received by the practice? (days)
or state if not clear:

7) Was the hospital discharge at least a month ago?

Yes/No (please circle as appropriate).

8) Was there any evidence of a prescription review having taken place by the practice within a month of hospital discharge?

Yes/No (please circle as appropriate).

9) Was there any evidence of the practice making adjustments to the patients' medication following the hospital discharge?

Yes / No (please circle as appropriate)

10) Was there any discrepancy between the medicines on the hospital discharge communication and those subsequently prescribed to the patient (or recorded in the patients' medication record)?

Yes/No/Not applicable* (please circle as appropriate)

*use 'not applicable' if no prescription issued and no change to medication record made, e.g. practice has not had time to make changes to the medication record or to issue a further prescription following hospital discharge.

If 'Yes' go to question 11, if 'No' or 'Not applicable' go to question 14.

The PRACTICE Study (Final version 13.0: 30 July 2010)

FORM 4: Reconciliation of hospital discharge prescriptions

Database Unique ID No.

11) For how many of the medications on the discharge communication was the following noted:

Issue	Number of medications where issue noted	Comments (including whether any justification recorded)
Drug newly prescribed by the hospital not continued by the practice		
Drug newly prescribed by the hospital not prescribed subsequently by the practice at the dose suggested by the hospital		
Drug newly prescribed by the hospital not prescribed subsequently by the practice with the dosage instructions suggested by the hospital		
Drug newly prescribed by the hospital not prescribed by the practice for the duration suggested by the hospital		
For a drug that the patient was taking <i>before admission</i> , a change of dosage suggested by the hospital was not made by the practice following discharge		

12) How many drugs that appeared to have been stopped by the hospital were subsequently restarted by the practice within a month of hospital discharge?

For how many of these was a justification given for restarting the medication?

13) Do you believe that any possible errors occurred for this patient in the reconciliation of medicines following hospital discharge?

Yes/No (please circle as appropriate)

If 'Yes', please provide further details overleaf, If 'No' go to question 14.

Appendix 6: Medicines requiring blood test monitoring

1) Monitoring following the initiation of therapy

Drug/drug group	Monitoring on initiation
ACE inhibitor/Angiotension-II receptor antagonists	On initiation: Pre U&E and 2 weeks after
Digoxin	Pre U&E
Diuretics	Pre U&E and 1 month after starting
Glitazones	Pre LFT
Statins	Pre LFT before starting treatment

2) Monitoring of maintenance therapy

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

Appendix 7: Examples of judgements made by the error judging panel on scenarios identified as part of the study

Scenario	Judgement	Rationale for judgement
Helicobacter eradication treatment to a patient who is Helicobacter negative.	Error: unnecessary drug.	Significant increased risk of harm with no likely benefits from the antibiotic components of the treatment.
Combined oral contraceptive pill left on repeat prescription after an alternative hormonal contraceptive had been given.	Sub optimal prescribing: risk of duplication low.	The panel felt that it was suboptimal prescribing to leave a combined oral contraceptive pill on repeat prescription and alternative hormonal contraception had been given. Nevertheless, the panel felt that it was highly unlikely that the patient would request this medication having been given an alternative hormonal contraceptive.
Prescription of a second dose of the same influenza vaccine within one flu season (whether or not the patient received the second dose).	Error: duplication.	Significant increased risk of harm if patient were to receive a second dose (even if this was just a local reaction to the injection) without any benefits.
Prescription of paracetamol when another paracetamol containing product is on the patient's repeat prescription (or vice-versa): both products prescribed at the same time with no warning that they should not be taken together.	Error: duplication.	Significant increased risk to the patient if they were to take the two products together.
Prescription of paracetamol when another paracetamol containing product is on the patient's repeat prescription (or vice-versa): products not prescribed at the same time, e.g. >3 months between prescriptions, but no warning that the preparation should not be taken together.	Assess on a case by case basis.	The panel felt that it was difficult to produce case law on this scenario and so cases should be judged individually.
Prescription of a drug in circumstances where the pharmacist notes that an allergy to that drug has been recorded, and the prescriber gives no acknowledgement/justification for prescribing in light of the previous allergy documentation.	Error: allergy error.	Significant increased risk of harm. Not all allergy recordings represent true allergy. Nevertheless, at a minimum one would expect a prescriber to acknowledge that previous (potential) allergy had been recorded and to justify their prescription in these circumstances.
Prescription of a drug that is contraindicated according to the BNF (unless a clear and defensible justification has been given by the prescriber or in correspondence from secondary	Error: contraindication error.	Significant increased risk of harm.

Scenario	Judgement	Rationale for judgement
care). An example would be the prescription of combined hormonal contraceptives in patients with two or more risk factors for thromboembolism.		
Prescription of two oral NSAIDs at the same time.	Error: interaction error.	Significant increased risk of harm, e.g. from GI Bleed.
Aspirin 150 mg daily as secondary prevention for coronary heart disease.	Suboptimal prescribing: dose/strength error.	While the panel felt that doses >75mg daily increased the risk of harm while not being likely to increase benefits, it was felt that the increased risks were not sufficiently high to label this as an error. It was also noted that 150mg daily was a standard dose in the US.
Calcium tablets prescribed at lower than the recommended dose.	Suboptimal prescribing: dose/strength error.	Risk of harm (or reduction in probability of treatment being timely or effective) is probably low. Also, BNF is not very specific about calcium doses noting that dietary intake also needs to be taken into account.
Failure to act on a suggested dose change from secondary care correspondence, where that dose change was aimed at either increasing therapeutic benefits or reducing risk of harm.	Error: dose/strength error.	Significant increased risk of harm or reduced probability of treatment being timely and effective.
Overdose of an oral medication in a child, e.g. clearly above that recommended by BNF for height/age, unless the medication has extremely low risk of harm.	Error: dose/strength error.	Significant increased risk of harm.
Overdosage of an oral medication in an adult where there is clear increased risk of harm (unless a clear and defensible justification has been given by the prescriber or in correspondence from secondary care).	Error: dose/strength error.	Significant increased risk of harm.
Overdosage of a single dose of an oral medication (e.g. sulphonylurea) where BNF recommends dividing the dose above a certain dosage level (unless a clear and defensible justification has been given by the prescriber or in correspondence from secondary care).	Error: dose/strength error.	Significant increased risk of harm.
Prescription of a drug with	Error:	Significant increased risk of harm.

Scenario	Judgement	Rationale for judgement
significant potential for harm at a dose above that recommended by the BNF (for a specific indication) e.g. Rosuvastatin 40 mg in a patient without "severe hypercholesterolaemia or with high cardiovascular risk and under specialist supervision".	dose/strength error.	
Underdosing of oral antimicrobial agents.	Error: dose/strength error.	Significant increased risk of harm if infection not treated adequately (or if infecting organism not fully eradicated, thus increasing the risk of resistant strains developing)
Underdosing for a condition that is not serious and where failure to prescribe the recommended dose is unlikely to have a significant deleterious effect on the patient in terms of lack of control of symptoms.	Suboptimal: dose/strength error.	The panel felt that for non-serious symptomatic conditions it was not appropriate to label underdosing as an error because prescribers may have consciously used a low dose to avoid side-effects.
When a patient is under the care of a specialist, prescription of a drug with significant potential for harm at a dose above that recommended, e.g. failure to adjust doses in response to correspondence from secondary care.	Error: dose/strength error.	Significant increased risk of harm from prescribing a drug that a higher dose than that recommended.
Drug not prescribed in the correct formulation when this might lead to increased risk of patient harm, e.g. tacrolimus and other medications where the BNF states the importance of prescribing the correct formulation.	Error: formulation error.	Significant increased risk of harm, or reduction in the probability of treatment being timely or effective.
Oral antibiotics prescribed at a frequency below that recommended in the BNF.	Error: frequency error.	Significant increased risk of harm (development of antibiotic resistance) or reduced probability of treatment being timely and effective (due to failure to maintain adequate plasma levels of antibiotic).
Prescription of a hydrocortisone containing products in a child at a frequency higher than that advised by BNFC or SPC.	Error: frequency error.	The panel debated this at length, but with input from a paediatrician decided that prescribing hydrocortisone at a frequency greater than that recommended could increase the risk of harm to a child.
Prescription of a topical product which has low potential for harm, e.g. antifungal, mild corticosteroid	Suboptimal prescribing: frequency	Risk of harm not significant.

Scenario	Judgement	Rationale for judgement
(in an adult and not on the face), at a frequency different to that recommended by the BNF.	error.	
Bendroflumethiazide prescribed OD.	Suboptimal prescribing: timing problem.	While thiazide diuretics should normally be taken in the morning, the panel did not feel there was a significant increased risk of harm from this once daily dosage instructions.
Oral corticosteroids prescribed without instructions that they should be taken in the morning.	Suboptimal prescribing: timing problem.	The BNF states that the suppressive action of a corticosteroid on cortisol secretion is least when it is given as a single dose in the morning. The panel felt that the risks of harm to patients from not stating that the drug should be taken in the morning were small in the majority of patients. Therefore this was classified as suboptimal prescribing rather than error.
Simvastatin prescribed without instructions that it should be taken at night.	Error: timing error.	Significant reduction in the probability of simvastatin being effective if not taken in the evening/at night.
Benzodiazepines at low dose, e.g. 2 mg, and small numbers of tablets, e.g. 10, prescribed "as directed" for conditions such as flight phobia and muscle spasm.	Suboptimal: information incomplete.	The panel felt that in the majority of patients there would not be at significant increased risk of harm from this pattern of prescribing.
Ear drops prescribed without indicating which ear they should be used in.	Suboptimal prescribing: information incomplete.	The panel felt that risks of harm to the patient would be low here as it is highly likely that the patient would know which ear to use the drops in.
Eye drops (for non-serious symptomatic conditions such as conjunctivitis or dry eye) prescribed without indicating which eye the drop should be used in.	Suboptimal prescribing: information incomplete.	The panel felt that risks of harm to the patient would be low here as it is highly likely that the patient would know which eye to use the drops in.
Eye drops for glaucoma prescribed as directed or without indicating which eye the drop should be used in.	Prescribing error: information incomplete.	Given that glaucoma is usually asymptomatic, and that there are serious risks to sight if treatment is not administered correctly, the panel felt that risk of harm would be significantly increased by not having clear dosage instructions.
Eye drops containing steroids prescribed as directed or without indicating which eye the drop should be used in.	Prescribing error: information incomplete.	Given the risks of steroids in the eye, it is important to give clear instructions.
GTN sublingual tablets/spray	Suboptimal	It was felt that patients will almost certainly

Scenario	Judgement	Rationale for judgement
prescribed “as directed”.	prescribing: information incomplete.	have been informed about how to take GTN sublingual tablets/spray and that these products come with a Patient Information Leaflet that gives detailed unequivocal instructions on how to take the medicine.
Inhaled corticosteroid prescribed without clear dosage instructions, e.g. PRN, BD.	Error: information incomplete.	The panel felt that given that inhaled corticosteroids are normally prescribed regularly for asthma in order to prevent exacerbations, there was a significant increased risk of harm from not having clear dosage instructions.
Inhaled salbutamol prescribed PRN.	Suboptimal .prescribing: information incomplete.	The panel felt that there was unlikely to be a significant increased risk of harm here because salbutamol inhalers come with clear dosage instructions on the PIL.
Medication, with significant risk of harm if not taken according to precise dosage instructions, prescribed “as directed” (e.g. amiodarone, betablockers, methotrexate, n.b. warfarin not included).	Error: information incomplete.	Significant increased risk of harm if the patient does not know what is meant by “as directed”.
Medication prescribed without stating the number of tablets to be taken each time, e.g. metformin 500 mg tablets “twice daily” provided that the default dose of one tablet/capsule each time would be an appropriate dose (n.b. very high risk drugs not included in this scenario).	Suboptimal: information incomplete.	The panel felt that most community pharmacists and patients would interpret the instructions to mean one tablet to be taken at each dose, and that in most circumstances the inadequate dosage instructions would not present an increased risk to the patient.
Oral corticosteroids prescribed “as directed” without further instructions.	Error.	Significant increased risk of harm if patients do not have clear instructions on how to take oral corticosteroids.
Oral corticosteroids prescribed “as directed by X” (where X is usually a secondary care clinician).	Suboptimal.	The panel felt that while there was a potential increased risk of harm to patients, by specifying the patient was to follow directions given by another clinician it is likely that the patient had been given specific dosage instructions.
Phosphodiesterase type-5 inhibitors with “as directed” dosage instructions.	Suboptimal prescribing: information incomplete.	The panel felt the risks of harm in this situation were low.
Prescription of a preparation for an adult that is available OTC and is prescribed with “as	Sub optimal prescribing: information	OTC preparations come with clear dosage instructions and so use of “as directed” is not likely to expose a patient to significant

Scenario	Judgement	Rationale for judgement
directed" dosage instructions (n.b. NSAIDs to be considered on a case-by-case basis).	incomplete.	increased risk of harm.
Prescription of a topical product which has very low potential for harm, e.g. emollient, antifungal, without clear dosage instructions.	Sub optimal prescribing: information incomplete.	Risk of harm not significant.
Prescription of a topical product with significant potential for harm if dosage instructions are incorrect or not clear, e.g. moderate-potent corticosteroid in a child, or potent corticosteroid in an adult, or products containing antibacterial agents (includes lack of information on duration of use).	Error: information incomplete.	Risk of harm significant.
Prescription of oral antibiotics without clear dosage instructions, e.g. PRN.	Error: information incomplete.	The panel felt that there was a significant increased risk of harm from prescribing oral antibiotics without clear dosage instructions, e.g., due to risks of harm from underdosing, overdosing or prolonged treatment, and potential problems with development of antibiotic resistance.
Prescription of hormone replacement therapy without detailed dosage instructions, e.g. "as directed", for preparations where the PIL contains clear and unambiguous instructions.	Suboptimal prescribing: information incomplete.	For preparations where the PIL contains clear and unambiguous instructions the panel felt that there was not a significant increased risk of harm from "as directed" instructions.
Prescription of hormone replacement therapy without detailed dosage instructions, e.g. "as directed", for preparations where the PIL does not contain clear and unambiguous instructions.	Error: information incomplete.	The panel felt that there was significant increased risk of harm from overdose if "as directed" instructions were given for a HRT preparation where the PIL did not give unambiguous dosage instructions.
Prescription of the combined hormonal contraceptive pill/patch without detailed dosage instructions, e.g. "as directed".	Suboptimal prescribing: information incomplete.	It was felt to be common practice for some GPs to use "as directed" instructions knowing that patients will have been informed about how to take the contraceptive pill and that all pill packets come with a Patient Information Leaflet that gives detailed instructions on how to take the medicine.
Sofradex eye/ear drops prescribed without specifying whether they were to be used for eye or ear.	Prescribing error: information incomplete.	Given dangers of inadvertent use of steroids in the eye the panel judged this to be an error.

Scenario	Judgement	Rationale for judgement
Steroid eye drops prescribed as directed or without indicating which eye the drop should be used in.	Prescribing error: information incomplete.	Given the dangers of topical eye drops, clear dosage instructions are essential.
Strong opioids with inadequate dosage instructions.	Prescribing Error: information incomplete.	Given legal requirements and risks from overdose, the panel felt that risk of harm to the patient was significantly increased if dosage instructions were not clear.
Topical preparation prescribed with dosage instructions implying an oral route for administration, e.g. take one twice daily.	Suboptimal: information incomplete.	The panel judged that while these dosage instructions could be misinterpreted, it is almost certain that a community pharmacist would put the correct instructions on the dispensing label.
Unclear dosage instructions on a corticosteroid inhaler for asthma in a patient with poorly controlled asthma.	Error: information incomplete.	Significant increased risk of harm if the patient is not receiving an adequate dose.
Varenicline starter pack with "as directed" instructions.	Sub optimal prescribing: information incomplete.	Instructions for use of the starter pack are complicated and these are clearly explained in the Patient Information Leaflet. The panel felt that it was not an error to write "as directed" as full and unequivocal instructions are available in the PIL.
Antiepileptic treatments (modified release preparations) prescribed generically for epilepsy where more than one brand is available.	Error: generic/brand name error.	The panel felt there was a significant increased risk of patient harm from generic prescribing in these circumstances where there may be differences in bioavailability between brands.
Failure to prescribe calcium and vitamins D to a patient who is receiving a bisphosphonate for osteoporosis or fracture prevention.	Suboptimal: omission error.	The panel felt that while all trials of bisphosphonates had included calcium and vitamin D, some patients may be taking sufficient calcium and vitamin D through OTC supplementation or diet.
Prescription of an NSAID to an older person (>65 yrs) without an ulcer-healing (younger patients to be judged on a case-by-case basis).	Omission error related to failure to prescribe concomitant medication.	Significant increased risk of harm (although judgement required in cases at the lower risk end of the spectrum, e.g. occasional use of low dose ibuprofen in a 65-year-old with no other risk factors - such cases were discussed by the panel to reach a judgement).
Prescription of a drug in circumstances where the pharmacist notes that a previous adverse drug reaction (ADR) has been recorded, but the details of that ADR have not been documented and the patient has used the drug since without apparent problems.	Sub optimal prescribing: inadequate documentation in medical records.	Risk of harm probably not significant given that patient has been taking the drug without apparent ill effects.

Scenario	Judgement	Rationale for judgement
Prescription of a drug with very high potential for harm (e.g. immunosuppressants, strong opioids) without documented evidence of an indication for the drug.	Error: inadequate documentation in medical records.	Significant increased risk of harm from prescribing high risk medication without a recorded indication.
Prescription of any medication (except those with very high potential to cause harm) without documentation of the indication in the medical records.	Suboptimal prescribing: inadequate documentation in the medical records.	Lack of documentation made it difficult to judge whether the prescription was associated with a significant increased risk of harm. Therefore sub-optimal prescribing classification used rather than error.
Anthelmintics (for threadworms, head lice, scabies) prescribed on a single prescription with a quantity large enough to treat a whole family.	Suboptimal prescribing: quantity issue.	Even though the quantity is large, this does not necessarily imply an error and there is no legal issue unless the prescriber has explicitly suggested that someone other than the patient can use the medicine.
Oral antibiotics prescribed with a quantity that is clearly below that normally recommended for successfully treating infection.	Error: quantity issue.	Significant increased risk of harm if infection not treated adequately (or if infecting organism not fully eradicated, thus increasing the risk of resistant strains developing)
Prescription of a very large quantity (e.g. greater than six months) of a drug that is not high-risk and has low potential for misuse.	Suboptimal: quantity issue.	The panel felt that there was probably not a significant increased risk of harm to patients.
Prescription of a large quantity (e.g. greater than three months) of a drug that is either high-risk or has significant potential for misuse.	Error: quantity error.	The panel felt that there was a significant increased risk of harm.
Oral terbinafine prescribed (e.g. for fungal nail infection) for 3-6 months without review.	Suboptimal: duration problem.	The panel felt that in order to consider whether a prescription was still necessary, a patient should not go 3-6 months without a review. See further case below for prescribing beyond six months without review.
Oral terbinafine prescribed (e.g. for fungal nail infection) for greater than six months without review.	Error: duration error.	Beyond 6 months without review, the panel felt that continuing prescribing might increase risks for patients when no assessment had been made as to whether further treatment was necessary.
Not responding to a request from secondary care to undertake laboratory test monitoring where this request is justified in terms of risks from the medication the patient is taking.	Error: monitoring not requested.	Significant increased risk of harm.

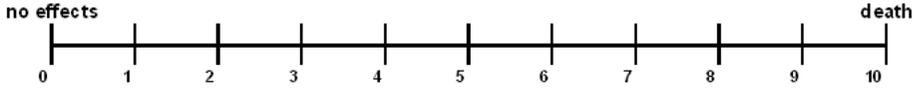
Scenario	Judgement	Rationale for judgement
Increasing the dose of an ACE inhibitor/AR II antagonist without checking U&E within three weeks.	Error: monitoring not requested.	Increased risk of harm if adverse effects not picked up early.
Dosage instructions given using decimals rather than words, e.g. 0.5 tablets.	Not a problem.	The panel felt that while the use of decimals may be dangerous in some circumstances, it is unlikely that they would be transmitted on to the dispensing label having gone through a community pharmacy or dispensary.
Eye drops prescribed without indicating how many drops to use.	Not a problem.	Eye drops designed so that one drop gives a sufficient volume; patient inadvertently using more than one drop are unlikely to come to harm as excess liquid spills out of the eye.
Loop diuretics prescribed "twice daily" without stating "one to be taken in the morning and one at lunchtime".	Not a problem.	The panel felt that while the usual twice daily dosage for loop diuretics was in the morning and at lunchtime some patients might wish to take the doses at different times.
Prescription of a broad spectrum oral antibiotic to a woman receiving the combined oral contraceptive pill (for contraception) without instruction (on the prescription, or documented in the patient's records) that extra contraceptive precautions should be taken.	Not a problem.	In light of WHO and RCOG advice that risks of pregnancy are not increased by use of non-enzyme inducing antibiotics, the panel judged this not to be a problem.
Prescription of a cephalosporin to a patient with previously recorded history of penicillin allergy (but no evidence of anaphylaxis).	Not a problem.	Although cross sensitivity is a potential problem, the panel felt that it was not a significant risk unless the patient had previously had an anaphylactic reaction to penicillin.
Prescription of a drug, e.g. an oral NSAID, at a frequency greater than that recommended in the BNF, but with the total daily dose no higher than the recommended maximum.	Not a problem.	The panel felt there was no increased risk to patients from this pattern of prescribing.
Prescription of mild opioids to patients with mild-moderate COPD.	Not a problem.	The panel felt that the risk to patients was very low.
Prescription of two or more antihypertensive drugs to a patient with blood pressure in the normal range (this also includes prescriptions of ACE inhibitors and non-potassium-sparing diuretics (or spironolactone in	Not a problem.	Risk of harm low and patients likely to receive benefit from having blood pressure in the normal range.

Scenario	Judgement	Rationale for judgement
heart failure)).		
Stating oral doses in milligrams, e.g. “amoxicillin 125mg/5mL, 125mg three times a day” is acceptable practice, as is stating the volume per dose, e.g. 5mL three times a day.	Not a problem.	Either way of stating the dose is acceptable practice.

Appendix 8: Examples of scenarios used in the questionnaire assessing the severity of prescribing and monitoring errors made by general practitioners

Assessors were given the following instructions: Below are a number of prescribing and monitoring errors identified in a study of errors in general practice. We are now asking you to assess their severity. This method is a validated and reliable tool for assessing the severity of medication errors.

Please could you rate these error scenarios in terms of *potential clinical significance*. The scale runs from zero to ten, where zero should be given to a case which will have no effects on the patient, and ten should be given to a case that would result in death. Mark the scale clearly by either circling the appropriate number or placing a mark on the scale anywhere between the numbers. Please assess the cases based on the information available, but feel free to look up any information you need in the BNF or elsewhere.

001.	Methotrexate 2.5mg, ten tablets weekly, prescribed to a patient in June 2009. Liver function tests and full blood counts have been done regularly (every three months), but urea and electrolytes done less often than 6-monthly.	
002.	Furosemide 40mg prescribed to patient. Urea and electrolytes (U+E) were checked the same day as the treatment was started, but no further monitoring of U+E after two weeks.	
003.	Sofradex® (dexamethasone, framycetin sulphate, gramicidin) prescribed to 12-year old patient with dosage instructions 'two drops TDS (three times a day)'. Sofradex can be used as eyedrops as well as eardrops, the route was not specified on the prescription.	
004.	Letters from epilepsy review clinic state total dose of lamotrigine should be 375mg daily. The current dose prescribed is 175mg in the morning and 275mg at night, giving a total dose of 450mg daily.	
005.	Simvastatin prescribed to patient to be taken daily rather than at night.	

Appendix 9: Quantitative analysis plan

PREvalence And Causes of prescribing errors in general practiCE (PRACtiCE study) – Analysis plan for the quantitative output of the study

The aim of this study is to determine the prevalence and nature of prescribing errors in general practice. This analysis plan will describe in detail, the steps that are going to be taken to achieve the quantitative study objectives.

Description of general practices;

The PRACtiCE study is being carried out in three Primary Care Trusts (PCTs) – one in Nottinghamshire, one in City and Hackney, London, and one in Luton. Information on the characteristics of these practices will be obtained from the practices themselves or extracted from online resources and summarised in tabular form. The following characteristics will be compared informally between the practices and the average for practices in England (wherever national figures are available):

- List size (e.g. median, interquartile range)
- Number of GPs (e.g. median, interquartile range)
- Percentage of practice population aged ≥ 75 years (e.g. median, interquartile range)
- Training status (percentage)
- Deprivation using Index of Multiple Deprivation 2004 score (median and interquartile range)
- QoF medicines management points (median, interquartile range)
- QoF total points (median, interquartile range)

Description of patients

A 2% random sample of all patients will be obtained from each practice. For each practice and for the total data sample, the following characteristics will be summarised in tabular form and compared among practices and with figures for England (where available e.g. from 2001 census):

- Total number of patients in the study (and total number from each practice)
- Percentage of patients from each practice contributing to the overall study population (this is to check that 2% sample obtained)
- Age (median, IQR)
- Age distribution (median percentage in each of the following age groups: 0-14, 15-64, 65-74, 75 and over)

- Gender (percentage male/female)
- Months registered with the practice during the 12 months of the study (median, IQR and total patient months)

Description of prescribed drugs

Information provided on prescribed drugs will be obtained from study Form 1 (prescribing record sheet). Drugs will be classified on the basis of British National Formulary (BNF) chapters and subchapters. We will calculate and present the following:

- Total number of drugs reviewed
- Median (and interquartile range) drugs per patient
- Total number (and percentage) of drugs on the monitoring list
- Total numbers (and percentages) of acute and repeat items
- Median (and interquartile range) acute and repeat items per patient
- The top twenty classes of drugs prescribed
- The top twenty drugs prescribed
- The form of the medications (numbers and percentages from the total in terms of tablets, capsules etc.)
- Number of “possible prescribing errors”
- Number and proportion of drugs with at least one “possible prescribing error”
- “Possible prescribing error” rate per 100 drugs
- Number of “possible monitoring errors”
- Number and proportion of drugs with at least one “possible monitoring error”
- “Possible monitoring error” rate per 100 drugs

Description of types of prescribers

The following characteristics will be summarised for the overall study population and by practice in tabular form:

- Nature of prescribers (e.g. GP partner, salaried GP, locum, GP in training, non-medical prescriber etc.)
- Acute to repeat prescribing ratio per type of prescriber
- Number (and percentage) of drugs per type of prescriber
- “Possible prescription error” rate for different types of prescriber
- “Possible monitoring error” rate for different types of prescriber

Description of types of errors

The following will be determined based on data from the Forms 2s that have been completed by pharmacists for drugs where there has been a possible error:

- Numbers and percentages of “possible errors” assigned to the following categories (for all possible errors, and those involving either acute prescriptions or repeat prescriptions):
 - Prescribing error
 - Monitoring error
 - Sub-optimal prescribing
 - Legal error
 - Not an error
- The top twenty classes of drug prescribed associated with prescribing errors
- The top twenty classes of drug prescribed associated with monitoring errors
- The top twenty classes of drug prescribed associated with sub-optimal prescribing
- The top twenty drugs associated with prescribing errors
- The top twenty drugs associated with monitoring errors
- The top twenty drugs associated with sub-optimal prescribing
- The form of the medications (numbers and percentages from the total in terms of tablets, capsules etc.) associated with prescribing errors, monitoring errors and sub-optimal prescribing
- Numbers and percentages of each type of prescribing error (See Form 2 for classification)
- Numbers and percentages of each type of monitoring error (See Form 2 for classification)
- Numbers and percentages of each type of suboptimal prescribing (See Form 2 for classification)
- Numbers and percentages of each type of legal error
- Number and prevalence of different types of prescribing and monitoring errors for acute and repeat prescriptions.
- For categories of error that are most common the top 10 classes of drug associated with these errors
- For categories of error that are most common the top 10 drugs associated with these errors
- For categories of error that are most common the numbers and percentages associated with each type of formulation

Estimation of relative risk of prescribing error in primary care

Logistic regression techniques will be used to model the relationships between the risk of medication errors (a combination of prescribing errors and monitoring errors) and selected predictor variables and apriori confounders. The principle outcome variable will be a dichotomous level dependent variable of medication errors versus no medication problems (this, therefore, excludes the suboptimal and legal problem categories). We may also undertake an analysis of suboptimal prescribing versus no medication problems. Predictor variables that we will consider modelling will include:

Patient characteristics

- Age of patient
- Gender of patient
- Number of drugs per patient

Practice and prescriber characteristics

- The practice
- Type of prescriber (GP partner, salaried GP, locum GP, GP in training, etc)
- The computer system used by the practice
- Whether the practice was involved in GP training or not
- Whether the practice was a dispensing practice or not
- Index of Multiple deprivation 2004 score
- QoF points for medicines management
- Overall QoF points

Prescriptions characteristics

- Type of prescription (repeat or acute)
- Category of drug (e.g. BNF chapter)
- Formulation of drug

Initially, the risk of medication error will be fitted against each predictor variable and apriori confounder in several univariate models. Likelihood ratio tests will be used to select the most significant factors. A parsimonious model will then be fitted using multivariate logistic regression. Odds ratios and 95% confidence intervals for the adjusted risk of prescribing error will be reported in tabular form.

Appendix 10: Participants for face-to-face interviews letter and information sheet.

Part B) Interviews with GPs and Practice staff (Draft version 3.0/Final version 1.0: 8 March 2010)

University Letterhead
Practice
Address

Date

The PRACTICE study

Dear *Title Name*

We are writing to ask if you would be willing to participate in an interview to explore the reasons why prescribing errors occur in general practice. This is part of a research project that has been funded by the General Medical Council as part of their work on Patient Safety. They would like to know the prevalence and causes of prescribing errors in general practice

Previous research on medication errors has shown that patients are exposed to risk from hazardous prescribing or inadequate therapeutic monitoring in general practice. However, it is not clear how often prescribing errors occur and what are the underlying causes

In the PRACTICE study we are interested to investigate the prevalence and causes of prescribing errors in general practice. This is important to establish strategies for their prevention. The Study is being conducted by the Universities of Nottingham, Hertfordshire, Reading and the London School of Pharmacy. The study has been granted ethical approval by xxxxxxxxxx and organisational approval by xxxxxxxxxx.

Please find enclosed an information sheet which explains the background to the study and what the interview will involve. Please read the information sheet. If you are willing to be interviewed you will be asked to sign a consent form by the PCT pharmacist who will be undertaking the project in your practice.

Yours sincerely

Professor Tony Avery
Chief Investigator

Dr Maisoon Ghaleb
Study Co-ordinator

Practice Information Sheet for potential interviewees
(Draft version 3.0/Final version 1.0: 8 March 2010)

The PRACTICE Study
"Investigating the prevalence and causes of prescribing errors in general practice"

Invitation to take part

You are being invited to take part in the above study, however before you decide to take part, it is important to understand why this research and what it involves. The information sheet provides you with a brief explanation of what will happen during the study and will provide you information on all aspects that the study will cover. Please take the time to read the information provided and feel free to ask questions and discuss it with other practice members. Please take your time and decide whether or not you would like to be a part of this study.

Thank you for taking the time to read this leaflet.

What is the Purpose of the study?

The aim of this study is to explore the prevalence and causes of prescribing errors in general practice.

Why have I been chosen?

You have been chosen because your Primary Care Trust (PCT) and practice agreed to take part in the study. The first part of the study has involved the detection of prescription errors in a random sample of patients in the practice. Where clinically important errors have been detected, we wish to interview those involved in the care of the patient. You have been chosen because you may be able to provide useful insights to help us better understand the causes of errors.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time, and without giving a reason. If you decide not to take part, or to withdraw from the study at a future date, this will not affect the standard of care you receive.

What will happen if I decide to take part?

We would like you to take part in a 20-30 minute interview to explore the causes of prescribing errors in your practice, either face-to-face or by telephone, depending on your availability and which method you would prefer. The interview will be conducted by the PCT pharmacist and will be conducted at a venue of your choice, for example a consulting room, or wherever would be most convenient for you. We would like to make an audio-tape of the interview, or we can just take detailed notes if you would prefer. We will ask you not to divulge any patient identifiable information during the interview. You can ask the researcher to stop the interview at any time if you no longer wish to participate.

Recordings and notes will be stored on password-protected computers with access only to research personnel.

We will offer you the opportunity to check our notes or the interview transcript, after the interview, to identify any errors on our part, and to inform us of any sections that you do not wish to be used as direct quotes in our final report. If you would like to do this, we will need to keep a temporary record of your identity, but this record will be destroyed once you have approved the notes or transcript.

Should the PCT pharmacist be made aware of an error that resulted in significant patient harm, or was potentially the result of a serious breach of practice, they will ask you whether the error has been reported on the PCT's incident reporting system. If the error has not yet been reported, then the interviewer will liaise with the local study co-ordinator to ensure that the error is reported, according to local incident reporting procedures (n.b. these reporting procedures have been set up principally to help the NHS to learn from errors).

What are the possible disadvantages and risks of taking part?

The interviews will focus on the causes of prescribing errors. We understand that this is a potentially sensitive topic. However, we will take care to conduct the interviews in a sensitive manner. Although we may directly quote your words, you will not be identifiable from those words.

What are the possible benefits of taking part?

The benefit to staff and their organisations will be a better understanding of the causes of prescribing errors. This will hopefully lead to improved quality of care and may also have benefits in improving the system and making it safer for patients.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your question (Professor Tony Avery – Division of Primary Care, Nottingham University Medical School, contact number 0115 8230209; Dr Maisoon Ghaleb – School of Pharmacy, University of Hertfordshire, Contact number 01707 285087). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure. Details can be obtained from the Trust.

Will my taking part in this study be kept confidential?

Your taking part in the study may be known by some other members of your practice, for example if your name was suggested by someone who helped us identify potential participants. However any information which is collected, or any comments or opinions expressed by you during the course of the research, will be strictly confidential, and will not be attributable to you.

What will happen to the results of the research study?

We will present the key findings at meetings of the participating sites, as well as preparing written summaries for dissemination to staff. Our findings will be published in peer-reviewed journals and presented at relevant conferences, as well as being included in a final report to the General Medical Council.

Who is organising and funding the research?

The research is organised by the Division of Primary Care, University of Nottingham in collaboration with the schools of Pharmacy in universities of Hertfordshire and Reading as well as the London School of Pharmacy, University of London.

The research is funded by the General Medical Council. The official name for the study is the "PRACtICE study".

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nottingham REC 2 Research Ethics Committee.

Contact for further information

If you wish to ask any questions about this study before deciding to take part, please contact one of the following people, who will be pleased to help you:

PRACtICE Study Co-ordinator:

Dr Maisoon Ghaleb, School of Pharmacy, University of Hertfordshire, College Lane campus, Hatfield AL10 9AB. Tel: 01707285087; Fax: 01707284506, e-mail: m.ghaleb@herts.ac.uk

Chief Investigator:

Professor Tony Avery, Head of Division of Primary Care, School of Community Health Sciences, University of Nottingham Medical School, Nottingham, NG7 2UH.
Tel 0115 8230209; Fax: 0115 8230214; email: tony.avery@nottingham.ac.uk.

If you agree to take part in this study, you will be given a copy of the Practice Information Sheet and a signed consent form to keep.

Thank you for considering taking part in this study

Appendix 11: Participants for focus group letter and information sheet

Part C) Focus groups with GPs and Practice staff

(Draft version 3.0/Final version 1.0: 8 March 2010)

University Letterhead
Practice
Address

Date

The PRACTICE study

Dear Title Name

We are writing to ask if you would be willing to participate in a focus group to explore the reasons why prescribing errors occur in general practice. This is part of a research project that has been funded by the General Medical Council as part of their work on Patient Safety. They would like to know the prevalence and causes of prescribing errors in general practice

Previous research on medication errors has shown that patients are exposed to risk from hazardous prescribing or inadequate therapeutic monitoring in general practice. However, it is not clear how often prescribing errors occur and what are the underlying causes

In the PRACTICE study we are interested to know systems in general practice for reporting prescribing errors. The Study is being conducted by the Universities of Nottingham, Hertfordshire, Reading and the London School of Pharmacy. The study has been granted ethical approval by xxxxxxxxxx and organisational approval by xxxxxxxxxx.

Please find enclosed an information sheet which explains the background to the study and what the focus group will involve. Please read the information sheet. If you are willing to be part of the focus group, you will be asked to sign a consent form by the PCT pharmacist who will be undertaking the project in your practice.

Yours sincerely

Professor Tony Avery
Chief Investigator

Dr Maisoon Ghaleb
Study Co-ordinator

Practice information Sheet for potential practice participants in focus groups

The PRACTICE Study ***"Investigating the prevalence and causes of prescribing errors in general practice"***

Invitation to take part

You are being invited to take part in the above study, however before you decide to take part, it is important to understand why this research and what it involves. The information sheet provides you with a brief explanation of what will happen during the study and will provide you information on all aspects that the study will cover. Please take the time to read the information provided and feel free to ask questions and discuss it with other practice members. Please take your time and decide whether or not you would like to be a part of this study.

Thank you for taking the time to read this leaflet.

What is the purpose of the study?

The main aim of this study is to estimate prevalence and causes of errors in general practice.

Why have I been chosen?

You have been chosen because your Primary Care Trust (PCT) and practice agreed to take part in the study. The first part of the study has involved the detection of prescription errors in a random sample of patients in the practice. We wish to conduct a focus group with those involved in the care of the patient. You have been chosen because you may be able to provide useful insights to help us better understand the causes of errors, and systems in primary care to prevent patient harm.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time, and without giving a reason. If you decide not to take part, or to withdraw from the study at a future date, this will not affect the standard of care you receive.

What will happen if I decide to take part?

We would like you to take part in a 60-70 minute focus group to explore the systems in general practice for reporting prescribing errors and the formal and informal safeguards that exist to prevent patient harm. You will be part of 6 -10 group members. This will be conducted at a venue that is convenient to you, for example a room within your practice. We would like to make an audio-tape of the focus group or we can just take detailed notes if you would prefer. We will ask you not to divulge any patient identifiable information during the focus group. You can ask the researcher to stop the focus group at any time if you no longer wish to participate.

Recordings and notes will be stored on password-protected computers with access only to research personnel.

We will offer you the opportunity to check our notes or focus group transcript, after the focus group, to identify any errors on our part, and to inform us of any sections that you

do not wish to be used as direct quotes in our final report. If you would like to do this, we will need to keep a temporary record of your identity, but this record will be destroyed once you have approved the notes or transcript.

Should the researcher be made aware of an error that resulted in significant patient harm, or was potentially the result of a serious breach of practice, they will ask you whether the error has been reported on the PCT's incident reporting system. If the error has not yet been reported, then the researcher will liaise with the local study co-ordinator to ensure that the error is reported, according to local incident reporting procedures (n.b. these reporting procedures have been set up principally to help the NHS to learn from errors).

What are the possible disadvantages and risks of taking part?

The focus group will focus on systems in general practice to prevent patient harm. We understand that this is a potentially sensitive topic. However, we will take care to conduct the interviews in a sensitive manner. Although we may directly quote your words, you will not be identifiable from those words.

What are the possible benefits of taking part?

The benefit to staff and their organisations will be a better understanding of the systems and safeguards to prevent prescribing errors. This will hopefully lead to improved quality of care and may also have benefits in improving the system and making it safer for patients.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your question (Professor Tony Avery – Division of Primary Care, Nottingham University Medical School, contact number 01158230209; Dr Maisoon Ghaleb – School of Pharmacy, University of Hertfordshire, Contact number 01707285087). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure. Details can be obtained from the Trust.

Will my taking part in this study be kept confidential?

Your taking part in the study may be known by some other members of your Trust, for example if your name was suggested by someone who helped us identify potential participants. However any information which is collected, or any comments or opinions expressed by you during the course of the research, will be strictly confidential, and will not be attributable to you.

What will happen to the results of the research study?

We will present the key findings at meetings of the participating sites, as well as preparing written summaries for dissemination to staff. Our findings will be published in peer-reviewed journals and presented at relevant conferences, as well as being included in a final report to the General Medical Council.

Who is organising and funding the research?

The research is organised by the Division of Primary Care, University of Nottingham in collaboration with the schools of Pharmacy in universities of Hertfordshire and Reading as well as the London School of Pharmacy, University of London.

The research is funded by the General Medical Council. The official name for the study is the "PRACtICE study"

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nottingham REC 2 Research Ethics Committee.

Contact for further information

If you wish to ask any questions about this study before deciding to take part, please contact one of the following people, who would be pleased to help you:

PRACtICE study Co-ordinator: Dr Maisoon Ghaleb, School of Pharmacy, University of Hertfordshire, College Lane campus, Hatfield AL10 9AB. Tel: 01707285087; Fax: 01707284506, e-mail: m.ghaleb@herts.ac.uk or Chief investigator: professor Tony Avery, Head of Division of Primary Care, School of Community Health Sciences, University of Nottingham Medical School, Nottingham, NG7 2UH.

Tel 0115 8230209; Fax: 0115 8230214; email: tony.avery@nottingham.ac.uk

If you agree to take part in this study, you will be given a copy of the Practice Information Sheet and a signed consent form to keep.

Thank you for considering taking part in this study

Appendix 12: GP and Practice Staff interview schedule

PRACTICE Study

EXPLORING THE CAUSES OF PRESCRIBING AND MONITORING ERRORS: GP and practice staff interview schedule

DATE _____ INTERVIEW REFERENCE NUMBER _____
INTERVIEWER _____ CONSENT FORM SIGNED _____
PROFESSION OF INTERVIEWEE _____

INTRODUCTION

Please introduce the interview as follows:

"All prescribers, being human, are prone to making errors, and many factors can contribute to increasing the risk of error. As you are aware, we are carrying out a study to find out the prevalence and nature of prescribing errors in general practice.

The main purpose of the interview is to understand why prescribing errors occur to help identify strategies for preventing them in the future. The interview should take around 20-30 minutes.

The definition we are using of a prescribing error is as follows:

'A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant:

- (1) reduction in the probability of treatment being timely and effective or
 - (2) increase in the risk of harm
- when compared with generally accepted practice'.

This definition is used by the National Patient Safety Agency, the Department of Health and many researchers.

In addition, we are using the following definition for monitoring errors:

'A monitoring error occurs when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. It includes the absence of tests being carried out at the frequency listed in the criteria, with tolerance of +50%. This means for example, that if a drug requires liver function tests at 6 monthly intervals, we would class as an error if a test has not been conducted within 9 months. If a patient refused to give consent for a test, then this would not constitute an error'.

Your participation is entirely voluntary and you are free to withdraw at any point. If you do not wish to answer any particular questions, then please say so. There are no right or wrong answers and I am interested in your own personal point of view.

The identities of all participants will remain strictly confidential and it will not be possible to identify individual patients, members of staff or clinical teams from the findings.

I will start off by asking some general questions about yourself and will then give you details of the possible prescribing [or monitoring] error. You will then have the opportunity to give me your views on the possible error, including whether or not you think it was an error. I will then ask some further questions to explore other possible contributing factors to prescribing and monitoring errors. There will also be opportunity for you to tell us about the strategies that you think are important in preventing error.

Would you mind if I audio-record our conversation so that I do not have to write everything down? If so, I would ask that you do not give the names of any patients, health care professionals or places during the course of the interview. For example, you might refer to "the patient", "another GP in the practice", "the local hospital" or "our surgery" rather than giving specific names.

Do you have any questions before we begin?"

BACKGROUND

"Can you tell me a bit of background about yourself?"

This will include:

- 1) Which medical school did you go to? (n.b. adjust questions if the prescriber is from a different profession such as nursing or pharmacy)
- 2) When did you qualify as a doctor?
- 3) Where did you do your GP training?
- 4) What education and training have you had in therapeutics and practical aspects of prescribing as either an undergraduate or postgraduate?
- 5) Do you have any particular clinical interest or speciality within your work as a GP?
- 6) How many years have you worked as a GP?
- 7) How many years have you worked in this Practice?
- 8) How many sessions a week you work in the Practice? (n.b. a session usually equates to half a day)
- 9) How would you describe your role within the Practice? e.g. GP partner, salaried GP, locum, etc.

[Add other background questions as needed – the main aim here is to put the interviewee at ease]

THE CASE (and discussion of factors relating to the causes of, and prevention of, prescribing and monitoring errors in general practice)

"While reviewing patient case notes, I came up across this event:

[Mention the following: On (date) you prescribed (drug) for (patient), then give details of the event, and the (possible) involvement of the interviewee in the event]

This meets our definition of a possible prescribing [or monitoring] error".

- 1) What you think about it?

[if prompts needed, explore interviewee's views on:

- Whether or not they think it is an error
 - Would you regard this as an error? If so, why? If not, why not?
- Their views on the risk to the patient

- o What do you think are the risks to the patient, if any, from this pattern of prescribing?]

2) What can you remember about this event? (if they cannot remember anything, go to question 4, otherwise try to explore things further. In particular, using open questions, *try to elicit the prescriber's story of how the event occurred*).

3) I am going to ask you some specific questions in a moment, but what factors do you think may have contributed to this event? (n.b. although we have a number of specific prompts below, try to encourage the prescriber to give a detailed account of their views of the contributing factors)

4) Thinking about this event in particular, and prescribing and monitoring errors in general, please let me know your views on how important you think the following factors are (if not mentioned already):

- a) **Patient characteristics** (prompt: What factors relating to the patient contribute to errors, such as seriousness and complexity of their condition(s), communication challenges and personal and social factors?)
- b) **Your knowledge of the patient** (prompt: does familiarity with the patient make errors more or less likely?)
- c) **Your therapeutic knowledge and prescribing skills** (prompts: How familiar are you with the drug(s) identified in the above scenario? Does experience of prescribing particular drugs make errors more or less likely? How do you feel about your knowledge of therapeutics and skills in prescribing?)
- d) **Use of information sources and technology** (prompt: What information do you use to help guide your prescribing and how useful is this in preventing error? To what extent does the use of your computer system either help prevent errors or cause them?)
- e) **Task factors** (prompt: Is there anything about the way in which prescribing tasks are organised and structured in your practice that might lead to increased risk of errors? Examples might include: availability of information on the patient and the drug at the point of decision making, competing priorities for time during consultations, interruptions, lack of protocols (or lack of use of these) for safe prescribing (including repeat prescribing) and/or medication monitoring).
- f) **Your working environment** (prompt: What do you think of the working environment within the surgery? To what extent (and how) does it contribute to the occurrences of (or prevention of) prescribing and monitoring errors? *n.b. possible factors include staffing levels and skills mix, workload and shift patterns, design, availability, and maintenance of equipment, administrative and managerial support*)
- g) **Team factors** (prompt: What do you think of the teamwork within the surgery? To what extent do teamwork, team structures and communication contribute to prescribing or monitoring errors, or prevent them from happening? *n.b. possible related factors include verbal communication, written communication, supervision and seeking help*)
- h) **Organisational and management factors** (prompt: To what extent do you think the organisation and management within the practice (or PCT) contributes to prescribing or monitoring errors, or helps to prevent them? What do you think of the safety culture within the practice? *n.b. possible related factors include financial resources and constraints, organisational structure, policy standards, goals, and priorities*)

- i) **Individual factors** (prompts: are there any personal strategies you have for helping to prevent medication errors? Conversely, do you feel there are sometimes individual factors that put you (or other prescribers) at increased risk of making a prescribing or monitoring error?)
 - j) Are there any **other factors** that you think may be important in causing or preventing prescribing or monitoring errors?
- 5) Overall, what do you think are the most important causes of prescribing and monitoring errors in general practice?
- 6) Overall, what you think are the most important strategies for preventing prescribing and monitoring errors in general practice?
- 7) If not mentioned already, are there any safeguards in your practice that you think are particularly important in preventing prescribing or monitoring errors?
- 8) Is there anything you wish to add?

CLOSING THE INTERVIEW

"Thank you very much for your time and for being willing to talk to me. Your comments have been very helpful and will be used together with those of the other participants to gain an understanding of why prescribing errors occur from the prescribers' point of view. The identities of all individuals will, however, remain strictly confidential".

"If you would like to see a copy of the transcript from the interview we can arrange to send this to you and the research team will welcome any comments you wish to make on it".

[If interviewee wishes to see a copy of the transcript, confirm plans for sending this to them and for getting feedback – n.b. this process will need to be handled by the pharmacist so that the identities of interviewees is not revealed to members of the research team].

Appendix 13: Topic Guide for Focus Groups

PRACTICE Study **Topic guide for focus groups**

5 Minutes: introduction, welcome from organiser & ground rules

- The purpose of the group today is to discuss your experience/opinion on prescribing errors in general practice.
- What you say is confidential and whatever views you express will be anonymised so that no one outside of this room will know who has said what.
- You should therefore treat information and views expressed in this room as confidential
- Please feel free to say what you want and feel free to discuss comments or add your own experiences
- Please allow others to have their say (even if you disagree)
- With your consent the discussions will be recorded so that we can analyse them later, but the data will be anonymised
- It's not so much a question and answer session as a forum for discussion
- I may need to stop a discussion if going over time in order to get all topics discussed

10 Minutes: Group Introduction

Researcher and participants (Names and Professions)

Record names/positions

State the three topics to keep the structure of the discussion:

- Safeguards in general practice to protect patient against potential harm
- Reporting prescribing errors in general practice
- Practice safety culture

15 Minutes

TOPIC 1: Safeguards in general practice to protect patient against potential harm

What are the safeguards whether formal or informal that exists in GP practice that protects patients against potential harm from prescribing errors?

15 Minutes

TOPIC 2: Reporting prescribing errors in general practice

What are the systems if any that exist in general practice to report prescribing errors and learning from them?

15 Minutes

TOPIC 3: Practice Safety Culture

What is the practice safety culture and what is unique to the culture that might have an impact on prescribing error rates and incident reporting?

5 Minutes: CLOSURE

All know what I am trying to do - anything else to add?