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Evaluation of community pharmacy electronic patient medication record systems' functionality focusing on safety features and alerts

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Abstract

Studies on electronic patient medication record (ePMR) systems that are used in community pharmacy in England have focused primarily on the ability of these systems to highlight potentially hazardous co-prescriptions and prevent clinical hazards and harm to patients. As such, there is a scarcity of literature on the use of ePMR systems, other safety functionality of the systems and user responses to alerts. This thesis aims to fill this gap by examining the functionality of ePMR systems used in community pharmacy in England, focusing on safety features and alerts.

This research was conducted in England between July 2010 and July 2013. Evidence for the effectiveness of safety features and alerts in ePMR systems during the dispensing process was evaluated through a systematic review of the literature. Stakeholder perspectives of ePMR systems' functionality were then obtained through qualitative interviews. The performance of ePMR systems licensed for the electronic prescription service (release 2) in the community pharmacy setting were then assessed using a simulated observational testing approach. Ethnographically informed observations in community pharmacies were subsequently used to study how community pharmacy professionals use ePMR systems and manage alerts in practice.

The systematic review included five studies - three randomised controlled trials and two before-after studies, with drug-drug interaction (1), drug-laboratory (2), drug-pregnancy (1) and drug-age (1) alerts. The review revealed that ePMR systems in conjunction with embedded safety features are effective in picking up clinical hazards at the point of dispensing. However, there are problems of false alerts and inconsistencies in alert management. Empirical findings indicate that there are significant issues with the way ePMR systems and alerts are designed and used. Thirty participants took part in the qualitative interviews - community pharmacy professionals (13), health care policy makers (5), legal practitioners specialising in pharmacy (3), ePMR systems' software vendors (4) and ePMR systems' software

knowledgebase creators (5). Participants attributed alert ineffectiveness in community pharmacy practice to factors such as lack of harmonisation of alert severity levels in systems, poor alert design, over-presentation of alerts and absence of management advice in alerts. Five unique ePMR systems were evaluated in eight participating pharmacies with a sixth ePMR system assessed in a demonstration setting. The systems' performance was variable and sub-optimal. The ethnographically informed observations took place in the eight pharmacies where system assessment was conducted. The observations revealed that the current design of ePMR systems and presentation of alerts are limiting the quality of support provided to pharmacists and their support staff.

This research is part of a growing body of work on the functionality of ePMR systems, their safety features and alerts indicating that ePMR systems require improvements if they are to effectively support patient safety and consistently deliver better patient outcomes. The findings highlight the need to incorporate patient context into alerting to increase alert relevance. In addition, system vendors need to make use of the evidence in the literature to design effective ePMR systems, alerts and user interfaces.

An authoritative body should set the minimum specifications for ePMR systems and alerts, and identify the critical alerts that pharmacy professionals should evaluate at the point of dispensing. Additionally, training of pharmacy professionals in health information and communication technology is required to improve patient safety. This should cover areas such as informatics, human factors, safety culture, clinical decision-making, alert management, risk management and communication.

Many of the findings are likely to be relevant to similar medication record systems in ambulatory pharmacies around the world; however, further work is required to understand fully the extent of the issues identified in this research.

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Ojeleye, O., Avery, A. & Boyd, M. (2013). Safety features and alerts in electronic patient medication record systems used in community pharmacy in england: An exploratory study. *Studies in health technology and informatics.* MEDINFO 2013. The Netherlands: IOS Press.
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Presented at the Society of Academic Primary Care (SAPC) 2013 conference, Nottingham, UK, 3-5 July 2013

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Abbreviations

ACE	Angiotensin Converting Enzyme
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AHRQ	Agency for Healthcare Research and Quality
BNF	British National Formulary
CI	Confidence Interval
COC	Combined Oral Contraceptive
CPD	Continuing Professional Development
CPOE	Computerised Physician Order Entry
CUI	Common User Interface
DM+D	Dictionary of Medicines and Devices
DUR	Drug Utilisation Review
EPMR	Electronic Patient Medication Record
EPS	Electronic Prescription Service
ETP	Electronic Transfer of Prescriptions
FDA	Food and Drug Administration
GP	General Practitioner
GPhC	General Pharmaceutical Council
HIT	Health Information Technology
IG	Information Governance
IT	Information Technology
MHRA	Medicines and Healthcare Products Regulatory Agency
MUP	Medication Use Process
MUR	Medication Use Review
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NHS	National Health Service
NPSA	National Patient Safety Agency

NRLS	National Reporting and Learning System
PCSQ	Pharmacy Safety Climate Questionnaire
PCT	Primary Care Trust
PINCER	Pharmacist-led Information Technology Intervention for Medication Errors
PMR	Patient Medication Record
POE	Pharmacy Order Entry
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSNC	Pharmaceutical Services Negotiating Committee
RCT	Randomised Controlled Trial
SLS	Selected List Scheme
SNOMED	Systematised Nomenclature of Medicine – Clinical Terms
SOP	Standard Operating Procedure
SPC	Summary of Product Characteristics
UK	United Kingdom
US	United States of America

Chapter 1

Background to the research

1.1 Introduction

The National Health Service (NHS) modernisation plan is based on 10 core values collectively known as '*The NHS Principles*' (Department of Health, 2000a). The fifth principle states that, "The NHS will work continuously to improve quality services and to minimise errors." It suggests that health care providers will work to make health care safer and support a culture where everyone can learn from and effectively reduce mistakes (Department of Health, 2000a). The role of pharmacy and how pharmacy can help to deliver the vision of an improved NHS is set out in the document titled, 'Pharmacy in the Future – Implementing the NHS Plan.' The goal is to increase the use of technologies such as electronic prescribing, to make patient and consumer access to health care more convenient and safer (Department of Health, 2000c). Additionally, to create a health service where patients and pharmacy patrons benefit from increased opportunities that pharmacists have in making use of information technology to support their practice (Department of Health, 2000c). A NHS that offers people "fast and convenient care, available when required, tailored to their individual needs and delivered to a consistently high standard" (Department of Health, 2000c).

Pharmacists help patients, pharmacy patrons and consumers to make informed choices and best use of medicines, including using their knowledge and expertise to ensure that patients are protected from avoidable clinical hazards, errors and harm related to medications (Avery et al., 2012a; Kelly, 2012). They are well-placed to help deliver the NHS's goal of preventing or reducing the occurrence of medication errors

(Department of Health, 2004). Towards achieving this goal and central to community pharmacy operation in England, is the electronic patient medication record (ePMR) system (please see appendix A.1 for the list of system suppliers in England). These systems have many uses including recording details of dispensed prescriptions and preventing clinical hazards from medicines and harmful co-prescriptions. The literature is sparse on the safety functionality of ePMR systems that are used in community pharmacy when compared with studies that have been published on electronic prescribing systems in primary and secondary care in England. Available studies on ePMR systems' safety functionality date back to the 1990s and have focused mainly on the ability of the systems to highlight potentially hazardous drug interactions and some other clinical hazards (Rogers et al., 1994; Stevens and Balon, 1997).

The next section in this chapter indicates how this research fills gaps in the body of knowledge about ePMR systems whilst the third section describes the organisation of the thesis. The fourth section provides some working definitions as used in this thesis and the fifth section provides the context for this study against the background of medication use process (MUP) in primary care in England. The sixth section focuses on medication errors in primary care and community pharmacy in England. It carries out an examination of the sources of errors in community pharmacy, the cost of errors; the Swiss cheese model of error causation, the models of errors and error management, and human factors approach to medication safety. The seventh section of the chapter focuses on the defences employed at the point of dispensing with an overview of some of the methods employed to prevent medication errors at the point of dispensing in community pharmacies. The eighth section reviews designs for effective alerts based on the human factors principle. The concluding section of the chapter provides a summary of the main themes of the research and thesis.

1.2 Research purpose

The overall purpose of this research was to explore, describe, explain and understand, ePMR systems' functionality focusing on safety features and alerts, including alert management practices in community pharmacy in England. The focus was on England because the systems are not congruent across the other constituent countries of the United Kingdom (UK), namely Northern Ireland, Scotland and Wales.

The literature on ePMR systems, their safety features and alerts in England is sparse. There is no clear evidence that ePMR systems are effective in highlighting and preventing clinical hazards and errors at the point of pharmacy order entry (POE). To date, there is little research focusing on the functionality of ePMR systems in community pharmacy in England, how the systems are used in community pharmacy practice and how users manage alerts. There are currently no common information technology (IT) specifications for these systems in England. Additionally, there is no coordinated, formal monitoring or evaluation of the systems' ability to prevent or reduce errors and harm to patients. Furthermore, data are sparse on the role and performance of safety features of ePMR systems in stemming error rates at the point of dispensing in community pharmacy in England. The impact and influence on pharmacy professionals' practice is also unknown.

The perceptions of stakeholders including users of the systems regarding areas where improvements are needed and the type of improvements required are relatively unknown. The level of performance of ePMR systems in their current state of maturity is also unclear. With increased emphasis on the role of IT systems such as the electronic transfer of prescriptions within and outside the NHS (National Audit Office, 2006), it is important to understand how ePMR systems are used and their impact on community pharmacy practice.

1.3 Thesis aims and organisation

This research seeks to explore the issues identified in section 1.2 and to pave the way for understanding the impact of ePMR systems, their safety features and alerts on community pharmacy practice.

Figure 1.1 below illustrates the organisation of this thesis.

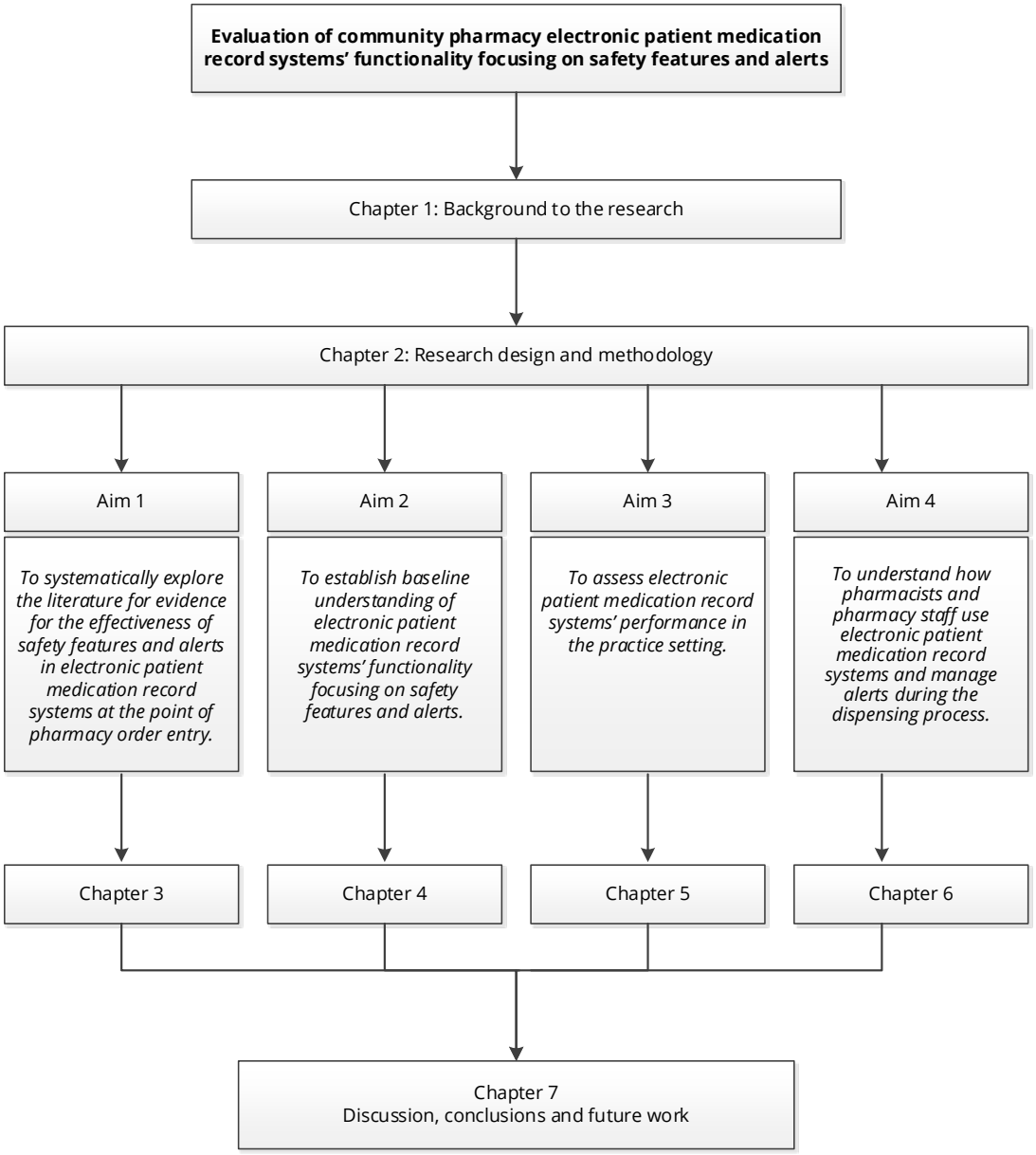


Figure 1.1. Organisation of this thesis

To address the four aims illustrated in Figure 1.1, a mixed-methods approach comprising of a systematic review of the literature, participant interviews and observations was employed. The research explores problems that users encounter in practice, and potential facilitators and inhibitors of safety alerts' usefulness, to identify opportunities to intervene appropriately. In doing so, the research presented in this thesis contributes to existing knowledge and understanding of the functionality of ePMR systems, focusing on safety features and alerts.

1.4 Definitions

Research

The use of the word 'research' in this thesis refers to the systematic investigation into and study of ePMR systems, focusing on their safety features and alerts. It is the sum total of the work undertaken to understand the research problem and provide answers to the research questions.

Study

The word *'study'* in this thesis refers to the individual, detailed investigations and analysis conducted to address a particular research question. The various studies are presented in chapters 3, 4, 5 and 6.

Patient medication record

The term '*patient medication record*' denotes a record of medications dispensed to an individual, which is derived solely in the pharmacy. It relates to the record of prescriptions dispensed to an individual within that pharmacy. This term applies specifically to ePMR systems used for dispensing medications and various other functions related to pharmaceutical care services.

Computerised prescriber order entry

Computerised prescriber order entry (CPOE) is the process of entering medication orders or other physician instructions electronically into clinical computer systems by using text boxes and drop-down menus rather than handwriting notes (Dixon and Zafar, 2009). When prescribing medications electronically (electronic prescribing), physicians and clinicians may be alerted to clinical hazards and medication errors

such as particular patient's drug allergies and current medications. Electronic patient medication record (ePMR) systems are used for processing medication orders presented on paper-based prescriptions issued by clinicians for dispensing and prescriptions received electronically directly from CPOE or electronic prescribing systems. These ePMR systems are also equipped with integrated safety features, which provide alerts about clinical hazards and errors during the dispensing process. Irrespective of the foregoing differences, there are liabilities both clinically and legally at the relevant stages of the MUP. The term Computerised Prescriber Order Entry (CPOE) in this thesis is synonymous with electronic prescribing.

Pharmacy order entry

In this thesis, the process of entering prescription information into the ePMR system manually or electronically during the dispensing process in community pharmacy practice is referred to as '*pharmacy order entry.*' Additionally, wherever the term '*user*' appears in this thesis, it is with reference to all those who use ePMR systems in community pharmacy practice.

Safety feature

The meaning of a *'safety feature'* depends on the domain of examination. For the purpose of this research, a safety feature is defined as, "*an integrated feature of an ePMR system that generates patient-specific advice or alert about potential and known clinical hazards, independently or by comparing diverse pieces of clinical and patient information, thereby eliminating or minimising the risk of harm to patients.*"

Medication errors

The literature lacks a universally agreed definition for medication errors. A systematic review by Lisby et al. (2010) found inconsistencies in the definitions of medication errors, multiplicity in terminology and in many cases, lack of association between definitions and the documented prevalence of medication errors. The authors opined that the definitions and methods of error detection seemed to be subject to researchers' preferences; are unreliable and non-reproducible. For example, Ferner and Aronson (2006) defined a medication error as '*a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient.'* However, the term 'treatment' in this definition is ambiguous because a treatment may be about medical

care but not medications. In addition, the focus of this definition on harm alone automatically excludes potential errors due to inappropriate medication use, resulting in delayed or failed medication therapy. For example, taking glycerol suppository orally may not cause any injury to the patient; however, use by this route is inappropriate and is therefore an error.

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) in the US defined a medication error as "*any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.*" (National Coordinating Council for Medication Error Reporting and Prevention, 2014). Based on the foregoing, the definition by the NCC MERP was adopted in this research.

1.5 The context

The scope of this thesis extends only to England; the other constituent countries of the United Kingdom (UK) namely Northern Ireland, Scotland and Wales are excluded, as the systems are not congruent across them.

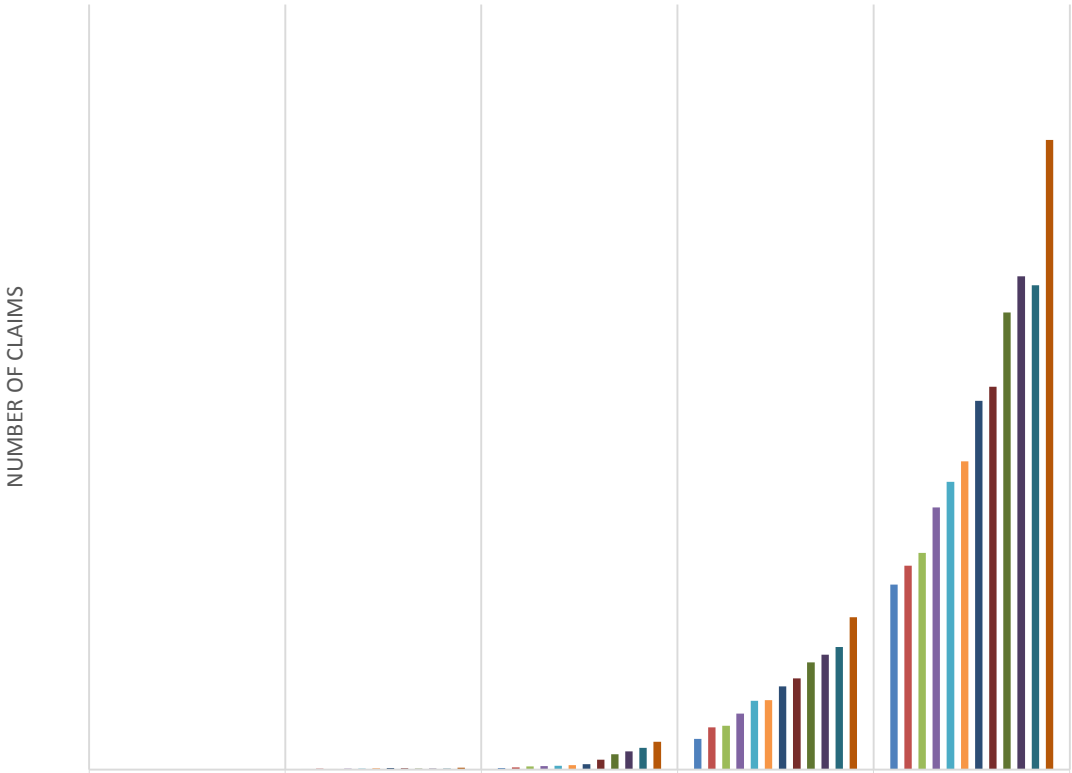
1.5.1 The process for obtaining medicines

In primary care in England, prescription generation usually takes place in general practices within the National Health Service (NHS). Paper prescriptions are taken to a community pharmacy for dispensing. This means that re-entry of prescription information into the ePMR system is a regular task in community pharmacies in England. Prescriptions can also be sent from the general practice surgery using the Electronic Prescription Service (EPS), through the national prescription server (the '*spine*'). These prescriptions are then downloaded electronically in community pharmacies via an ePMR system. Table 1.1 compares the proportion of items dispensed versus electronic (EPS R2) prescription claims (Figure 1.2) for community pharmacy contractors in England since EPS R2 started in April 2009 to March 2014. The figures suggest that the uptake of electronic prescriptions in English community pharmacy is on the rise.

Table 1.1. Number of items dispensed versus number of electronic (EPS R2) prescription claims for community pharmacy contractors in England

Year (April – March)	Number of Community pharmacies	Number of items dispensed (in millions)	Number of EPS R2 claims	Number of EPS R2 claims (%)
2009-10	10,691	813.3	4,945	0.0006
2010-11	10,951	850.7	115,611	0.0136
2011-12	11,236	885.0	1,070,234	0.1209
2012-13	11,495	914.3	8,979,292	0.9821
2013-14	11,647	948.2	39,147,078	4.1286

Note: The numbers of items dispensed were obtained from the Health and Social Care Information Centre (Health and Social Care Information Centre, 2014b). The numbers of fully electronic prescription (EPS R2) claims were obtained from the NHS Business Services Authority (NHS Business Services Authority, 2014a; NHS Business Services Authority, 2014b).



	2009-10	2010-11	2011-12	2012-13	2013-14
Apr	0	6,330	15,296	279,636	1,690,798
May	0	7,369	18,879	385,938	1,865,325
Jun	0	5,318	27,861	399,222	1,981,761
Jul	15	8,827	31,908	511,468	2,396,747
Aug	67	8,790	35,383	629,463	2,632,997
Sep	123	12,269	40,459	635,017	2,820,414
Oct	114	13,402	47,913	760,877	3,372,432
Nov	369	11,423	90,206	834,044	3,503,027
Dec	330	6,812	140,796	979,052	4,182,345
Jan	29	9,022	167,481	1,050,840	4,511,492
Feb	639	9,276	199,794	1,120,142	4,430,899
Mar	3,259	16,773	254,258	1,393,593	5,758,841

Figure 1.2. Number of EPS R2 claims for pharmacy contractors (2009-10 to 2013-14)

1.5.2 The problem of errors

Many government white papers have focused on the subject of medication errors and the need to prevent or reduce them (Department of Health, 2000b; Department of Health, 2000c; Department of Health, 2000a; Department of Health, 2004). The focus of the NHS's modernisation programme for community pharmacy is for pharmacists to benefit from using information technology to support their practice and bring an end to "illegible and incomplete prescriptions, which waste everyone's time, as well as being a risk to patient safety" (Department of Health, 2000c). The electronic transfer of prescriptions was introduced to solve this problem but it is not without its own problems, which include incomplete prescriptions and incorrect instructions being generated (Barber et al., 2013; Franklin et al., 2013).

Although prescribing and dispensing are completely separate in England, the prescriber and the dispensing pharmacist legally share any liability for inappropriate prescribing. As a result of this, additional clinical checks are required at the point of dispensing in community pharmacies to ensure due diligence with respect to pharmacist liability. It is also a legal requirement to dispense medications under the supervision of a registered pharmacist (Department of Health, 1968; Department of Health, 2006).

1.6 Medication use process in primary care in England

The medication use process (MUP) in primary care outlines the steps involved in providing medications to patients: prescribing, dispensing, administration and monitoring (Institute of Medicine, 2007).

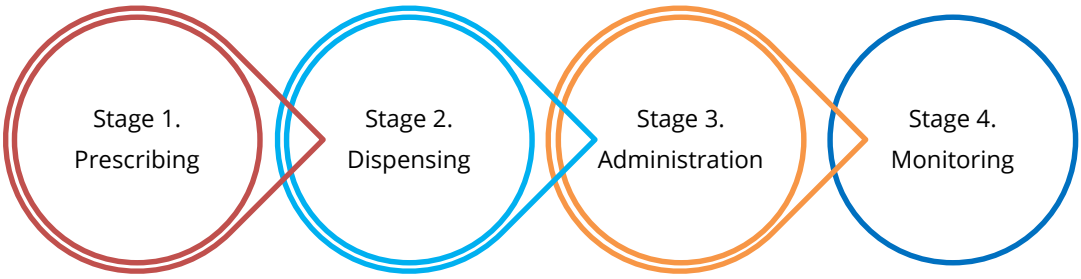


Figure 1.3. Simple representation of the medication use process in community care in England (adapted from (Institute of Medicine, 2007))

Figure 1.3 is a simple representation of the MUP in community care in England (adapted from Institute of Medicine (2007)). The prescribing stage is where decisions about whether to prescribe a medication and which medication to prescribe are made. Once the regimen is determined, a record is made, the order is generated and the patient is advised about the medication. Dispensing involves entering the prescription information into the ePMR system, screening for clinical hazards and preparing the required medication. The medication is double-checked by the responsible pharmacist before being handed out to the patient or carer. The patient or carer usually administers the prescribed medication, including verifying their understanding of the instructions against the medicine label, preparation and measurement of the prescribed dose. The patient or carer also monitors the response to the medication, while the prescriber too monitors for therapeutic and adverse effects during any follow up visit or call (Institute of Medicine, 2007). In primary care, prescribing and dispensing take place mainly in the general practice surgery and community pharmacy respectively, with occasional exceptions where rural general practices also dispense medications to their own patients.

The majority of prescriptions issued in primary care in England are computer generated. The usual scenario is that the general practitioner (GP) within the National Health Service (NHS) generates a prescription - '*prescribing*,' which is then presented at a community pharmacy contracted by the NHS for dispensing. A prescription may also be handwritten. At the pharmacy, a record of the prescription is made in the ePMR system to enable the production of the medicine labels. This requires manual re-entry of the prescriber's order into the ePMR system, a step in the dispensing process referred to as pharmacy order entry (POE).

A prescriber in primary care can also authorise a prescription so that it can be issued repeatedly at agreed intervals (without additional consultation) when further supply of a medication is required (National Prescribing Centre, 2008). The prescriber has to ensure that provisions are available for any monitoring, including a regular review of the need to continue issuing the prescription on repeat. Where a prescription is issued to an ambulatory patient by a hospital prescriber, the prescription is usually filled in the hospital pharmacy except where the prescription request has been sent to the patient's own GP for the prescription to be issued in the community.

The pharmacist or any other qualified member of staff in the dispensary such as a dispenser can perform the task of order entry and dispensing, depending on the workflow adopted within the respective pharmacy and other prevalent factors, such as staff availability. The workflow with Electronic Prescription Service (EPS) mirrors that of the physical paper prescription except that the prescription is received electronically thus allowing the electronic transmission of a prescriber's intentions direct to a nominated dispensing pharmacy, making it possible for the ePMR system to be populated directly with information from the general practice computer system (Barber et al., 2013; Pharmaceutical Services Negotiating Committee, 2014). Nevertheless, adequate point of order entry checks are still required.

Medications are helpful in disease treatment and prophylaxis, but one issue accompanying them is that errors involving medications are common and can happen at any of the stages of the MUP (Bates, 2000; Santell et al., 2003; Kaushal et al., 2007; Knudsen et al., 2007a; Lynskey et al., 2007). Wrong dose, frequency, route or quantity, mismatching between patient and medicine, allergy, contra-indication and avoidable adverse drug reaction (ADR) have also been identified as errors arising from medication use (Cousins et al., 2011).

Medication safety is the freedom from avoidable clinical hazards and harm from the medications that are intended to help patients. The number of prescription items generated and dispensed from community pharmacies in England each year has been on an upward trajectory. In 2012-2013, 914.3 million items were dispensed from community pharmacies. This increased by 33.9 million in 2013-2014 to 948.2 million items (Health and Social Care Information Centre, 2014b). This figure is likely to grow in the future and with the increasing number of dispensed medications comes an intrinsically higher risk for medication errors and other clinical hazards. The error producing and error provoking environment in which pharmacists work, also provides numerous opportunities for medication errors and adverse drug events to occur (Reason, 2000). Nevertheless, understanding and recognising errors and how they happen is vital in identifying solutions to the problems, to facilitate improvements in patient outcomes and quality of health care (Institute of Medicine, 2001).

1.6.1 Medication errors in primary care

The PRACtICe study in primary care in England highlighted the number of medication errors originating from primary care (Avery et al., 2012b). The study detected medication errors for one in eight patients, involving about one in 20 prescription items. The majority of the errors were judged to be of minor or moderate severity, with one in 550 prescription items containing a severe error. Based on the number of items dispensed by community pharmacy contractors in England each year, 948.2 million in 2013-14 (Table 1.1), error rates such as the aforementioned one error per 20 prescription items translate into over 47 million errors encountered by English community pharmacies per year, of which over 1.7 million would be severe errors.

This translates to over 4000 errors per community pharmacy per year and potentially, over 140 severe errors per community pharmacy.

In primary care, the dispensing stage of the MUP is often the last opportunity for a health care professional to identify, correct and prevent medication errors that have come through the prescribing stage. Authors of the PRACtICe study identified a wide range of defences being deployed against errors at multiple stages of the medicines management process, including strategies that can be used by individual prescribers, and general practices, and effective use of health information technology (Avery et al., 2012b). One randomised controlled study showed effectiveness in reducing a range of medication errors that could escape detection at the prescribing stage by employing a pharmacist-led information technology intervention for medication errors (PINCER) in general practices (Avery et al., 2012a). However, if errors escape the prescribing stage of the MUP, the defences at the dispensing stage should be robust enough to prevent such errors from getting through and causing harm to patients. Avery et al. (2012b) commented in the PRACtICe study that many of such errors would be picked up by community pharmacy.

1.6.2 Medication errors in community pharmacy

1.6.2.1 Definition of errors and error measurement

The problems of medication errors also extend to community pharmacy practice. It has been suggested that many medication errors go unreported (Pape, 2001; Singh et al., 2009). In addition, there are challenges to estimating the extent and rate of medication errors in health care systems because of variations in the definitions, methods of identifying and measuring errors and the units of measurement used (Aronson, 2009; Garfield et al., 2009; Franklin et al., 2014).

The results obtained from medication error studies should therefore, be interpreted cautiously. For example, some studies were based on self-report of errors (Chua et al., 2003; Ashcroft et al., 2005b; Lynskey et al., 2007), while others were based on direct observation (Franklin and O'Grady, 2007; Franklin et al., 2014). Self-reporting of errors has been implicated in the reduced number of errors reported by some studies (Franklin and O'Grady, 2007; Knudsen et al., 2007a).

The specific stages of the MUP on which the investigation is based are also important in interpreting the results of medication error studies in community pharmacy. For example, a US based study (Flynn et al., 2003) and some UK based studies (Chua et al., 2003; Ashcroft et al., 2005b; Franklin and O'Grady, 2007; Franklin et al., 2014) focused mainly on dispensing errors at the dispensing stage of the MUP. Other studies focused on errors originating at multiple stages of the MUP. For instance, the study conducted by Martínez Sánchez (2013) in a Spanish community pharmacy focused on both prescribing and dispensing errors at the point of dispensing and used the term 'medication errors' for errors.

One Danish study focused on prescribing, transcribing, dispensing, administration and counselling (Knudsen et al., 2007a). The authors defined an administration error as, "*Storage, distribution and delivery by the community pharmacy, and administration to or by the patient*." However, 'administration' in the context of the MUP is usually administration of a medication by or to a patient or the consumer. Storage, distribution and delivery by the community pharmacy are usually regarded as part of the logistics of the dispensing process. The UK study conducted by Lynskey et al. (2007) focused on dispensing errors and what was described as '*other errors outside of the dispensary's control*.' The '*other*' errors according to the study authors, "*included the prescribing errors made by general practitioners (GPs) and patients' administration errors which had either been noted and rectified before issue to the patient (near miss) or overlooked (actual error).*" However, this may not be realistic because there is no assurance that the patient would report an 'overlooked' administration error. All of the aforementioned differences may influence the reported number of errors and error rates.

1.6.2.2 Prevalence of errors

Although the prevalence of dispensing errors in community pharmacies in many countries has been reported, it is difficult to do a direct comparison of error rate across different studies because of differences in the definitions and methods used. Similarly, it is not appropriate to make direct comparison of results of studies from other countries with results of studies from the UK because of differences in the

mode of community pharmacy practice. The results from some notable studies from the UK, the US, Denmark and Spain are presented.

A self-report, feasibility study by Chua et al. (2003) in four community pharmacies from Hull Primary Care Trust and East Riding Primary Care Trust, UK reported 247 (0.48 percent) near misses and 39 dispensing errors (0.08 percent) in 51,357 items. The self-report study by Ashcroft et al. (2005b) in 35 community pharmacies recording dispensing errors and near misses for 4 weeks reported 50 (0.04 percent) dispensing errors and 280 (0.22 percent) near misses of 125,395 items. Another study in 11 UK community pharmacies found a content error in 49 (1.7 percent) and a labelling error in 46 (1.6 percent) of 2,859 dispensed items (Franklin and O'Grady, 2007). A recent study that investigated the effect of the electronic transmission of prescriptions on dispensing errors and prescription enhancements made in 15 English community pharmacies identified labelling errors in 885 (5.4 percent) of 16,357 dispensed items and content errors in 222 (1.4 percent) (Franklin et al., 2014). Some of the error types reported by these studies were selection errors, such as wrong drug, wrong strength and wrong formulation; labelling errors including wrong drug quantity, wrong product name and wrong patient name and bagging errors, such as wrong name or address on bag.

Some studies investigated medication errors at different stages of the MUP. One study from the US measured the dispensing accuracy rates in 50 pharmacies located in 6 cities across the US and described the nature and frequency of the errors detected by trained pharmacists during a one-day observation in each of the pharmacies. The study found an overall error rate of 1.7 percent (77 errors; range 0 to 12.8 percent) in 4,481 items (Flynn et al., 2003). In Denmark, Knudsen et al. (2007a) had 976 cases of prescription corrections, 229 cases of near misses, 203 cases of dispensing errors and 198 cases of adverse drug events. The data were obtained retrospectively. Only adverse drug events' data were obtained prospectively. The error rate per 10,000 prescriptions was 0.2 percent for prescription corrections, 0.01 percent for dispensing errors and 0.02 percent for near misses. A Spanish study of 42,000 individual prescriptions had 2,117 medication errors. Out of these, there were 1,127 prescribing errors, 216 dispensing errors, and 774 dispensing near misses. The error rate was 5.0 percent, including the near misses (Martínez Sánchez, 2013). In

primary care, the point of dispensing remains the only opportunity for a health care professional other than the prescriber to intervene before the medication is taken by or administered to the patient or consumer. The ePMR system could help prevent or reduce some of the errors highlighted in the various studies earlier presented. The community pharmacy '*safety net*' is therefore important to ensure that errors and clinical hazards do not slip through to harm patients.

1.6.2.3 Medication error reporting

Out of over 500,000 medication incidents that were reported to the National Reporting and Learning System (NRLS) from England and Wales between 2005-2012, there were 106 reports of severe harm and death attributable to medication incidents in community pharmacy (Table 1.2). Over 1.4 million incidents occurred between October 2012 and September 2013 in England alone, of which 1,725 incidents originated from community pharmacy and 1,654 (96 percent) were medication incidents (National Patient Safety Agency, 2014). One incident caused severe harm to the patient but no patient death was reported. Opioids, antibiotics, warfarin, low-molecular weight heparins, insulin, benzodiazepines and non-steroidal anti-inflammatory drugs were the medications most frequently associated with severe harm or death (Cousins et al., 2011). There were instances where ePMR systems could have helped to prevent the negative outcomes obtained. For example, ePMR systems integrated with safety features are capable of picking up some of the reported medication incident types (Table 1.3), such as wrong dose, wrong strength, wrong drug, wrong formulation, wrong quantity, wrong frequency and contra-indications. In spite of the initiatives to reduce medication incidents, the total number of incidents reported appeared to be increasing year on year (see Table 1.2).

1.6.2.4 Probable reasons for the increase in number of medication error reports

One possible explanation for the increased number of incidents reported to the NRLS is that the number of errors has also been increasing. This may be attributable to the increasing number of prescriptions filled in community pharmacies and the associated workload (Health and Social Care Information Centre, 2014b). It is also possible that pharmacy professionals also feel more comfortable reporting errors

without any fear of being blamed or disciplined for making or recording errors. Furthermore, awareness about the potential for errors is also increasing and perhaps, people are more inclined to resolve issues quickly to prevent harm to patients. Although the number of errors in the clinical categories - no harm to moderate appeared to be increasing year on year, there seemed to be little or no change in the number of severe harm and death. This suggests that the line of defence in place in community pharmacies, including the use of ePMR systems is having positive, reducing impact on the number of medication incidents that are getting through to patients.

Additionally, key health policies in England and Wales appear to have influenced the reporting of incidents and errors. The NHS Plan dictates that health care providers work to make health care safer and support a culture where everyone can learn from and effectively reduce mistakes (Department of Health, 2000a). Specifically, pharmacy as a profession is expected to help deliver the vision of a NHS, which offers people fast and convenient care, delivered to a consistently high standard (Department of Health, 2000c). The National Patient Safety Agency's (NPSA) was established in 2001 and was mandated to improve patient safety within the NHS (National Patient Safety Agency, 2003). In 2003, a voluntary scheme to electronically collect information about incidents that affect patient safety within the NHS, identify any emerging patterns, learn from such incidents and develop solutions to improve patient safety was established (National Patient Safety Agency, 2003; Cousins et al., 2011; National Patient Safety Agency, 2013a).

Significant events within the NHS also seem to have influenced the number of errors reported. The case of a former family doctor, Dr Harold Shipman, who systematically killed many of his patients over a period of 20 years, led to the requirement for reporting errors involving controlled drugs (Shipman Inquiry and Smith, 2002; Shipman Inquiry and Smith, 2004). In addition, investigation into the care provided by the Mid- Staffordshire NHS Foundation Trust between January 2005 – March 2009 revealed many instances of medication incidents and errors, such as lack of warnings to patients about the side effects of medications and missed flag about patients' allergies to specific medicines (Mid Staffordshire NHS Foundation Trust Inquiry and

Francis, 2010). The outcomes of both events may have inspired pharmacy professionals to report more.

A new NHS community pharmacy contract was introduced in 2005 with the aim of reimbursing pharmacy contractors based on the quality of services provided instead of the volume of dispensing, as proposed originally in the NHS plan (Department of Health, 2000c; Department of Health, 2005). The contract defined the services provided by community pharmacy on three levels: essential, advanced and enhanced. All contractors must provide essential services such as dispensing, disposal of unwanted medicines and clinical governance. Advanced services, such as medicines use reviews (MURs) are commissioned nationally and require accreditation of the pharmacist and the pharmacy. The specification and value of enhanced services, such as the minor ailment scheme, palliative care services, care home services and substance misuse services are agreed nationally but commissioned at local level. The NHS Information Governance requirements are part of the essential services provided by pharmacy contractors (Pharmaceutical Services Negotiating Committee, 2010). Section number 320 stipulates that community pharmacies should have documented incident and near-miss recording, reporting and management procedures in place (Pharmaceutical Services Negotiating Committee, 2010). All of these have perhaps contributed to the increased level of reporting.

Table 1.2. Medication incidents reported by clinical outcomes in England and Wales*

Clinical Outcome	2005	2006	2007	2008	2009	2010	2011	2012	Total
No Harm	769	2,548	4,777	5,838	5,084	5,108	9,365	10,175	**43,664**
Low	86	289	354	448	445	383	586	748	**3,339**
Moderate	40	71	96	119	144	165	186	212	**1,033**
Severe	2	15	7	9	6	18	18	13	**88**
Death	0	2	1	2	1	4	3	5	**18**
Total	**897**	**2,925**	**5,235**	**6,416**	**5,680**	**5,678**	**10,158**	**11,153**	**48,142**

Note: * Based on all incidents reported to have occurred in community pharmacy and exported to the NRLS dataset on or before 17 April 2013 (National Patient Safety Agency, 2013c)

Table 1.3. Medication incidents by category of error reported in England and Wales*

Category of error	2005	2006	2007	2008	2009	2010	2011	2012	Total
Wrong / unclear dose or strength	248	967	1,693	1,994	1,844	1,706	3,118	3,208	**14,778**
Wrong drug / medicine	317	780	1,181	1,494	1,388	1,387	2,269	2,757	**11,573**
Wrong formulation	66	280	681	809	644	534	1,161	1,292	**5,467**
Wrong quantity	50	219	439	591	447	458	814	835	**3,853**
Mismatching between patient and medicine	48	134	252	358	313	323	657	690	**2,775**
Wrong / transposed / omitted medicine label	42	137	186	196	227	218	243	376	**1,625**
Wrong / omitted / passed expiry date	18	51	113	124	112	127	185	167	**897**
Omitted medicine / ingredient	20	41	66	115	74	92	186	209	**803**
Wrong frequency	16	33	74	88	87	83	129	151	**661**
Wrong method of preparation / supply	12	36	56	54	64	76	160	146	**604**
Contra-indication to the use of the medicine in relation to drugs or conditions	7	25	18	33	22	17	20	25	**167**
Wrong storage	3	12	14	5	25	8	24	30	**121**
Adverse drug reaction (when used as intended)	6	11	32	17	9	15	16	11	**117**
Wrong / omitted verbal patient directions	1	7	6	10	9	13	28	23	**97**
Wrong route	0	3	6	6	8	12	12	12	**59**
Patient allergic to treatment	2	8	4	4	8	7	6	15	**54**
Wrong / omitted patient information leaflet	0	6	9	6	6	4	9	9	**49**
Others	14	23	163	298	211	379	634	692	**2,414**
Unknown	15	107	199	129	78	100	402	346	**1,376**
Not stated	12	45	43	85	104	119	85	159	**652**
Total	**897**	**2,925**	**5,235**	**6,416**	**5,680**	**5,678**	**10,158**	**11,153**	**48,142**

Note: * Based on all incidents reported to have occurred in community pharmacy and exported to the NRLS dataset on or before 17 April 2013 (National Patient Safety Agency, 2013b)

1.6.3 Sources of errors in community pharmacy practice

James et al. (2009) listed various factors that were cited as contributing to dispensing errors in the studies evaluated by the authors in their literature review of the incidence, type and causes of dispensing errors in both community and hospital pharmacy in Australia, Denmark, Brazil, Spain, UK and US. Some notable causes of medication errors that have been reported in community pharmacy studies in England include wrong drug selection, errors related to prescriptions, wrong selection from computer menu and wrong quantities (Ashcroft et al., 2005b; Franklin and O'Grady, 2007). Table 1.3 also lists medication incidents reported in England and Wales by category of error, including wrong dose or strength, wrong drug, wrong formulation, wrong quantity, wrong label and mismatching between patient and medicine. It has been suggested that poor handwriting can aggravate the problem of medication error caused by confusion of drug names (Hoffman and Proulx, 2003; Velo and Minuz, 2009). In support of these assertion, studies in many countries, including Spain (Martínez Sánchez, 2013), Denmark (Knudsen et al., 2007b) and England (Ashcroft et al., 2005b) have identified poor handwriting as a source of medication errors. It has been suggested that electronic prescribing systems can help to eliminate illegible handwriting and automate screening for clinical hazards, such as allergies and potentially hazardous co-prescriptions (Jenkins and Vaida, 2007).

The electronic transfer of prescriptions in England also has its problems as Franklin et al. (2014) pointed out in their study, which compared the prevalence and types of dispensing errors and pharmacists' labelling enhancements for electronically transmitted prescriptions versus paper based prescriptions in England. The study authors found that electronically transmitted prescriptions had a higher prevalence of labelling errors (7.4 percent of 3,733 items) than other prescriptions (4.8 percent of 12,624) even though the reverse would be expected. However, the prevalence of content errors and enhancements were similar across all prescription types. The errors increased the number of interventions community pharmacists had to make to ensure that prescription items were correctly labelled and dispensed.

1.6.3.1 The role of false alerts in error causation

False alerts also contribute to errors in practice. An alert that activates when there is no need for a user to be aware of the event being warned about or the need to take any corrective action is referred to as a false alert. This may result from incorrect alert sensitivity (Abarca et al., 2006) or safe situations being flagged as unsafe. For example, the study by Raebel et al. (2007a) sought to determine whether a computerised alert was effective in decreasing the dispensing of United States Food and Drug Administration (US FDA) pregnancy risk category D or X medications prescribed to pregnant patients. These FDA pregnancy categories indicate the potential for a drug to cause birth defects if used in pregnancy. With category D medications, evidence of fetal risk exists but therapeutic benefits can outweigh the risks. With category X medications, evidence from human or animal studies suggests that the risks to the fetus outweigh therapeutic benefits.

The study was stopped because of two false-positive alert types. These were misidentification of medications as contraindicated in pregnancy by the pharmacy information system, and patients being identified as pregnant when they are not due to delayed transfer of diagnosis information. The outcome could have been prevented by carrying out simulated pre-study tests with dummy patient profiles similar to the studies by (Jankel and Martin, 1992; Abarca et al., 2006; Saverno et al., 2011). The extent to which false and spurious alerts are generated (or not generated) by ePMR systems used in English community pharmacy practice and the behaviour of users towards such alerts are unknown. It has been suggested that primary care clinicians may continue to override important and useful alerts even when relatively few false positive alerts are displayed (Slight et al., 2013). Research is required to establish if this is the case in community pharmacy practice as well and to work out how to prevent such a situation, if the assertion is true.

1.6.3.2 The role of safety culture in error causation

Pharmacy professionals have to be disciplined enough to engage in and demonstrate appropriate, safety-oriented behaviour within a framework of responsibilities. In a culture of safety, people have responsibilities not jobs. This implies that everyone must be situationally aware of what is going on in their practice environment,

recognise what can turn into a safety issue or lead to harm and act swiftly to stop it. The medication safety chain is as strong as its weakest link. It has been suggested that '*teams create safety*' so, ensuring medication safety in community pharmacy requires teamwork (Vincent, 2010).

In one randomised controlled study to improve prescribing safety in patients with renal insufficiency in the ambulatory setting, a medication decision guide was printed in lieu of the prescription label (Bhardwaja et al., 2011). The guide outlined for the pharmacist, the intervention process. In reality, it is also possible for the pharmacist to use printed guide during the clinical checking process or when counselling a patient. However, it may be argued that printed alerts would not be as effective as alerts presented onscreen in real time during the dispensing process because the alerts' clinical relevance may not be fully understood or may be taken out of context. It is therefore essential that individual pharmacists and pharmacy organisations demonstrate a culture of safety to ensure that errors are not missed.

To develop a safety-culture assessment tool for community pharmacies in England, Ashcroft et al. (2005a) initially developed a safety culture assessment framework for community pharmacy in England through a series of 10 focus groups with a purposive sample of 67 community pharmacists and support staff in the UK. Participants expressed willingness to use the framework to improve safety in community pharmacy practice. However, they acknowledged that they would need protected time to complete the assessment as a team. The work was extended, leading to the development of a 34-item Pharmacy Safety Climate Questionnaire (PSCQ), which was designed specifically to assess safety climate in the community pharmacy setting (Ashcroft and Parker, 2009). The PSCQ was developed further and was extended to community pharmacies in Denmark, Germany, the Netherlands, Portugal and Great Britain (Phipps et al., 2012). This version was made up of a four-factor framework (organisational learning, blame culture, working conditions and safety focus) and contained 24 items. The impact of these tools on individual pharmacy professional and organisational safety culture in English community pharmacies is unclear.

1.6.4 The cost of medication errors

Medication errors and harm from medicines are problematic around the world, difficult to quantify and come at an enormous cost, financially and emotionally (Van Dusen and Pray, 2011). The sum of £8.5 billion was spent on prescription drugs in England alone in the year 2012 (Health and Social Care Information Centre, 2013). This was part of the total healthcare expenditure for the UK, which grew by 1.9 percent to £144.5 billion in the same year (Office for National Statistics, 2014).

No recent figure about the cost of medication errors to the NHS in England was found. In 2007, the NPSA gave a conservative estimate of total annual costs of up to £774 million as the cost of harms from medicines to the NHS (National Patient Safety Agency, 2007c). A multicentre study that looked at three specific prescribing errors in general practice showed that when pharmacists were able to identify and resolve a prescribing event they were able to reduce health expenditure by £75 per error avoided at 6 months or £85 per error avoided at 12 months (Avery et al., 2012a).

1.6.5 The Swiss cheese model of error causation

This research was informed by Reason's accident causation framework (Reason, 1997). The framework serves as a practical resource for understanding the contributions of users, ePMR systems and organisations to medication errors. To understand how errors occur, a conceptual model - the '*Swiss cheese*' model has been proposed to show that there are barriers to making any type of error (see Figure 1.4). The model is often used to illustrate how defences may be breached by an accident trajectory. It also provides an opportunity for understanding the role that various forms of defences play in preventing medication errors (Reason, 2008). Each slice of cheese represents a defence or barrier against error. These barriers are full of holes like Swiss cheese and the position of the holes keeps changing. The holes could line up, leading to serious errors or harm getting through to patients. If an error is caught before it gets to the patient, it is called a '*near miss*' error. Unfortunately, the processes of eliminating the holes to make the barriers effective and to prevent errors and harm to patients are neither easy nor direct.

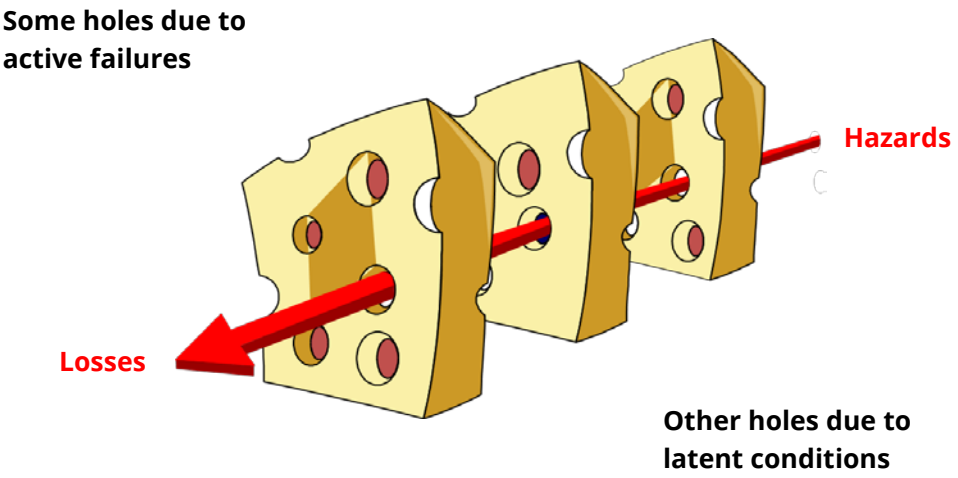


Figure 1.4. Swiss cheese model: A system view of error causation (taken from Reason, 2008)

Note: Active failures - the unsafe acts perpetrated by people who are in direct contact with the patient or system (Reason, 1997). Latent conditions are necessary for the causal agents to have their effect (Reason, 2008).

1.6.6 Models of error and error management

In the paper on human error by Reason (2000), the author presented two models of error - person model and system model. These models offer a way of understanding and dealing with the problem of errors and error management within health care, including the MUP. The need to strike a balance between the two models was suggested by the author, who also emphasised that it is difficult to get the balance right.

1.6.6.1 The person model

The person model holds a person or group accountable when an error occurs. It focuses on and blames individuals for being forgetful, distracted, careless or failing to pay attention. Various treatments are meted out to the individuals who are usually at the '*sharp end*' of the error, such as naming, blaming, shaming and retraining.

1.6.6.2 The system model

The system model on the other hand, focuses on the system. It suggests that health care practitioners are human and are bound to make errors because of poorly designed tasks, processes and systems within which they work. Therefore, efforts to prevent errors are focused on changing the conditions under which people work instead of focusing attention on changing the human condition (Reason, 2000).

1.6.7 Human factors approach to medication safety

The human factors approach to medication safety is based on the system model of error. It presumes that the main source of risk is the system surrounding and interacting with caregivers. It concentrates on the conditions under which individuals work and tries to build defences to avert errors or mitigate their effects. The approach emphasises that the system is where risk should be effectively recognised, managed and controlled (Dekker, 2011).

A good example of the human factors approach to medication error prevention and patient safety in the NHS is the patient safety series produced by the NPSA, which focused on using better design to help reduce risks, improve the environment within which people work and ensure better, patient-centred care. Examples include the guidelines for the safe onscreen display of medication information (National Patient Safety Agency, 2010), the guide to the design of the dispensing environment (National Patient Safety Agency, 2007a) and the guide to the graphic design of medication packaging (National Patient Safety Agency, 2007b). Another initiative by the NHS in collaboration with Microsoft Corporation is the common user interface (CUI), which was created with the intention of providing a common look and feel for NHS systems to help improve patient safety (Microsoft Corporation, 2010).

High reliability organisations, such as aviation and the energy industry are work settings where there have been much learning about human factors. These industries understand that human beings are unpredictable so they focus attention on that unpredictability as a reminder of the likelihood of error and the need to have solid defences against them (Reason, 2000). Therefore, efforts to minimise patient safety

incidents in health care should include learning from these industries to target underlying system factors that could lead to errors.

1.7 Defences employed at the point of dispensing

Pharmacists play a vital role in health care to ensure that patients and pharmacy patrons do not come to iatrogenic harm. Pharmacists also help patients make best use of their medicines (Kelly and Rucker, 2006). This role incorporates identifying, correcting and reducing errors, and preventing the dispensing of unsafe co-prescriptions (Mangino, 2004; Dhillon, 2009; The Health Foundation, 2012). Identification and correction of errors often occur as pharmacists check prescriptions and dispensed medications, and provide clinical pharmacy services.

Some of the safety methods that have been introduced in health care, which have also found use in community pharmacy practice are checklists, structured communication techniques, team briefings, simulator training, as well as incident and error reporting. Other defences that have been developed to help pharmacy professionals avoid making errors include policy writing, standard operating procedures (SOPs), regulations, giving feedback on errors, educational interventions and automation. Information technology interventions to improve medication safety include barcode medication verification, electronic prescribing and ePMR systems integrated with safety features and alerts (Clark et al., 2012; Calhoun et al., 2014).

1.7.1 The evolving scope of safety features and alerts in electronic patient medication record systems

There is no official figure for the number of ePMR systems in England now. There were 11,647 community pharmacies in England as at the end of March 2014 (Health and Social Care Information Centre, 2014b). Information provided by the Health and Social Care Information Centre also indicates that 11,293 (96.9 percent) pharmacies were EPS R2 enabled as of November 2014 (Health and Social Care Information Centre, 2014a). The NHS Pharmaceutical Services Regulations of 2005 and the Responsible Pharmacist Regulations of 2008 stipulate keeping and maintaining records of drugs and appliances provided, to facilitate the continued care of the patient, advice given and

any interventions or referrals made in appropriate cases (Department of Health, 2005; Department of Health, 2008). Without an electronic system, pharmacists would be handwriting labels and recording interventions or referrals made, checking for clinical hazards, such as unsafe drug combinations and contraindications via paper-based sources, an exercise that is highly unlikely. In light of this, it can safely be assumed that the remaining 3.1 percent pharmacies also use ePMR systems.

Other names that have been used to describe ePMR systems in the literature include pharmacy computer system (Abarca et al., 2006; Mansour et al., 2010; Saverno et al., 2011), pharmacy information system (Mackowiak and Hayward, 1998; Schiff et al., 2003), pharmacy information management system (Hartzema et al., 2007; Humphries et al., 2007; Raebel et al., 2007b; Lin et al., 2008) and pharmacy practice management system (National Association of Pharmacy Regulatory Authorities, 2013). Most ePMR systems are stand-alone systems designed to support the operation of individual pharmacies. Sometimes, terminals in a single pharmacy or the same pharmacy group may be networked together making patient information and medication records readily available. They can also interact with other clinical systems if the system has the functionality and it is enabled (Egton Medical Information Systems Limited, 2014).

The systems are used for dispensing – including electronic prescriptions, improving communication with other health care professionals, managing inventories, assisting with monitoring and calculations, reporting and making clinical knowledge readily accessible. In addition, they are used to record details of medications dispensed to patients and pharmacy patrons, producing labels for dispensed medications, stock ordering and a host of other administrative and reporting functions. They are also used to support review of medications for appropriateness and for keeping record of various services provided by community pharmacists.

In addition to manual safety checks conducted by pharmacists, the safety features often embedded in ePMR systems are useful for highlighting clinical hazards, a situation referred to by Boulding and Purohit (1996) as ‘preventive safety,’ in their commentary on the price of safety in the automotive industry. These safety features are used to highlight errors and clinical hazards, performing background safety checks in real-time. For example, some ePMR systems check for drug allergies,

adverse events, and potentially unsafe medications and drug combinations. This ability to improve the quality of dispensing and patient outcomes is considered a safety net in preventing harm to patients once a prescription has been issued (Reichley et al., 2005; Kilbridge et al., 2006).

A study by Koppel et al. (2005) identified some medication-error sources that users reported were facilitated by Computerised Physician Order Entry (CPOE) systems. For example, the authors found that ordering new medications or modifying existing ones was usually a separate process from discontinuing an existing medication. This separation of functions leads to a fragmented view of patients' medications. If the existing dose is not discontinued, the physician can mistakenly increase or decrease the dose of a medication leading to double doses. This can also occur in ePMR systems if a duplicate medication is ordered for a patient without the existing one being discontinued. Also, if there is no alert that a patient is currently on the same medication that is about to be dispensed and the medication record is not displayed onscreen and reviewed by the system operator during the dispensing process, such an error can be missed.

Patient safety is a major consideration in the implementation of safety alerts for the reasons previously highlighted. In addition, medication errors are still occurring and it has been suggested that health care professionals frequently ignore alerts, including the information and advice provided by alerts (Bates et al., 1999; Evans et al., 1999; Indermitte et al., 2007a; Institute for Safe Medication Practices, 2007; Patanwala et al., 2012). It is possible that pharmacy professionals may fail to use important safety features or ePMR systems may fail to warn when a warning is necessary or expected, similar to findings obtained from a study of general practice computer systems (Fernando et al., 2004).

Across ePMR systems around the world, the sensitivity and specificity of safety warnings, the way warnings are presented, the type of alerts and the severity levels of alerts are some of the areas where variations and problems exist (Jankel and Martin, 1992; Hazlet et al., 2001; Abarca et al., 2006; Heikkila et al., 2006; Cremades et al., 2009; Saverno et al., 2011). Other problems include missing alerts, inadequate alert information, false alerts, over-alerting, alert fatigue and automatic behaviour towards

alerts without considering the implications (Abarca et al., 2006; Raebel et al., 2007a; Saverno et al., 2011; Ojeleye et al., 2013). The extent to which systematic, evidence-based research findings in allied areas such as chemical labelling and general warning research is used in the design and implementation of alerts in ePMR systems remains unclear.

1.7.2 The role of educational interventions and training

Little is currently known about how pharmacists and other pharmacy staff learn to use ePMR systems, the quality of the learning and the impact on their ability to use ePMR systems and safety features effectively. There is currently no accredited initial or refresher training programme for pharmacists and other pharmacy staff in this respect either.

Inadequate knowledge of the safety features available in ePMR systems coupled with lack of training could result in sub-optimal use of the safety features in the systems. It is therefore important to raise pharmacists' awareness about appropriate use of ePMR systems and any deficiencies of the safety features in the systems, ensuring that relevant training is available to users. This assertion is supported by Goodman et al. (2011) who suggested that safe and successful use of health information technology (HIT) systems require significant education about how to install, configure and use the respective HIT product. The authors suggested that this should take place collaboratively between vendors and their customers and should be targeted at key stakeholders, including users of the system as required. The educational programme should be appropriate, addressing issues such as patient safety, workflow and workarounds, disclosure of system defects, confidentiality and security challenges.

Morris et al. (2005) investigated the stated knowledge, use and training needs of 381 GPs from six English primary care trust via a questionnaire survey, regarding the safety features of general practice computer systems. The authors reported that many of the GPs were unsure as to whether the system they were using possessed some of the safety features specified in the survey. In addition, the study found that some of the respondents incorrectly believed that their clinical computer systems would warn them about potential hazardous situations, such as contraindications,

abnormal doses and frequencies. Only a few of the respondents said they had received formal training on how to use the safety features in their clinical computer system. It is not known whether a similar situation exists in community pharmacies in England. The positive role of education and training was also emphasised by Barach and Moss (2001) who suggested that development of an understanding about patient-centred safety should be supported from the first day of health care training. This suggests the need to train pharmacy professionals on how to use ePMR systems and manage alerts effectively.

Situation awareness and foresight training

The level of situation awareness and extent of application of foresight skills to avert medication safety incidents by pharmacists and pharmacy staff is not clear. Situation awareness involves constantly monitoring the situation in a task environment to understand what is going on and what might happen at any point in time (Endsley and Garland, 2000). Flin et al. (2008) highlight that some industrial accidents in aviation and other work settings can be attributed to failure in situation awareness. The model of situation awareness by Endsley (1995) highlights its importance and potential usefulness to patient safety in the community pharmacy work setting.

Foresight on the other hand, is the ability to identify, respond to and recover from the initial indications that a patient safety incident could take place (National Patient Safety Agency, 2008). Health care professionals use it to develop and practise the skills needed to identify situations where a patient safety incident is likely to occur. Foresight training aims to improve awareness of the factors, which can increase the likelihood of patient safety incidents. This empowers health care professionals to intervene to avoid such incidents, increase learning from sharing experiences and improve understanding of '*risk-prone*' or '*near miss*' situations and what should be reported.

1.7.3 Other input variables for effective medication safety alerts

Other factors to consider when deciding how best to create effective alerts and make alerts useful in community pharmacy practice include data, data quality and completeness, standards and regulations.

1.7.3.1 Data, data quality and completeness

The primary purpose of information is to enable better decision making (Wyatt, 1996). However, incomplete information or medications that are prescribed to be taken or used as required, create alert implementation problems for system designers (Stutman et al., 2007).

Information can emanate from a variety of data sources. For example, in community pharmacies, decision-making information about patient care can come from prescriptions, clinical information systems, other health care professionals and patients. Separation of community pharmacies from other health care delivery sites such as general practice surgeries and hospitals however means that community pharmacies often lack clinical data that could assist them in making appropriate clinical decisions about patient care and sometimes the impact of alerts at the time prescriptions are filled (Murphy, 2005). Floor-Schreudering et al. (2013) found in their study that non-appearance of drug therapy alerts in some Dutch community pharmacies were due to incomplete electronic patient records. Electronic transfer of prescriptions to the pharmacy offers potentials for transmitting patients' clinical information along with prescriptions from sources such as general practice surgeries. This could help facilitate safety checks at the point of dispensing.

An investigation of the frequency and nature of missing clinical information in the outpatient department of three NHS hospitals revealed that various types of information required by doctors for patient care were missing. These include information about patients' current medications, allergies, blood lab results and diagnostic test results (Burnett et al., 2011). Doctors who participated in the study said they perceived that the missing clinical information resulted in delays in patient management and cancellation of operations. The study authors suggested a regular

audit of the prevalence of missing clinical information to establish its impact on clinical decision-making and patient care.

1.7.3.2 Standards and regulations

Pharmacy organisations intending to purchase ePMR systems can select from a wide variety of commercial ePMR systems or develop their own; however, there is no formal framework in the literature, to guide their choices. There also seems to be differences in the desirability of safety features offered by systems based on pharmacists' domain of practice (Jankel and Martin, 1992). The role of safety leadership, socio-economic characteristics, demand for safety features and other factors in influencing the choice of system and functionality in English community pharmacies is relatively unknown and warrants investigation in the interest of patient safety.

In comparison with general practice computer systems, there are no known standards or common specifications for ePMR systems and alerts in England. However, there are specifications for aspects of the electronic prescription service module in ePMR systems. Numerous documents that are currently used as guides vary in origin. The question then arises about whether ePMR systems should be standardised or regulated.

A group of organisations in the US gave recommendations on how to develop and implement processes for monitoring and regulating clinical software systems (Miller and Gardner, 1997). The goals were to encourage a coordinated effort to safeguard patients, users and institutions as clinical systems are implemented. In addition, to improve clinical care processes, and support the development of innovative and more effective software systems. The consortium proposed four categories of clinical software system risks and four classes of measured regulatory actions as a template for determining how to monitor or regulate any clinical software system. The group recommended supervising clinical software systems locally and focusing regulatory efforts on systems that pose the highest levels of clinical risk, with limited opportunities for competent human intervention.

Furthermore, adoption of a code of good business practices, including standardised and detailed product labelling, use of industry-wide standards for handling and sharing electronic information, including standards for the format, content and transport of health care information were suggested (Miller and Gardner, 1997; Miller et al., 1997). Possibly, standardisation may be the solution to some of the problems leading to inconsistent system performance in community pharmacy practice.

1.8 Design for effective alerts based on human factors principles

An alert in the context of POE or dispensing can be used to indicate that a proposed prescription, product selection or co-prescription may be clinically hazardous based on a number of reasons such as age, gender or allergy status. The question then arises as to how alerts should be designed for effectiveness.

It has been suggested that matching the hazard inherent in a situation being warned about and the hazard implied by the associated alert, improves alert effectiveness. In addition to informing that a threat exists, hazard-matched warnings also indicate the severity of the threat so that recipients have more information on which to base their behavioural decision making (Hellier et al., 2000b). The level of conformity to such recommendations, the consistency across the systems and interpretation of the significance of alerts by community pharmacy professionals in England is unclear. It is also possible for users to become used to alerts due to repeated exposure, especially alerts where no hazards are present, causing users to behave automatically towards alerts, perhaps without considering the implications. This situation is referred to as '*habituation*' or '*automaticity*' (Thorley et al., 2001).

To avoid the situation described above, careful consideration should be given to the design and implementation of alerts if the alert is to accomplish its aim. There is a wealth of research outside community pharmacy practice, demonstrating performance benefits of applying ergonomic principles to the design and implementation of alerts to improve their effectiveness. Prioritising alerts according to the severity of risk and the likelihood of an injury occurring if alert compliance does not take place and using appropriate wordings for alerts have all been shown to

improve alert performance (Edworthy and Adams, 1996b; Edworthy, 1998; Hellier and Edworthy, 2006; Hellier et al., 2006; Hellier et al., 2007).

1.8.1 Alarm philosophy

Alarm philosophy indicates the logic behind the decisions about events that should be classified as hazardous and associated with an alert (Phansalkar et al., 2010). It has been suggested that a rigorous alarm philosophy should include a holistic consideration of all alarms to ensure that the user is able to respond to them with the appropriate level of priority (Rail Safety and Standards Board Limited, 2003). In addition, safety critical alarms should be clearly distinguishable from other alarms and audible indications should be used only for safety critical failures and/or failure rectification or where it is necessary to alert the user to take some action.

It has been suggested that design criteria could improve the probability of alarm detection as well as producing an appropriate response (Rail Safety and Standards Board Limited, 2003). The design criteria should include the level and the form of the alarm, be informative with some indication of the appropriate action to take and take into consideration people's limited capacity to discriminate between auditory signals. They should not lead to an excessive number of simultaneous alarms, which could rapidly degenerate into noise. Related alarms should also be prioritised, to prevent confusion and avert the risk of wasted time and alert fatigue due to a low priority alert being dealt with prior to a more important one (Cash, 2007). Non-safety audible alarms should also be kept to a minimum, the guidance suggested (Rail Safety and Standards Board Limited, 2003). The extent to which such ideas have been implemented in ePMR systems is unknown.

1.8.2 Alert modality

The mode of the alert must be determined once the alarm logic has been specified, whether it should be auditory or visual or a combination of both modalities. Each of these modes has its advantages and disadvantages. Auditory alerts are not common in community pharmacy practice environment because of the potential to add to workplace noise or cause distractions (Peryer et al., 2005). Although there are

occasions when auditory alerts or a combination of both auditory and visual alerts can help prevent a hazardous medication safety incident, there are limits to how far the concepts can be applied in the community pharmacy practice environment. The corollary of this is that visual alerts are the most used alerts in ePMR systems used in community pharmacies.

1.8.3 Placement of alerts

Effective visual alert design involves onscreen alert placement for easy detection by the operator of the system, providing appropriate information in the alert, clear visibility, alert prioritisation with hazard and urgency matching using features such as colours, icons, fonts and signal words, thereby reducing the potential for confusion with other alerts (Edworthy et al., 2000; Hellier and Edworthy, 2006). However, Wogalter and Mayhorn (2005) argue that the static nature of colour and most other physical design factors of traditional printed warning labels are passive and unhelpful because in some contexts, an unchanging stimulus can lead to habituation, meaning that the stimulus has become less effective at attracting people's attention. It was suggested that stimulus change is required and one of the potential ways to achieve that is to illuminate a warning when someone encounters a hazardous situation. This would also help to focus people's attention at the right time and slow the habituation process in some situations.

1.8.4 Features of alerts

In clarifying the role of warnings, Edworthy (1998) highlighted two things, the iconic - '*attention-getting*' features of warnings such as signal words, colour, font size, and the use of icons and their informational elements, which are texts that elaborate upon the attention-getting information. The author argued that each plays a different part in warnings but the iconic elements have a significant influence on a user's decision to demonstrate safety behaviour.

The study by Hellier et al. (2000b) aimed to determine the arousal strength associations with warning signal words in the UK population. The authors suggested using signal words in mapping the situation that is implied by a warning with the

hazard that is inherent in the referent - '*hazard mapping*'. They used different experiments to demonstrate that signal words have a range of meanings. They also investigated three categories of words with the result that the hazard dimension is a dominant feature of the words used. The words relate to behaviour – stop, don't, careful; the characteristics of the product – hot, toxic, explosive and the information that is being presented - important, reminder, note warning. Results from the study suggest the need to match hazards and signal words correctly so that a signal word is not used so often that it dilutes the effect of the word and the hazard severity implied by the word.

In another experiment involving 982 adults and 547 children (Hellier et al., 2000a), the authors found that the mean hazard ratings assigned by both groups of participants decreased from danger to warning to caution in that order. Signal word and age did not have any significant effect on hazard ratings. However, the authors noticed that the 15-24 year olds failed to differentiate between the signal words in terms of the hazard they implied consistently. Female participants also tended to assign higher hazard ratings to all of the signal words than male participants. Current safety alerts in ePMR systems suggest that far too little attention has been paid to this subject of hazard mapping. This means that pharmacy staff may fail to differentiate between the levels of hazard implied by safety alerts they receive during the dispensing process, perhaps also resulting in automatic behaviour towards alerts or alerts being ignored. These results suggest that arousal strength associated with warning signal words and hazard mapping should be taken into consideration to ensure that alert design promotes effectiveness.

1.9 Summary

Community pharmacists play and will continue to play a key role in reducing and preventing medication errors, clinical hazards and potential adverse drug events. However, iatrogenic harm and death from drug treatment is still occurring, even when evidence shows they could have been prevented. This is increasing health care costs and adding to the National Health Service's burden of delivering quality health care. If medication safety is to improve in the community, it is vital to exploit every opportunity that pharmacy professionals and the information technology systems

they are using can offer. However, this requires understanding the current situation in terms of the functionality of ePMR systems, focusing on safety features and alerts.

This chapter has presented an overview of the medication use process. It highlighted the importance of medication safety at various stages of the process but with a special focus on the dispensing stage. Furthermore, the chapter focused on the issue of medication errors, why they happen and the associated costs. A description of relevant research that has been done in both primary and secondary care was presented and a conceptual model of error causation was examined to show that there are barriers to making errors and to highlight the human factors approach to patient safety.

The literature is silent on how electronic patient medication record (ePMR) systems are being used to achieve medication safety in England. No study has explored the effectiveness of the safety features in ePMR systems. Studies examining the perspectives of stakeholders about ePMR systems and safety alerts are fragmented whilst the few studies that tested the performance of ePMR systems focused mainly on drug-drug interactions. Even then, the existing studies need updating to reflect current day practice.

The ultimate goal of having and using ePMR systems in practice is to ensure that systems are delivering on error and clinical hazard reduction, keeping patients out of hospital and increasing workforce effectiveness. In spite of an acknowledgement of this important role played by ePMR systems in community pharmacy, no study has looked at the effectiveness of safety features and alerts at the point of dispensing. The safety performance of current ePMR systems, how pharmacists use ePMR systems and manage alerts in community pharmacy practice in England are also not known. This research and the remaining chapters of this thesis fill the aforementioned gaps in the body of knowledge on ePMR systems.

Chapter 2

Research design and methodology

2.1 Introduction

Research is a systematic process of inquiry to find answers to problems of interest (Peh and Low, 2013). Social research as a part of that systematic process of inquiry, seeks to describe a social problem and explain the reasons behind the description to provide potential solutions to the problem (Grix, 2010). The general design and methodology for this research are presented in this chapter while the full details of the conduct of the individual studies are presented in the respective chapters 3, 4, 5 and 6.

2.2 Research design

Blaikie (2010) identified three main phases of social research: planning, execution and reporting. He suggested that depending on the kind of research, these phases may be separate and followed in that order or may blend into each other. Based on his approach to research design, the following five concepts were adopted in this research: research questions, research purposes, research strategies, research paradigms and research methods. This research focuses on their assumed meanings and application.

2.2.1 Research questions

Research questions guide the research. These are the questions to be answered in this research. Each type of question, such as, 'what' and 'how', produces a specific type of knowledge.

The first research question, addressed in chapter 3 is, 'What is the evidence for the effectiveness of safety features and alerts in electronic patient medication record (ePMR) systems at the point of pharmacy order entry?' The second research question, addressed in chapter 4 is, 'What are the views and experiences of key stakeholders concerning ePMR systems, their safety features and alerts?' The third research question, addressed in chapter 5 is, 'How do electronic patient medication record systems perform at the point of pharmacy order entry?' The fourth and last research question addressed in chapter 6 is, 'How do pharmacists and pharmacy staff use ePMR systems and manage alerts during the dispensing process?'

2.2.2 Research purposes

Research purposes identify the type of knowledge a researcher wishes to generate, such as descriptions and explanations (Ritchie and Ormston, 2013). Social research can have several purposes: to explore, describe, explain, understand, predict, change, evaluate and assess impacts (Blaikie, 2010). A researcher can pursue just one or a number of these purposes in sequence.

This thesis focuses on the first four purposes of research mentioned above. For example, the purpose of the exploratory study was to develop an initial description and understanding of stakeholders' perceptions of ePMR systems' functionality focusing on safety features and alerts. The descriptive aspects of the research sought to provide a detailed account of the characteristics of the pharmacies and pharmacy professionals who took part in the ethnographically informed observational study. The explanatory aspect accounted for the patterns observed in ePMR system use and alert management, including the attitudes and behaviour of participants. It involved establishing the elements and factors that are responsible for the way users perceive and manage alerts at the point of dispensing. Understanding grows from reasons given by participants for their actions.

2.2.3 Research strategies

Research strategies are described as ways of knowing or finding out about the social world or the logic used to generate new knowledge (Blaikie, 2010; Ormston et al., 2013). They are ways of answering the research questions.

According to Blaikie (2010), the four logics of enquiry that social researchers employ to answer research questions are inductive, deductive, retroductive and abductive research strategies.

Rubin and Rubin (2012) described inductive or '*bottom-up*' strategy as building explanations from the ground up, based on the data. It is exploratory and aims to establish descriptions of characteristics and patterns. Existing concepts or theories guide the analysis framework, search for associations and explanations.

Broad theories and hypotheses drive deductive or '*top-down*' strategy. Theories or existing concepts determine the analysis framework, search for associations, the explanations and systematic testing of their implications (Rubin and Rubin, 2012; Spencer et al., 2013).

Retroductive strategy endeavours to identify underlying mechanisms that may have led to the patterns in the data, working back from the data obtained, to a possible explanation (Blaikie, 2010).

Abductive strategy involves uncovering meanings based on an interpretation of the collected data. It attempts to give the most suitable and possible justification for the data, develop a theory and elaborate the theory, iteratively.

This research employed the inductive approach to provide understanding of the functionality of ePMR systems, focusing on their safety features and alerts. The findings were then linked to the research questions and evidence from the literature.

2.2.3.1 Ontology and Epistemology

In order to understand the various ways of finding out about the social world, a researcher needs to know about ontology, which denotes the nature of social reality to be investigated. The researcher also needs to know about epistemology, which refers to what constitutes valid knowledge and how this can be obtained (Ormston et al., 2013). Both ontology and epistemology are important components of the research strategy because the ontological and epistemological assumptions that a researcher has influence the choice of methodology and methods employed in answering the research questions.

2.2.4 Research paradigms

Research paradigms incorporate particular ontological and epistemological assumptions, including one or more of the research strategies earlier mentioned. They refer to the belief system that guides the way people do things, providing the methodological and theoretical contexts within which research is conducted (Blaikie, 2010).

2.2.4.1 Positivism

An objectivist ontology suggests that there is a single objective reality and this can be measured without bias using a deductive, theory-testing approach and standardised instruments. The goal is a universal truth that is always true under specified conditions (Rubin and Rubin, 2012). This ontology underpins positivism and is the basis for quantitative research. With positivism, there is a clear theoretical focus for research from the beginning. The researcher is able to retain control of the research process and data is easily comparable. The limitations of this paradigm include difficulty in making changes to the direction of a study once data collection has begun, and weakness in understanding social processes and meanings people attach to social phenomena.

2.2.4.2 Interpretivism

Interpretivism emphasises interpretation and observation in understanding the social world (Ormston et al., 2013). A subjectivist ontology underpins interpretivism. It suggests that people perceive reality differently, based on prior experience, knowledge and expectations, which in turn affects what people see and how they interpret what they find (Rubin and Rubin, 2012). Interpretivism emphasises multiple realities and subjectivity of what we know because direct measurement of multiple realities is problematic. Data collection is often laborious, data analysis can be complex and challenging and clear patterns may fail to emerge from the data. Despite the associated problems, the approach is favoured in ethnographic studies and in-depth interviews because it is always contextual and facilitates understanding of '*how*' and '*why*' of a research inquiry.

2.3 Research methods

Methodology is defined as the general principles behind research (Hall et al., 1996). It outlines the research design process, choice of methods and the justification for their selection in relation to the research project. The two main research methodologies are quantitative and qualitative methodologies. The philosophical basis for quantitative methodology is positivism. This is often used for distinguishing between quantitative and qualitative research although it has been suggested that such categorisation may be overly simplistic because each approach represents a different way of thinking about the social world and often involve some elements of the other (Blaikie, 2007; Holliday, 2007).

Methods on the other hand can be described as the techniques or procedures that are used to collect and analyse data (Hall et al., 1996; King and Horrocks, 2010). In selecting a particular research method, the researcher intentionally or unintentionally accepts their intrinsic methodological assumptions about the nature of the social world, what they believe as valid knowledge and how they think this knowledge can be obtained (Hall et al., 1996; King and Horrocks, 2010). The nature of this research suggested that both quantitative and qualitative methodologies were relevant in describing the data obtained from this research and in answering the research questions posed.

2.3.1 Choice of study sites

As suggested by Rubin and Rubin (2012), the choice of sites and cases should be based on the following four reasons: relevance to the research questions, ability to gain access, opportunity to test explanations and ability to help the researcher decide the extent to which any findings apply elsewhere.

There are several stakeholders with interests in the provision of pharmaceutical services and clinical decision making in community pharmacies. Each stakeholder group has its own distinctive and valued perspectives on medication safety. The choice of sites was naturally, where these stakeholders were located for the convenience of participants. These sites included health care organisations (community pharmacy organisations), health care industry (knowledgebase creators, system suppliers and legal experts) and health care policymaking organisations (the Department of Health, National Health Service Connecting for Health, National Patient Safety Agency and the Pharmaceutical Services Negotiating Committee). Appropriate cases for the interviews, were members of the stakeholder groups with experience of community pharmacy practice and ePMR systems, including their safety features and alerts.

In the case of the ethnographically informed observations to understand how community pharmacy professionals use ePMR systems and manage alerts during the dispensing process, community pharmacies were the appropriate sites because that is where ePMR systems are mostly used. Relevant cases were community pharmacies in the Nottinghamshire area of England that agreed to participate in the study.

2.3.2 Population and sampling

Population

Participants for the qualitative interviews were community pharmacy professionals including pharmacy superintendents, community pharmacists and dispensers; health care policy makers, legal practitioners, ePMR systems' software vendors and knowledgebase creators in England. For the ethnographically informed observational

study, participants were individuals involved in medication dispensing in community pharmacies in the Nottinghamshire area of England including pharmacists, pre-registration pharmacists and dispensers.

Sampling

The specific nature of this research dictated the choice of sampling strategy. Selection of individual participants and community pharmacies for this research followed the purposive sampling technique. It involved selecting participants with knowledge of the area of investigation and ability to provide detailed and relevant information about the subject of enquiry.

2.4 Data collection

2.4.1 Data collection: Interviews

Interviews may be conducted in various ways, formally or informally (for example, conversational interviews). They may also take the form of life histories (oral history interviews), feminist methods and focus groups (Patton, 2002; Rubin and Rubin, 2012) and may be:

- Structured - Participants are asked the same questions using the same words and in the same sequence
- Semi-structured - Participants are asked a pre-determined set of questions to ensure that the same information is obtained from participants but there is much flexibility. The interviewee does not have to follow the sequence in which the questions are listed
- Unstructured - Questions are not pre-arranged but are allowed to develop during the course of the interview thus allowing for spontaneity

The choice of interview method in this research was between individual interviews and group interviews ('*focus groups*'). Although focus group data can be analysed at participant or whole group level, the approach was not suitable for this research for the following reasons:

- It was difficult to get a mutually convenient date, time and location for all the stakeholders to attend focus group meetings because of varying individual schedules and locations

- The total cost of holding 6-8 sessions was prohibitive given the limited resources available for this research

Individual interviews avoid these problems (Smith, 2010) and were selected for the purpose of data collection in this research. The interviews took place at mutually convenient locations and times. These interviews were audio-recorded where possible or manually documented in the field notes and then transcribed verbatim. Where interviews were audio-recorded, any extra information was captured in the researcher's field notes. Debriefing took place at the end of each interview and any new emerging information was audio-recorded where possible or written in the field notes.

2.4.2 Data collection: Ethnographically informed observations

Ethnography is a qualitative research methodology that allows social researchers to collect data in context, directly in the natural practice setting. This is done primarily by watching participants, and recording their behaviour and response to specific situations in practice or through one-to-one interviews. The essence of observation in the context of this research is the naturally occurring behaviour regarding the use of ePMR systems and management of safety alerts, which takes place in the community pharmacy setting.

Observations were conducted in two phases: the first phase focused on the safety performance of ePMR systems, while the second phase concentrated on the use of ePMR systems and alert management. The observational sessions took place at a mutually agreed and convenient time. The researcher took notes during the observations. These notes were completed immediately after each period of observation to ensure that important information was not missed out or forgotten. Reflective interviews were conducted with pharmacy professionals involved in the second phase of the observational study immediately after each period of observation. These interviews were documented in the field notes.

2.4.2.1 Role and impact of the observer

A researcher using observation to gather data can do so as a participant (the researcher takes part in the activity) or non-participant (the researcher watches but does not take part in the activity). The researcher can assume one of the following four roles, depending on the degree of participation and observation (Cohen et al., 2007).

Participant

i. The complete '*participant-observer*' observes but is not identified. Ethically, the conduct of this kind of observation is regarded as deceptive.
ii. The '*participant-as-observer'* participates fully in on-going activities and is recognised by other participants as an observer.
iii. The '*observer-as-participant*' is recognised by other participants as an observer but participates in the ongoing activities only partially.

Non-participant

The '*complete observer*' strictly observes throughout the period of observation. The complete observer is identified but does not take part in any of the ongoing activities.

My role for the purpose of the empirical studies was mainly as a '*complete observer*' but where this was not possible, with minimal participation in the required activity ('*observer-as-participant*'), for example, the system assessment in chapter 5.

2.5 Quantitative data analysis: Descriptive statistics

Descriptive statistics can make research data more understandable by helping recipients of the information to construct a correct image of the data and the people, events or objects they relate to conceptually. The first step in choosing an appropriate descriptive statistical technique involves recognising the type of data. In this thesis, I have used the following types of descriptive statistics: categorical and numerical data (Pripp, 2013).

2.5.1 Categorical data

Data that can be grouped into categories are called categorical data. These can be divided into three based on the type of variable:

Nominal data are comprised of categories but with no clear order or rank. The values belonging to the data can be assigned codes, which are simply labels. For example, an alert could be coded as 0 if it is a pop-up alert or 1 if it is presented in an alert box or 2 if it is presented on a separate screen. These can be counted but they cannot be ordered or measured.

Binary data are data obtained from measurements that can only be grouped into two mutually exclusive groups (also called '*dichotomous data*'). This type of data can be reported in the form of '*yes*' or '*no*'. For example, the production of alerts during observations was reported as '*yes*' when an alert was produced or '*no*' when no alert was produced.

Ordinal data are data that are presented by their relative order of magnitude. For example, the severity of drug interaction alerts could be described as minor, medium, or severe interactions.

2.5.2 Numerical data

Numerical data are values that are measurable on a scale. There are two types of numerical data, discrete data and continuous data.

D*iscrete data* can take only integers (no decimals). An example is the number of times each participant took part in the observational sessions, such as 1, 2 or 3.

Continuous data are measured on a scale but can be expressed with decimals (Pripp, 2013). One example is the length of the interviews, such as 0.3 hours and 0.7 hours.

2.5.3 Summarising data

Examples of descriptive statistics used to summarise data in this research include:

- Frequency counts
- Percentages
- Measures of centrality such as mean, median and mode
- Measures of variability such as standard deviation, variance and range

2.5.3.1 Frequency counts

Frequency counts indicate the number of times something occurred. For example:

- System S4 produced alerts for four of the 12 scenarios
- Four of the eight participating pharmacies were using the same ePMR system

Sometimes, frequency counts may suffice. They can also serve as a base for other calculations, such as percentages.

2.5.3.2 Percentages

Percentages are used for expressing information as part of a whole. The percentages for the examples in section 2.5.3.1 above are:

- System S4 produced alerts for 33 percent of the scenarios
- Fifty percent of the participating pharmacies were using the same ePMR system

They are useful for showing relationships and comparisons between categories. For example:

- One hundred and seventy-seven (2.9 percent) of women in the '*intervention group*' were dispensed at least one medication from category D or X compared with 276 (5.5 percent) women in the '*usual care group*' (comparing intervention group to usual care group)

They are also used for classifying values into categories arranged in order of size or magnitude ('*frequency distribution*').

2.5.3.3 Measures of centrality

The measures of centrality summarise and describe what is typical for a set of data. These are mean, median and mode.

Mean

The arithmetic mean, commonly called the average, is the result obtained from dividing the sum of a set of numeric values by the number of the included values. It has been suggested that if data distribution is highly skewed, the mean may not be a good estimate of the central location of data because it can easily be affected by extreme observations (Yu and Afifi, 2009).

Median

This is the value at the midpoint of a series of numeric data ordered from the lowest to the highest. In a situation where there are even numbers of measurements, the average of the two middle values is taken as the median. Using the median helps researchers to avoid the influence of extreme values in a dataset (Lee, 2009; Yu and Afifi, 2009).

Mode

The mode represents the most commonly occurring value in a dataset.

2.5.3.4 Measures of variability

The measures of data variability are usually variance, standard deviation and range, which express the spread of the data or variation in the data.

Variance

Variance is a measure of the spread of the data in the sample. It is the mean of the squared differences from the mean.

Standard deviation

The standard deviation is the square root of the sample variance. It gives an indication of the average distance of data points from the mean.

Range

The range is a measure of the spread of the measured values. It is obtained by calculating the numeric difference between the smallest and the largest value in a dataset. For example, the difference between the shortest and the longest time spent interviewing participants. A greater range implies a wider spread of data values in a dataset than a smaller range (Lee, 2009). However, the presence of outliers ('*missing data*' and '*extreme observations*') may give a misleading impression of the variability of the data as only two data points are used to make the estimate.

Interquartile range

The quartile is a term used to describe each part of a set of data, which is divided into four equal portions, similar to a quarter. The interquartile range signifies the middle 50 percent of a set of data, where the bulk of the values lie. It is used to measure the spread of the values in a dataset from the mean. The smaller it is, the more clustered the data points; the higher it is, the more spread out the data points are around the mean.

2.6 Qualitative data analysis: Thematic data analysis

Qualitative data is often voluminous and unwieldy, often consisting of several components and overlapping topics. Gathering such data and subsequent analysis to obtain findings require time and resourcefulness. The process of analysis is iterative and when done systematically, prevents data loss and preserves context.

Grounded theory approach is useful for developing theories, but it could be time consuming and could make management of large volume of data difficult because every segment of text would need to be analysed (Guest et al., 2012). It was therefore, not suitable for this research. Phenomenological data analysis is another potential analytical approach. However, the approach focuses only on human experiences (which may be subjective) and may not be systematic. For the aforementioned reasons, both approaches were considered unsuitable for analysing the data from this research. Thematic analytical approach was adopted because the data informs and guides the analysis, not existing ideas or frameworks. Thematic analysis has been defined as a process for identifying, analysing and reporting patterns of meanings

(Braun and Clarke, 2006; Guest et al., 2012; Spencer et al., 2013). Illustrative quotes are used to support data interpretation, which is grounded in the data. It is also the choice analytical approach because of its flexibility, systematic nature and the exploratory nature of this research. The patterns of meanings were discovered by analysing the texts of the interview transcripts (Patton, 2002). This involved identifying emerging concepts from the data in the initial stages of the analysis and giving these concepts appropriate labels to describe them. Concepts with closely linked meanings were grouped into themes and themes with similar meanings were grouped into categories.

With a Framework (Spencer et al., 2013), it was then possible to look across the qualitative data in a matrix (case-based analytical approach - see Figure 2.1), a column (theme-based analytical approach - see Figure 2.2) or a combination of both approaches (Framework approach - see Figure 2.3), facilitating data management, display and interpretation.

Working with the qualitative data in this way provided a good opportunity to understand participants' shared experiences and observed behaviour through the researcher's interpretation of the data.

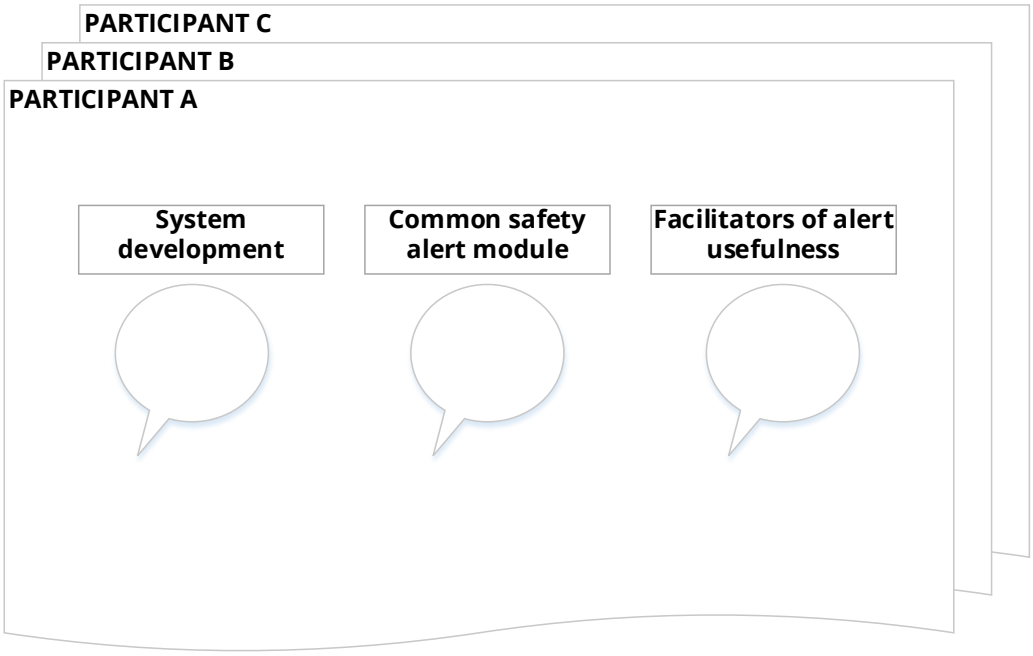


Figure 2.1. Case-based analytical approach



Figure 2.2. Theme-based analytical approach

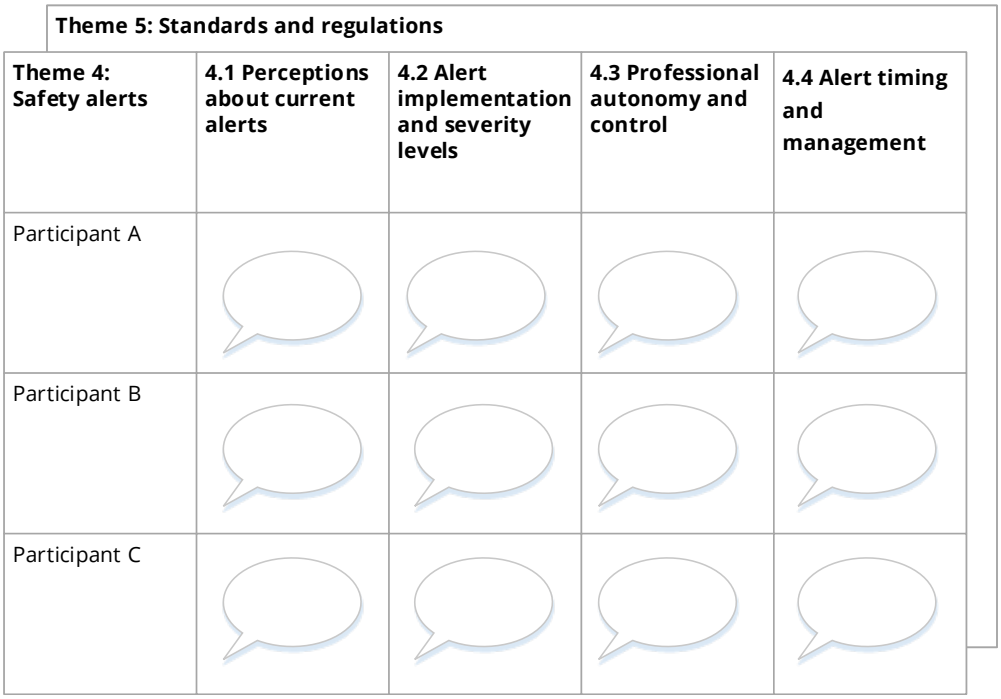


Figure 2.3. Framework approach with individual cases in rows and themes in columns

NVIVO version 10 was used for data management in this research. The software offered text search, code and retrieve, graphic display functions and Framework matrix to facilitate cross-sectional analysis of data.

2.6.1 The analytical process

The analytical process was a two-step process of data management, and abstraction and interpretation (Spencer et al., 2013).

Data management

The aim of data management was to reorder and combine fragmented data, reduce data volume and prioritise data in terms of the research questions posed. Data management and interpretation can be concurrent or sequential. Framework follows the sequential approach, resulting first in data ordering to facilitate interpretation.

The five stages of data management:

a. ***Familiarisation with the data***

This involved reading the interview transcripts and listening to the audio recordings, to understand what people were saying that was relevant to the research questions posed. This process was followed by identification of any recurrent or interesting topics in the text using a cross-sectional approach.

b. ***Construction of an initial thematic framework***

After familiarisation with the data, a thematic framework with headings for organising participants' views, experiences or behaviour was created. This began with reviewing the list of possible topics, which the researcher refined and sorted into themes and subthemes.

c. ***Indexing and sorting***

The initial thematic framework created above was used to label large pieces of similar data, which belonged together ('*indexing*'). After the process of indexing, the data were '*sorted*' or compared to bring together similarly indexed data appearing throughout the entire dataset.

d. ***Reviewing data extracts***

This step involved exploring other possible ways of organising the data to ensure a more coherent grouping. It involved modification of the initial thematic framework to ensure data coherence and to ascertain that important themes were not missing from the framework.

e. ***Data summary and display***

This was the final stage of data management, an additional step in the data management process facilitated by an analytic tool called 'Framework' (Spencer et al., 2013). It involved summarising what each participant said about a particular theme and displaying data by theme and by participant, in a matrix. This enabled across case and within case analysis of the qualitative data.

2.6.2 Abstraction and interpretation

This stage of the analytical process involved:

a. ***Describing the data*** began with developing categories to identify the range of things that people were saying about a particular theme or subtheme ('*descriptive analysis*'). This was followed by labelling the data in an interpretive way to capture the vital meaning ('*coding*') of the data, to describe and explain phenomena, and to address the central research questions.

b. ***Data linkage***

   Data linkage involved identifying how various parts of the data were connected and linking back to the literature, the professional field, policy or theory. Subsequently, association between links that have emerged during the process of data management or links with the literature were then explored to see what patterns emerged.

c. ***Explanation***

   This aimed to establish the reason an event happened and why data associated together in a particular way. Explanation may be explicit, based on reasons given by participants or implicit, based on the underlying logic inferred by the researcher based on participants' intentions, expectations or situational factors (Spencer et al., 2013).

2.6.3 Terminology: Code and coding

Saldaña (2013) described a code as '*a word or short phrase that symbolically assigns a summative, salient, essence-capturing and/or evocative attribute for a portion of language-based or visual data.'* The process of coding is an attempt to fix meaning, enabling the organisation and grouping of data with similar characteristics. In the early stages of data management in this research, coding was called '*indexing*' (Spencer et al., 2013), signposting to interesting bits of data rather than representing some final argument about meaning (Seale, 1999).

2.7 Research ethics

Informed consent

Participants provided informed consent on an official consent form before being allowed to participate in the studies. The researcher and the '*participant*' both signed and dated the consent form. Participants received a copy of the completed consent form while the original copy was retained in the study records. Participants were told that they were free to withdraw from the study or withdraw consent, during or after participating in the study without prejudice.

Ethical consideration

Participants were informed about the ethical consideration and confidential handling of data before being allowed to participate in any of the studies. They were provided with details of the relevant studies and explanation where required. Participants also received appropriate study information sheet and had a minimum of one day or a maximum of seven days to decide whether to participate in the study to which they had been invited. The names of participants, ePMR systems, system vendors and any other data that could lead to participants or ePMR systems being identified were anonymised.

Ethical approval was obtained from University of Nottingham Medical School Research Ethics Committee (please see appendix A.2 for a copy of the ethics letter). National Health Service (NHS) permission was obtained from NHS Nottinghamshire County and NHS Nottinghamshire City Primary Care Trust (PCT) (please see appendix A.3 and A.4 for the NHS permission letters for NHS Nottinghamshire County and NHS Nottinghamshire City PCT respectively).

2.8 Validity and reliability of data

Validity is an indication of the extent to which a study measures what it sets out to measure or the amount of value that can be placed on the study findings. Researchers use various means to assess the validity of their research. For example, they can link their findings with existing evidence or appraise the quality of the research. They also assess research validity by examining the nature of the

association between available evidence and the explanations, and any plausible interference with the research process that could have confounded the results (Hall et al., 1996).

Validity can be described as internal validity or external validity. The former examines if an independent variable is truly responsible for any variation observed in the dependent variable while the latter concerns generalisability to a wider population. Studies that use small samples such as interviews and observation may be criticised for being low in internal validity but high in external validity because they take place in real social settings and can therefore be generalised to other people in such a setting.

Reliability refers to the degree of consistency of the results obtained if applied by other researchers or repeatedly by the same researcher under standard conditions (Silverman, 2011). It is unlikely that two researchers would get the same data if they interview the same person or observe the same event at the same time or at different times, using a non-structured schedule. This creates a problem for reliability.

2.9 Summary

This chapter highlights the vital methodological building blocks of this research and the choice and justification for the research design. The outline presented above sets the boundary for the data analysis. In addition, this chapter clarifies the methods that were used to obtain the required data and how data interpretation was done to answer the research questions and achieve the aims of the research.

Chapter 3

The evidence for the effectiveness of safety features and alerts in electronic patient medication record systems at the point of pharmacy order entry: A systematic review

3.1 Introduction

This chapter presents a systematic review of the effectiveness of safety features and alerts in ePMR systems at the point of order entry in primary and secondary care pharmacy settings. The definition of the word '*effectiveness*' as used here is the extent to which the intervention (alert or warning) produced beneficial outcomes under ordinary day-to-day use and situations (Khan and Royal Society of Medicine, 2003).

3.2 Aim of review

The review aimed to systematically explore the literature and synthesise published evidence about the effectiveness of safety features and alerts in electronic PMR systems at the point of pharmacy order entry, in primary and secondary care. Systematic review of the literature provides an opportunity to methodically identify relevant studies, appraise their quality and combine all empirical evidence that meets pre-specified eligibility criteria to answer the given research question. It is also useful

for minimising bias, in order to produce reliable findings that can be used to inform decision making (Higgins and Green, 2011).

3.3 Methods

3.3.1 The review team

It is possible for an individual to conduct a review alone. However, experienced reviewers and practitioners are often involved in the review process for many reasons. Screening of titles and abstracts by two or more independent reviewers helps to ascertain that the review question is correctly formulated prior to starting the review process and ensures reliability of the review process (Khan and Royal Society of Medicine, 2003). The researcher Oluwagbemileke Ojeleye (OO), Anthony Avery (AA), Vaibhav Gupta (VG) and Matthew Boyd (MB) conducted this review. OO, AA and MB designed the review. OO developed the search strategy with support from AA and MB. OO ran the searches. OO and VG reviewed the titles and abstracts. OO, AA and MB reviewed the full papers to determine which to include in the review. OO abstracted the data from the included studies and this was checked by MB. OO and VG assessed the risk of bias for the included studies. All authors were involved in the interpretation of the findings.

3.3.2 The review process

The review was undertaken in five stages:
Step 1 – Framing and stating the question for the review
Step 2 – Systematic identification of potentially relevant studies
Step 3 – Assessing quality of the studies
Step 4 – Summarising the evidence, and
Step 5 – Interpreting the findings

Step 1: Framing and stating the question for the review

The review question had four elements: the population being studied, the interventions, the outcomes and the study types.

Box 3.1. Framing a structured question for the systematic review

Question components	
The population	Studies of electronic patient medication record (ePMR) or pharmacy order entry (POE) systems used in pharmacies were included while studies about other clinical information systems and clinicians other than pharmacists were excluded.
The interventions	The interventions included alerts, warnings or prompts about safety of medications appearing on ePMR systems during POE or at the point of dispensing in the pharmacy. Examples are drug-drug interactions, therapeutic duplications and allergy alerts. Drug Utilisation Review (DUR) alerts generated for non-safety reasons were excluded.
The outcomes	The outcomes of interest included changes in medication error, morbidity, mortality and adverse drug events. Studies with outcomes not related to safety were excluded.
The study design	Studies that used comparative design to evaluate the effectiveness of ePMR systems' safety features and alerts at the point of POE were included. For example, randomised controlled trials and before-after studies. Studies published only in abstract form were excluded.

Note: The question components above were adapted from Khan and Royal Society of Medicine (2003)

The above four elements were used to formulate a structured review question and in generating the inclusion and exclusion criteria to be employed in selecting relevant articles to be included in the review (Table 3.1). The review question was, 'what is the evidence for the effectiveness of safety features and alerts in electronic patient medication record systems at the point of pharmacy order entry?'

Table 3.1. Inclusion and exclusion criteria for selecting articles for the systematic review

Inclusion criteria	Exclusion Criteria
• patient medication record or pharmacy order entry (POE) systems • Alerts about safety of medications, appearing on ePMR systems during POE • Outcomes of interest included changes in medication error, morbidity, mortality and adverse drug events • Study used comparative design	• Study not about patient medication record systems or pharmacists • Studies with alerts generated for non-safety reasons or contained ineligible interventions • Studies with outcomes not related to safety were excluded • Ineligible (non-comparative) study designs or abstracts only

Step 2: Systematic identification of potentially relevant studies

Database search

Literature searches were conducted in MEDLINE (1946 to March 2012), EMBASE (1980 to March 2012), Inspec (1969 to March 2012), International Pharmaceutical Abstracts (1970 to March 2012), PsycINFO (1806 to March 2012) all on the OvidSP platform; and CINHAL (1986 to March 2012) on EBSCOHOST platform. Secondary sources, such as the online database Pharmacy Abstracts, COCHRANE database, website of the Agency for Health Care Quality (AHRQ), reference lists of included studies and Internet search engines were also searched.

Search strategy

Keywords for the searches included alerts, warnings, decision support, pharmacist, pharmacy, expert system, pharmacy information systems, PMR systems and POE. The search terms were initially used in MEDLINE and then tailored to other databases. Citations were retrieved into Endnote X5. The details of the search protocol used for identifying studies in MEDLINE are provided below. The modified search protocols used for other databases are in appendix B.1.

Box 3.2. Search protocol used for identifying studies in Medline

1. (e adj2 prescrip$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, unique identifier]
2. (elec$ adj prescrip$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, unique identifier]
3. exp Drug Labeling/
4. Drug Utili?ation Review.mp. [mp=title, abstract, original title, name of substance word, subject heading word, unique identifier]
5. Pharmacy Information System$.mp.
6. Patient Medication Record$.mp. [mp=title, abstract, original title, name of substance word, subject heading word, unique identifier]
7. (Pharmacy or Pharmacies or Pharmacist$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, unique identifier]
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. (Safety adj2 (Alert$ or Feature$ or Alarm$ or Warning$ or Prompt$)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, unique identifier]
10. (Over?rid$ adj25 Alert$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, unique identifier]
11. Reminder System$/
12. alert$.mp.
13. Decision Support$.mp.
14. exp Decision Making, Computer-Assisted/
15. exp Drug Dosage Calculations/
16. 9 or 10 or 11 or 12 or 13 or 14 or 15
17. 8 and 16

Note: The above list excludes duplicates. Any article that appeared in two or more databases was allocated to the first database with the most accurate and complete information in the order that the databases appeared in the list. Line 17 above was the final search strategy.

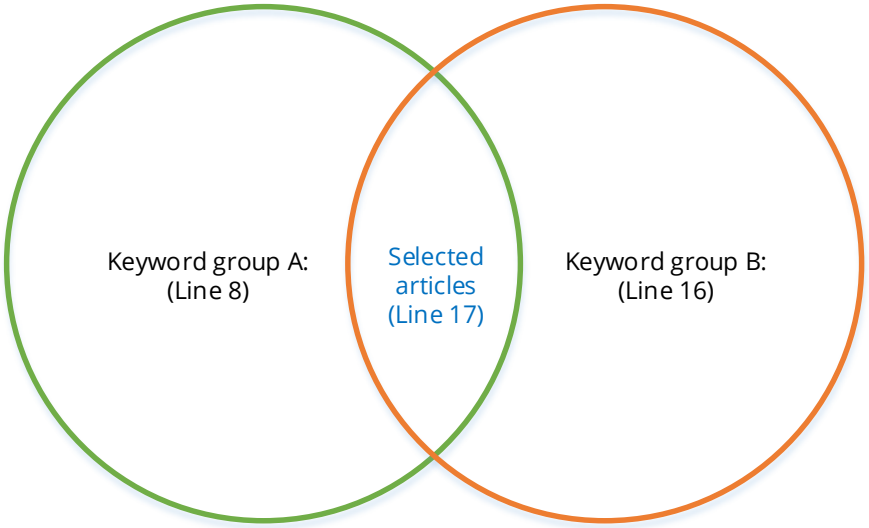


Figure 3.1. Logic for selecting articles

Selected articles contain keywords or related terms such as patient medication record systems, prescriptions and pharmacy (see Box 3.1, lines 1-7 and Figure 3.1, keyword group A) and safety features, safety alert and decision support (see Box 3.1, lines 9-15 and Figure 3.1, keyword group B).

Study selection

Two reviewers (OO and VG) independently screened the title and abstract of articles to identify studies that met the inclusion criteria. In the interest of efficiency, as soon as an article was identified for exclusion, no further assessment was made on the article. The full articles for the potentially relevant studies were retrieved and reviewed by three reviewers (OO, MB and AA) based on study type, study design, participants, settings, eligible outcomes and interventions. A hierarchical template (see Table 3.2) was used to exclude non-relevant studies. No language restrictions were applied to the study selection process.

Table 3.2. Hierarchical template for study eligibility and identification*

Category	Eligible characteristics	Y/N
A. Population	Patient medication record (PMR) or Pharmacy order entry (POE) systems used in pharmacies	
B. Interventions	Alerts (including Drug Utilisation Review (DUR) safety alerts), warnings or prompts appearing on electronic PMR or POE systems during pharmacy order entry, which notify users about potential clinical hazards, errors or harm to patients	
C. Study type	Comparative study designs such as randomised controlled trials, pre-post intervention design studies (historically controlled), time series analysis	

* Does article meet at least one criterion from each of the categories above? Accept if yes, reject if no.

Data extraction

Data from the articles included in the synthesis were extracted on to a pre-designed template (please see appendix B.2 for a copy of the pre-designed data extraction template). Two reviewers (MB and AA) verified the extracted data. Discrepancies were resolved by discussion until consensus was reached.

Reporting framework

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) was developed to help authors improve the reporting of systematic reviews and meta-analyses (Moher et al., 2009). A modified version of the 27-item checklist was adopted for reporting this review to ensure that only items that were essentially relevant to the review were retained. Non-relevant items omitted from the original checklist include systematic review registration number and results of any meta-analysis done.

Step 3: Assessing quality of the studies

Two reviewers (OO and VG) independently assessed the quality of the included studies using the Cochrane Collaboration's risk of bias tool (Higgins et al., 2011). The studies included in the synthesis were assessed individually for selection bias, allocation sequence concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias.

3.4 Findings

Step 4: Summarising the evidence

Retrieved articles

The literature search returned 6,084 articles: MEDLINE (1,034), EMBASE (1,703), Inspec (132), International Pharmaceutical Abstracts (1,026), PsychINFO (35) and CINAHL (2,154). None of the secondary sources searched returned any relevant article. After removing duplicate articles, two reviewers (OO and VG) reviewed the 5,086 remaining titles and abstracts. A total of 5,031 citations did not meet our inclusion criteria and were excluded. One article could not be located (Hardy et al., 1970). The full articles of the remaining 54 citations were retrieved and based on the set criteria, 49 articles were excluded (please see appendix B.3 for the list of excluded articles), leaving five eligible articles for the review. The excluded articles were not about PMR systems (11), contained ineligible interventions (2) or study designs (34) or were abstracts only (2). Figure 3.2 shows the summary of this information. Table 3.3 is a summary of the characteristics of the included studies and the key findings.

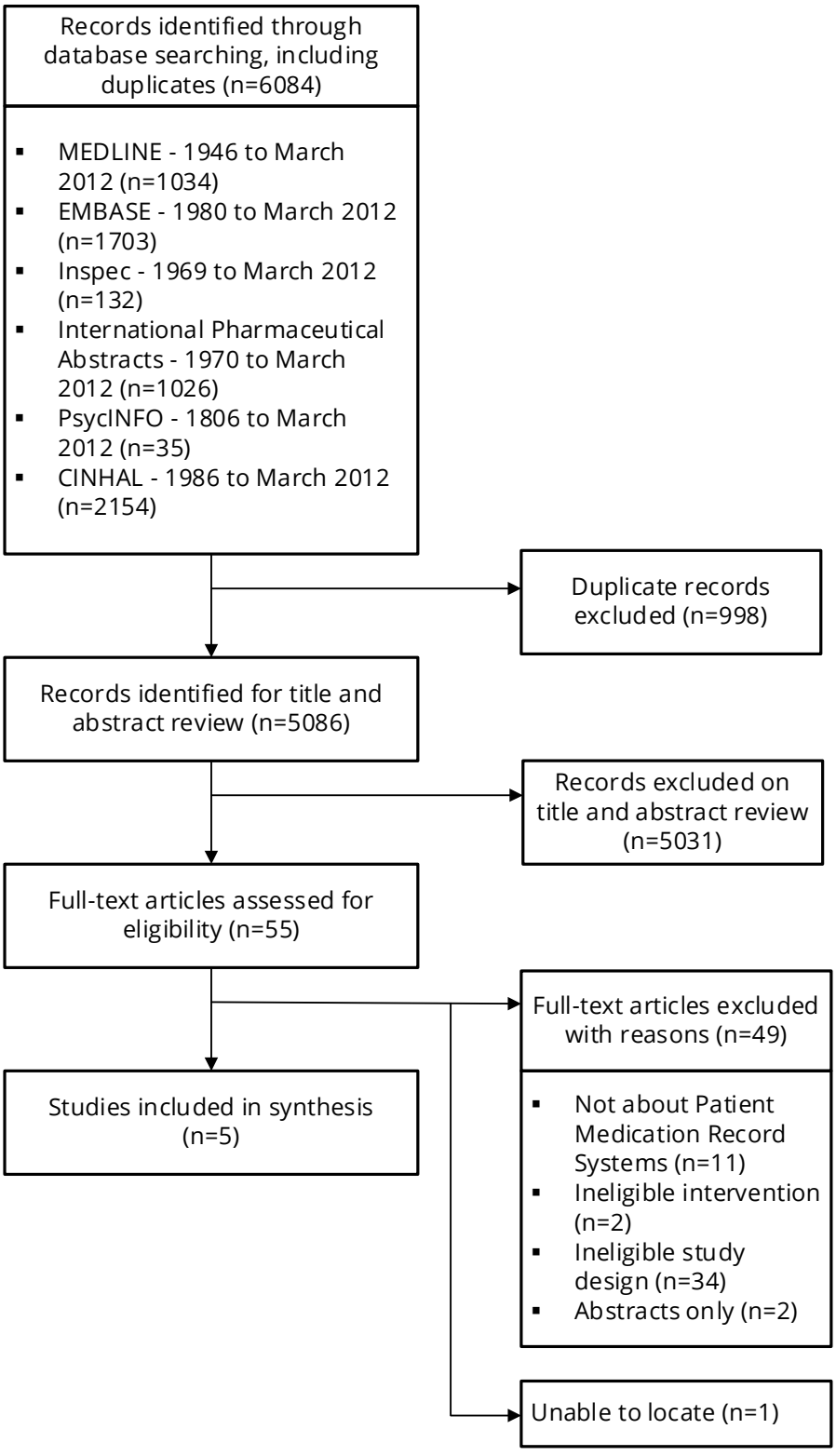


Figure 3.2. Flow diagram of included and excluded studies

Description of included studies and baseline characteristics of patients

All the studies were from the US. Four of the five studies were conducted in an integrated care facility (Health Maintenance Organisation (HMO)) (Humphries et al., 2007; Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011) and one in a hospital (Mansour et al., 2010). Three studies were randomised controlled trials (RCTs) (Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011) while two were before-after intervention design studies (Humphries et al., 2007; Mansour et al., 2010). The publication dates for the studies ranged from 2007-2011. Four studies (Humphries et al., 2007; Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011) compared baseline characteristics of patients but only one explicitly reported no significant differences in patients' characteristics at baseline (Bhardwaja et al., 2011). The five studies evaluated alerts to contraindicated prescribing in the following categories: drug-drug (Humphries et al., 2007), drug-laboratory (Mansour et al., 2010; Bhardwaja et al., 2011), drug-pregnancy (Raebel et al., 2007a) and drug-age (Raebel et al., 2007b) (see Table 3.3).

Description of alerts

Drug-drug interaction alerts (Humphries et al., 2007) are generated when administration of a drug with another drug is likely to result in an increase or decrease in the action of either drug or result in an adverse effect that is not normally associated with either drug. Drug-lab alerts (Mansour et al., 2010; Bhardwaja et al., 2011) are generated when administration of a drug requires close monitoring of certain physiological parameters both before and after administration. A drug-pregnancy alert (Raebel et al., 2007a) is generated when administration of a drug is contraindicated in pregnancy while a drug-age alert (Raebel et al., 2007b) relates to a warning to the user of the system that certain medications might be contraindicated based on the age of the patient. All four types of alerts are similar to alerts normally found in computerised prescriber order entry (CPOE) systems but are notified to the pharmacist or user of ePMR system at the point of POE or dispensing.

Table 3.3. Characteristics of studies and alerts included in the systematic review

Study	Bhardwaja et al. (2011)	Raebel et al. (2007a)	Raebel et al. (2007b)	Humphries et al. (2007)	Mansour et al. (2010)
Study Type	RCT	RCT	RCT	Before-After study (no other control)	Before-After study (no other control)
Intervention	Drug-lab alert (Renal)	Drug-pregnancy alert	Drug-age alert	Drug interaction alert (Contraindicated)	Drug-lab alert
Setting*	HMO	HMO	HMO	HMO	Large teaching hospital (504-bed)
Country	US	US	US	US	US
Outcomes measured	Proportion of medication errors in drug selection or dosing of targeted drugs	Primary - proportion of pregnant women dispensed a FDA category D or X medication. Secondary - total number of first dispensing of targeted medications	Proportion of first dispensing of medications on the targeted medication list	Proportion of patients co-dispensed two critically interacting drugs	Proportion of hospitalised patients requiring treatment for hyperkalaemia
Alert functionality**	Medication decision guide printed in lieu of the prescription label	Prescription label not printed until pharmacist intervened	Prescription label not printed until pharmacist intervened	Prescription label not printed, pharmacist must consult with the prescriber	Pop-up alert about patient's last reported potassium level
Improved primary outcome (Yes/No)	Yes	Yes	Yes	Yes	Yes
False positive alerts reported (Yes/No)	Yes	Yes	Yes	No	No
Note	Pharmacists were trained to ensure effective communication of the reason for alerts and the rationale for drug changes to prescribers and patients. All activities were documented electronically	False positive alerts led to early cancellation of study. Specific intervention guideline and patient counselling script were developed	Intervention guideline and patient counselling script were developed. Pharmacists were required to complete an intervention note in the system before being able to print the prescription label. Notes were reviewed retrospectively	Pharmacists could bypass the alert. They documented their activities electronically. Decision support guide was developed to aid them in interpreting and resolving critical alerts. Scripted conversations were used to explain to patients the reason for alerts and the rationale for medication changes	Pharmacists documented their response to the alert electronically. They could override the alert but were required to provide a reason for doing so. Number of alerts was retrieved through a report generated by the information technology pharmacist. Inconsistent response to the alert led to the development of a hyperkalaemia treatment guideline

Notes: FDA – Food and Drug Administration. RCT – Randomised Controlled Trial. * HMO – Health Maintenance Organisation. ** Alert generated when a trigger medication order was entered.

Risk of bias in included studies

The results of the risk of bias assessment of included studies are as shown in Table 3.4. Of the five studies reported, three (RCTs) used computer generated sequence for randomisation and reported blinding of staff and participants to group assignment consequently, selection and performance bias were judged as '*low risk*.' Allocation concealment was judged as '*unclear risk*' because it was not reported in any of the trials. The two before-after studies were judged to be at '*high risk*' of selection, sequence concealment and performance bias.

Assessment of the primary outcome measure was conducted in one of the studies and the study (Bhardwaja et al., 2011) was judged to be of '*low risk*' of detection bias. The risk of detection bias for the remaining four studies was judged as '*unclear*.' All the studies were judged as having a '*low risk*' of attrition and reporting bias. The three RCT studies reported false-positive alerts (alert wrongly indicating the presence of the attribute for which the alert should trigger) (Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011). It was not clear if this could have introduced other biases into the studies so the risk of other bias was judged as '*unclear.*' The two before-after studies were also judged to be of '*unclear risk*' of other bias because of the study design used.

Table 3.4. Risk of bias summary*

Study	Bhardwaja et al. (2011)	Raebel et al. (2007a)	Raebel et al. (2007b)	Humphries et al. (2007)	Mansour et al. (2010)
Allocation (selection bias)	Low	Low	Low	High	High
Allocation sequence concealment	Unclear	Unclear	Unclear	High	High
Blinding of participants and staff (performance bias)	Low	Low	Low	High	High
Blinding of outcome assessment (detection bias)	Low	Unclear	Unclear	Unclear	Unclear
Incomplete outcome data addressed	Low	Low	Low	Low	Low
Free of selective reporting	Low	Low	Low	Low	Low
Free of other bias	Unclear	Unclear	Unclear	Unclear	Unclear

* Please see appendix B.4 for the full risk of bias assessment

Analysis of intervention effect

The interventions had positive effects on the outcomes of interest in all the five studies.

Drug-drug interaction alert

In the study by Humphries et al. (2007), the primary outcome measure was the proportion of patients co-dispensed two critically interacting drugs. A 29 percent relative reduction in dispensing of critically interacting drugs was reported in the post-alert period, an average of 11.8 co-dispensing per 10,000 prescriptions over the entire post-alert period versus the pre-alert period (24.7 per 10,000 prescriptions). The overall rate of co-dispensing in the eight targeted drug pairs dropped sharply from 21.3 to 14.7 per 10,000 prescriptions ($p = 0.0125$), representing a relative decrease in co-dispensing of 31 percent (95 percent confidence interval CI -49.5 to -12.7) from the month before alert was implemented.

Drug-laboratory alert

The results of the two studies: a RCT (Bhardwaja et al., 2011) and a before-after study (Mansour et al., 2010) featuring drug-laboratory alerts indicated that the intervention had a beneficial effect. The primary outcome in the RCT was the proportion of medication errors defined as target drugs that should be avoided or were dosed inappropriately (Bhardwaja et al., 2011). In the usual care group, 1,853 patient-drug combinations were dosed inappropriately (49 percent, 95 percent CI 47–50 percent) out of 3,796. In the intervention group, 1,195 patient-drug combinations were dosed inappropriately (33 percent, 95 percent CI 31–34 percent) out of 3,639 which was significantly lower than the usual care group ($p<0.001$). With regard to target drugs that required a dosage adjustment, 1,291 of the 3,231 patient-drug combinations in the usual care group were dosed inappropriately (40 percent, 95 percent CI 38–42 percent). In the intervention group, 893 (27 percent, 95 percent CI 25–28 percent) out of 3,335 patient-drug combinations were dosed inappropriately, which was considerably lower than the usual care group ($p<0.001$).

In the before-after study by Mansour et al. (2010), the alert warned pharmacists about potassium level above the set value and was tracked 63 times over the 3-month alert implementation period with the largest number of cases occurring during order entry for a potassium supplement (20 cases) and an angiotensin converting enzyme (ACE) inhibitor (34 cases). Prior to implementation of alert, 48 hospitalised patients were treated for hyperkalaemia but only 14 cases of hyperkalaemia required treatment after the alert was implemented, a statistically significant decrease in ADEs related to hyperkalaemia ($p < 0.001$).

Drug-pregnancy alert

The primary outcome of the study by Raebel et al. (2007a) was the proportion of pregnant women dispensed US FDA category D (evidence of fetal risk exists but therapeutic benefits can outweigh the risk) or X (evidence from human or animal studies suggests that risks to the fetus outweigh therapeutic benefits) medications. One hundred and seventy-seven (2.9 percent) women in the intervention group were dispensed at least one medication from category D or X compared with 276 (5.5 percent) women in the usual care group ($p < 0.001$).

Drug-age alert

The intervention by Raebel et al. (2007b) led to a decrease in the proportion of patients aged 65 and over that were newly prescribed potentially inappropriate medications. In the analysis of dispensing of medications to patients aged 65 and over, 543 of 29,840 (1.8 percent) patients randomised to the intervention group were newly dispensed at least one potentially inappropriate medication compared to 644 of 29,840 (2.2 percent) in the usual care group ($p=0.002$; 16 percent relative risk reduction).

False alerts and alert management

The three RCT studies reported problems of false-positive alerts (Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011). In the study by Bhardwaja et al. (2011), false-positive alerts determined as the proportion of alerts that had a creatinine clearance level > 51 ml/min on medical record review, reduced from 32 percent to 0.5 percent one year after the alert was changed to drug-specific creatinine clearance cut-off. The study by Raebel et al. (2007a) was terminated early because of false-positive

alerts due to misidentification of medications as contraindicated in pregnancy and incorrect alert that patients were pregnant when not pregnant. In another study (Raebel et al., 2007b), alerts for excluded indications were considered to be false-positives but the authors did not indicate the extent of the problem.

Mansour et al. (2010) noted a lack of consistency in the way pharmacists managed alerts during the first few months following alert implementation. The management team then developed a hyperkalaemia treatment guideline to assist pharmacists when deciding whether to dispense the prescribed medication and what suggestions to give to the prescribing physician when calling regarding the hyperkalaemia alert.

In four of the studies, the medication alerts functioned by preventing the prescription label from being printed until the pharmacist had actively intervened to determine whether to dispense the prescription or contact the prescriber (Humphries et al., 2007; Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011). In one study, a decision support guide was printed for the pharmacist in lieu of the prescription label (Bhardwaja et al., 2011). In another, a pop-up screen appeared onscreen, warning pharmacists about patients' last reported potassium level, including a reminder regarding where to document the response to the alert. Pharmacists could override alerts as long as the reason for the override was explained and the action documented (Mansour et al., 2010).

3.5 Summary of key findings and discussion

Step 5: Interpreting the findings

Five studies were identified and each of these showed that using alerts in ePMR systems resulted in reductions in dispensing of critically interacting drug; contraindicated drugs based on age or pregnancy; adverse drug events related to hyperkalaemia and medication errors. Thus, ePMR systems have the potential to improve patient safety by processing personal and clinical information along with medication records to provide patient specific advice. This can help to reduce the risks that may arise from taking prescribed or non-prescribed medicines. Nevertheless, while the interventions had a positive effect on primary outcomes in the identified studies, there were instances of false alerts and discrepancies in alert management.

Comparisons with other studies

Results from this review support some of the findings from other studies that have looked at the performance of safety features in ePMR systems. It has been suggested that only known hazards and not theoretical possibilities should be listed as contraindicated drug-drug combinations and that alerts are taken seriously if users are alerted to situations that require action in order to improve patient safety (Hatton et al., 2011). This is a plausible explanation for why the evaluated studies focused on specific instances and groups of drugs.

False alert, intervention guideline and alert management

Problems of false-positive alerts appear to be prevalent (Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011). This may be because of programming deficiencies (Hazlet et al., 2001), lack of required information or misclassification of alerts (Raebel et al., 2007a), among other reasons leading to reduction in specificity and sensitivity of alerts. False alerts and alerts that are not clinically significant may result in pharmacists ignoring clinically important alerts (Magnus et al., 2002; Weingart et al., 2003; Indermitte et al., 2007a). It has been reported that pharmacists often override alerts generated about drug-drug interactions which they receive (Murphy et al., 2004) and information and advice from the alerts are often ignored (Murphy, 2005; Murphy, 2006). One of the studies was terminated early because of false-positive alerts (Raebel et al., 2007a).

Active collaboration between pharmacists, physicians and other stakeholders is necessary when developing target medication lists and indications for which an intervention should occur. Collaborative development of intervention guidelines and implementation of the intervention are also some of the ways in which stakeholders can work together to make alerts more relevant, useful and effective in practice thereby guaranteeing the success of any intervention programme.

Linking patient medication records with other clinical data when possible, expands the scope of checks for clinically hazardous situations at the point of POE (Raebel et al., 2007a; Raebel et al., 2007b). However, inadequate knowledge of the safety

features available or necessary in ePMR systems coupled with lack of training on how to deal with some alerts can result in sub-optimal use of the safety features in ePMR systems. Development of treatment and alert-response guidelines, decision support guides and training offer an opportunity to ensure consistency in the way pharmacists intervene or manage alerts.

Evaluating cases where pharmacists did not adhere to alert recommendations and the reasons for non-adherence would be useful in fine-tuning alerts during future developments to enhance the effectiveness of safety alerts and prevent over-alerting and alert fatigue. Results from observational studies have shown that pharmacists override or ignore alerts. In one observational study, pharmacists expressed lack of trust in the clinical significance and accuracy of the alert information consequently leading to alerts being overridden (Murphy, 2005). Indermitte et al. (2007a) found that alerts for potential drug interactions were graded as severe, moderate and minor. Pharmacists could select the levels of alerts to flag in the system during order entry leading to variation in the systems and overriding of alerts that were considered insignificant. User friendliness of the systems can be increased by customisation but may also lead to variation in the systems (Abarca et al., 2006). Lack of an agreed standard and consensus about severity levels for drug interactions is a major reason for the variation which exists between ePMR systems as vendors have no choice than to rely on their preferred or own classification system (Saverno et al., 2011).

The evaluated safety features were created based on the needs of the respective institutions and a desire to prevent adverse events in various clinical situations. This suggests that safety features embedded in ePMR systems in different domains may not always be the same. This has implications for commercial ePMR systems, as they may not always meet the needs of users in every domain without customisation. Although customisation of alerts is not often possible in primary care pharmacy practice, users of ePMR systems should be alerted about 'never events' involving medications and could be given the option to choose what they would like to be alerted about to prevent over-alerting and automatic behaviour towards alerts.

Strengths and limitations

One of the strengths of this systematic review is that it has been undertaken in a rigorous way. It is also the first one in the field, to have examined the effectiveness of safety features and alerts in ePMR systems at the point of POE in primary and secondary care.

There are some limitations to this review. Although pharmacists managed all of the alerts in the studies evaluated in this review, this may not be a true reflection of what happens in pharmacy dispensing practice. For example, some pharmacists allow their support staff to override alerts up to a certain degree of severity without an initial discussion with the pharmacist. In such circumstances, it is essential to keep the pharmacist informed about important alerts if someone else handles the prescription. There have been concerns that important interactions could be missed if dispensing staff do not alert pharmacists appropriately (Murphy et al., 2004).

Implications for policy and practice

One of the main purposes of pharmacy order entry is to provide a safety net to prevent medication errors and adverse drug events (ADEs) once a prescription has been issued (Nechvatal and Rice, 2004; Reichley et al., 2005). This systematic review provides evidence that alerts are useful for picking up medication errors and potential clinical hazards at the point of pharmacy order entry. From a policy perspective, it is important to consider strengthening regulations around the provision of safety features in ePMR systems. It is also important to ensure that such systems are designed in a way that maximises the likelihood of pharmacists taking appropriate actions. Increasing the specificity of alerts by taking into account individual patient context will help reduce the number of false alerts leading to alert bypass. From a practice perspective, it is important that pharmacists recognise the value of ePMR systems in preventing the dispensing of hazardous prescriptions and therefore pay attention to safety alerts even if over-alerting remains a problem for some time to come.

Further research

Although this review has provided some insight into the effectiveness of safety features and alerts in ePMR systems, it has also highlighted gaps in this subject area. The review did not identify any study that has evaluated the effectiveness of other safety features that may be found in ePMR systems such as screening for therapeutic duplication, allergies, adherence issues, excessive and sub-optimal doses, inappropriate prescribing and drug-drug interactions (non-contraindicated) at the point of POE. All the studies were from the US and none was from community pharmacy. The influence of various design features on user-acceptance of alerts is also unknown. These gaps in the literature need addressing.

The handling of alerts by migrant pharmacists and cross-sector pharmacists who often have to use ePMR systems that they may not be familiar with and the impact on practice is yet to be explored. Generating evidence in this area will help to promote understanding of the challenges faced by migrant pharmacists, to prevent error-promoting situations that may arise when using such systems.

More research needs to be done to investigate the impact of alert customisation and standards for ePMR systems and alerts on patient safety. Some alerts will not flag when prescriptions are dispensed from pharmacies that a patient does not use regularly if the relevant ePMR system does not have the historical medication record of that patient. The potential patient safety benefits from making information about medications prescribed to patients and other details such as patients' allergy status, available to the dispensing pharmacy at the point of order entry should be explored.

3.6 Conclusions

This systematic review shows that ePMR systems in conjunction with embedded safety features are effective in picking up and reducing potential problems and clinical hazards at the point of POE. There are, however, problems of false alerts and inconsistencies in alert management. Due to the low number of relevant studies, there was insufficient evidence to enable adequate comparison of the safety features evaluated across practice domains or studies. More studies are needed to assess the effectiveness of other safety features that are present in ePMR systems such as dosing guidance based on age, therapeutic duplication and drug-allergy screening. Design features associated with safety alert acceptance and effectiveness should be evaluated. Finding appropriate solutions to these problems is a challenge but it is of paramount importance to strengthen the safety net and to continue to prevent harm to patients.

Chapter 4

Understanding electronic patient medication record systems' functionality focusing on safety features and alerts: An exploratory study

4.1 Introduction

In chapter 3, the evidence for the effectiveness of safety features and alerts during prescription order entry at the point of dispensing was investigated. This chapter explores stakeholder perspectives on electronic patient medication record (ePMR) systems' functionality focusing on safety features and alerts. Topics to be explored include the design, functionality and choice of ePMR systems; safety features, alerts and alert databases; standards for ePMR systems and regulations; safety culture and user training.

4.2 Aim

This study aimed to explore stakeholders' knowledge and views regarding safety features and alerts in electronic Patient Medication Record (ePMR) systems, including any perceived inhibitors of their usefulness and development. The main research question was, 'What are the perceptions of stakeholders about ePMR systems' functionality focusing on safety features and alerts?' This was expanded into the following questions.

1. How do participants view pharmacists' role in the medication use process?
2. How do pharmacy owners choose the ePMR system to use in their pharmacies?
3. How do users learn to use ePMR systems?
4. What are the perceptions of participants regarding alerts in community pharmacy practice setting?
5. What account do pharmacists and other dispensing staff members give about how they manage alerts?
6. What are the opinions of participants regarding a common safety alert module?
7. What are the opinions of pharmacy professionals about alert categorisation?
8. How are ePMR systems evaluated by users?
9. Are participants aware of any standards and regulations governing the operation and administration of ePMR systems and alerts?

4.3 Methods

Sampling approach, sample size and justification

There is no universally agreed number of participants that can be regarded as enough for a qualitative study. It has been suggested that one participant ('*the person of interest*') may be all that is required in a qualitative study, but it may be necessary to continue interviewing if participants are providing different answers, subject to factors such as time and resources (Baker and Edwards, 2012). Participants were recruited using a purposive sampling frame (described in section 2.5), which consisted of people from various stakeholder groups with experiences of community pharmacy practice, ePMR systems, safety features and alerts. It was envisaged that a sample of approximately 30 participants who have knowledge of community pharmacy practice and processes would be sufficient to provide a range of perspectives and responses about the functionality of ePMR systems, focusing on safety features and alerts. This was due to limited number of participants in certain fields, such as patient safety policymaking and the numbers heading toward no new information being found.

Selection of participants

Inclusion criteria

- All pharmacy professionals including superintendent pharmacists, community pharmacists and dispensing staff practising in England with a minimum of three months experience of using ePMR systems
- Electronic patient medication record (ePMR) system vendors, drug database vendors, health care policy makers, and legal experts who have experience of and are involved in community pharmacy practice

Exclusion criteria

- Individuals under 18 years of age and anyone who could not give informed consent were excluded from this study

Pharmacy professionals were drawn from various pharmacy groups and sizes including independent pharmacies (one pharmacy), small chain pharmacies (2-4 pharmacies), medium chain pharmacies (5-25 pharmacies) and large multiple chain pharmacies (over 25 pharmacies) (Bradley et al., 2013). Health care policy makers were drawn from the following governmental and non-governmental agencies: Department of Health, National Health Service Connecting for Health (NHS CFH), National Patient Safety Agency (NPSA) and the Pharmaceutical Services Negotiating Committee (PSNC). The other group of participants were legal experts, drug database vendors and system vendors. The identification code for each quote was based on the respective participant's professional designation and the interview number, for example, '*System vendor (interview 30).*' An explanation of any abbreviation used by participants and featured in the interview quotes is given in square brackets. For example, *MST [a brand of modified release morphine sulphate tablets]*.

Development of interview guides

Semi-structured, broad and open-ended interview guides were developed in advance, through discussion with my supervisors, based on the aim of the study, information obtained from the literature and our collective practice experiences. The guides were individualised for each group of participants, such as pharmacy professionals (please see appendix C.5 for a consolidated version of the interview guides).

The interviews covered a range of topics related to ePMR systems, their safety features and alerts. Each guide contained a standard set of questions and was divided into three main sections. The opening section was used to gather information about participants' involvement with pharmacy and ePMR systems, as context for the specific topics participants would describe later in the interviews. The second section, explored participants' knowledge, views and experiences about the functionality of ePMR systems, focusing on safety features and alerts; training, regulations, standards and general oversight of electronic PMR systems in community pharmacy. The closing section offered participants the opportunity to state their views about the one thing they considered important to the future development and implementation of safety features and alerts in ePMR systems. It also provided the researcher and participants the opportunity to clarify any information from the interview and explore where possible, supplementary reactions by participants that may have arisen because of the interview.

Pilot test of interview schedule

Pilot interviews were held with two community pharmacists using the topic guide developed previously as a reminder to ensure that all the points of interest were covered during the interviews. The results of the interviews were discussed with my supervisors. The pilot interviews did not identify any problems to warrant any amendment to the interview guide. So, it was decided to include the pilot interviews in the analysis.

Interview process

Participants were interviewed between January and October 2012 using a semi structured open-ended interview technique to gain the most from participants. The interviews were conducted face-to-face or by telephone where a face-to-face meeting could not be arranged. Face-to-face interviews were conducted in settings chosen by participants using individualised interview guides (please see appendix C.5 for the interview guide) depending on participants' practice domain and subject to adaptation and change as the themes from the interviews evolved. The interviews were audio-recorded and transcribed verbatim. I transcribed 18 of the interviews and had the remaining 12 interviews transcribed commercially. All 30 transcripts were reviewed against the primary audio recordings to ensure accuracy of the interview transcripts

prior to analysis. The recordings and transcripts were anonymised and kept on a secure file storage server for research artefacts at the University of Nottingham.

Interviewer

As the primary researcher, I conducted the interviews and data analysis, under the guidance of my supervisors. Potential biases and expectations regarding several aspects of the study were discussed with my supervisors and documented to minimise their influence on the interviews and analysis.

Participant information sheet and consent form

Prior to the interviews, respondents received a letter of introduction (please see appendix C.2 for a copy of the letter of introduction) and an information sheet describing the study and its aim (please see appendix C.3 for a copy of the participant information sheet). Informed consent was also obtained from participants on a pre-specified consent form (please see appendix C.4 for a copy of the consent form).

Analytical approach

Data analysis took place concurrently with data collection. The interview transcripts were thematically analysed as described in section 2.6 using Framework approach (Ritchie et al., 2013). The technique of constant comparison was used to identify themes across the interview transcripts. NVIVO 10 software package was used for data management.

Participants' knowledge and views were explored in-depth regarding the functionality of ePMR systems, their safety features and alerts. In particular, participants' views about facilitators and inhibitors of ePMR systems and alert usefulness, what they perceived as their ideal characteristics and quality criteria were explored. In addition, how safety alerts are managed in practice, the impact of the organisational and institutional environment on community pharmacy safety climate and patient safety were sought.

Using Framework approach, detailed summaries of the individual cases and the themes were presented in rows and columns respectively. The summaries, coding and interview transcripts were shared with my supervisors for quality assurance checks. They were also used as a basis for discussion about what each interview revealed about participants' perspectives regarding ePMR systems, their safety features and alerts. A further quality assurance coding check was performed by a post-doctoral fellow with expertise in social shaping of information technologies and qualitative data analysis. The process involved checking that the raw data were sorted correctly into relevant domains and that the abstracted summaries and themes were appropriate and accurate. The post-doctoral fellow made suggestions for changes, which I evaluated and effected after consensus agreement with my supervisors. Some of the supporting quotes presented in this chapter are long but this helps to preserve the context of the issue being discussed.

4.4 Findings

Findings from the interviews show three main contexts in which ePMR systems, their safety features and alerts can be considered: user, technology and organisational environment. The user context is reflected in the form of concepts, such as the pharmacist's duty of care, competency, learning through reflection and training. The technology context is evident in concepts, such as evaluation of systems by users, facilitators of the usefulness of ePMR systems, perceptions about current safety alerts, alert implementation and severity levels, and professional autonomy and control. The organisational context refers to concepts, such as current standards and regulations; common safety alert module, safety climate and the choice of system (see Figure 4.1 for a diagrammatic representation of the themes). Although the 'safety alerts' theme is part of the central theme of ePMR system functionality, it is presented here as a separate theme because of the dominant nature of the subject in this thesis.

Table 4.1. Details of participants in each stakeholder group

Case Study Group	Stakeholder Groups*	Number of participants
	Pharmacy professionals	
	Locum pharmacists	**2**
	Employee pharmacists	**2**
1	Superintendent pharmacists (Independent)	**3**
	Superintendent pharmacist (Small multiple)	**1**
	Superintendent pharmacists (Large multiple)	**2**
	Dispensers	**3**
2	**Health care policy makers** (from DH, NHS CFH, NPSA, PSNC)	**5**
3	**Legal experts**	**3**
4	**Drug database vendors**	**4**
5	**System vendors**	**5**
Total number of participants		**30**

* Please see appendix C.1 for the full list of participants

Table 4.1 lists the five stakeholder groups and the number of participants in each group. Some pharmacy professionals in the sampling frame declined to participate due to time constraints. Recruitment of participants was limited to 30 participants because of limited resources, time available for collecting and analysing data, and number of participants in some of the sampled categories, such as ePMR system vendors and drug database vendors.

Participants had the following characteristics: 60 percent (n=18) was male; 83 percent (n=25) had personally used ePMR systems at some point in their careers and 57 percent (n=17) were actively using electronic PMR systems in their current role. All interviews lasted 17 to 82 minutes (mean = 40 minutes).

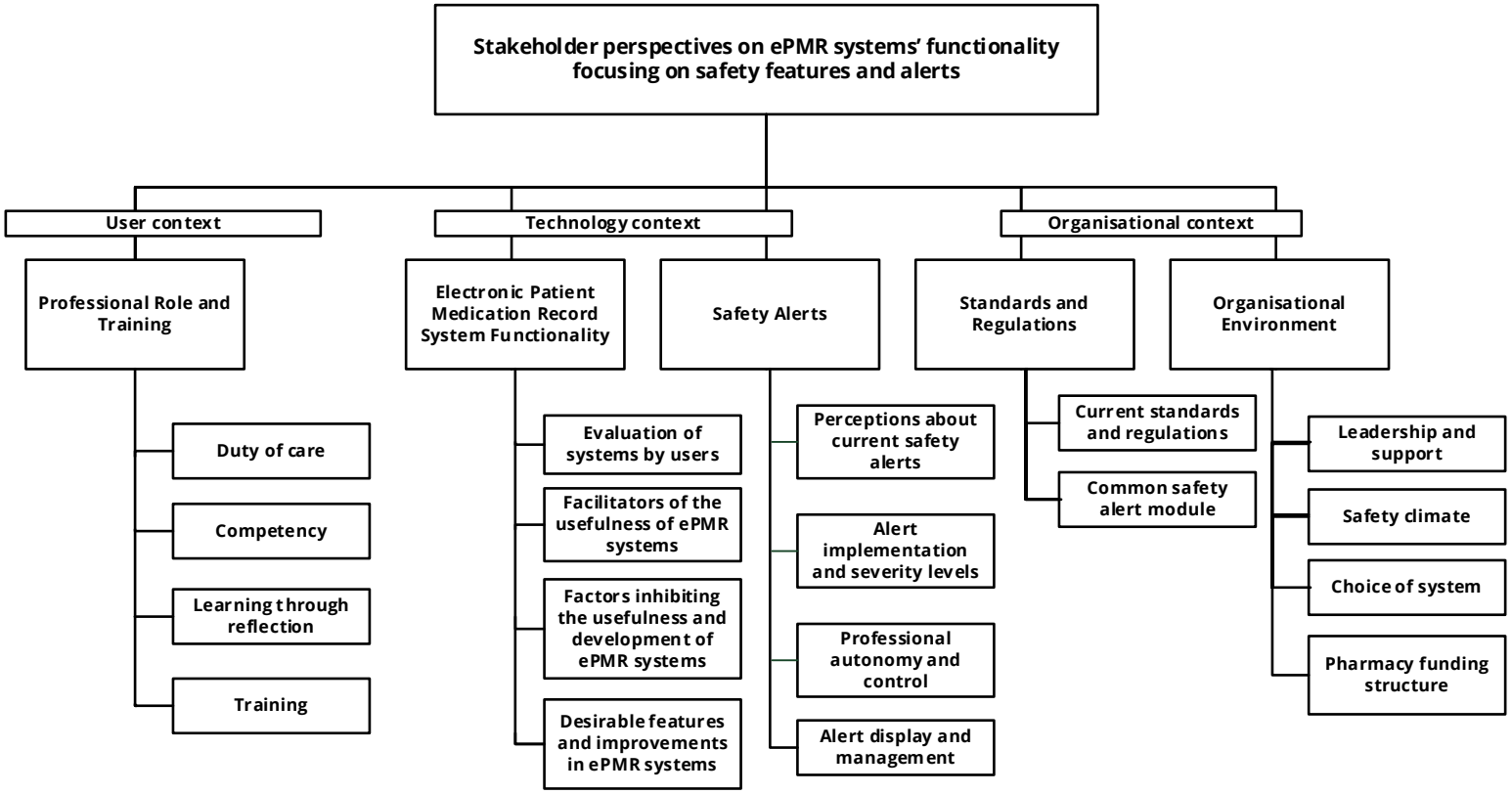


Figure 4.1. Themes from qualitative interviews on ePMR systems' functionality focusing on safety features and alerts

4.4.1 User context

The perceptions of participants about the role of pharmacists and factors affecting users' safety management performance in community pharmacies were captured in this section. The user context covers five different themes encapsulating the perceptions of participants about pharmacists' professional role, competency, training, punctiliousness and other user factors in safe medication practices and management.

Theme 1: Duty of care

Participants emphasised that pharmacists are legally obliged to safeguard patients and the public from harm while using pharmacy services or while in the care of pharmacy professionals and this sometimes requires them to use their professional judgement.

> *'I have run across surprisingly recently, cases where a pharmacist has said to me, 'what I did was absolutely fine because I dispensed what the doctor had written'…now, it may be that it's difficult to address that, through means of technology although…that was the case…where the pharmacist supplied a 100mg MST [a brand of modified release morphine sulphate tablets] when patient had previously not had…anything stronger than 10mg MST and so I think…that kind of thing at least could be addressed by an alert but…there's still a lot of room for it I think, getting the message across to pharmacists that they have to use their own independent judgement.'*
>
> Legal expert (interview 19)

It was suggested that clinical checks conducted by pharmacists should involve analysis of individual patient's medication record. However, as this may not always be the case, participants noted that potentially serious interactions and clinical hazards could be missed. A patient's medication record may be incomplete because people do not always use the same pharmacy for filling their prescriptions. As such, pertinent information required by the pharmacist for ensuring that a medication is suitable and safe for a patient may not be available. It is also possible that the prescriber had considered and had ignored alerts, or was not aware of alerts before issuing a

prescription. The pharmacist may not be aware of this situation but has legal and professional responsibility to confirm that the prescription is safe. Participants highlighted that pharmacy professionals often need to get extra information from other sources, such as the patient, patient representative or GP in order to ensure safety of dispensed medications.

Theme 2: Competency

Participants opined that ePMR systems and their safety features give a huge scope for safeguarding patients and improving patient care. However, users have to know what the systems can or cannot do, what safety features there are in the systems and how to use them effectively. A couple of times, safety features were referred to as security features. The drug interaction checker was the most common safety feature participants knew of.

Pharmacy professionals suggested that using ePMR systems efficiently could free up time for other pharmacy services and talking to patients about their medicines. It was suggested that inefficient use of ePMR systems could result in missed opportunities to save time on repetitive tasks and the opportunity to uncover potential patient safety issues. One participant suggested that those who use multiple ePMR systems might not be adequately familiar with them or know their full capabilities.

> *'….if you're a locum and you do use multiple IT [Information Technology] systems, you probably don't know each one intimately.'*
>
> Health care policy maker (interview 16)

Theme 3: Learning through reflection

Participants acknowledged that getting alerts during the dispensing process has benefits. However, some participants argued that it is more important to be punctilious when dispensing medications and reflect regularly on the tasks involved than relying on ePMR systems and alerts to ensure that medications are dispensed safely.

'… an analogy is probably…driving you know. You get all sorts of things coming up on the…on the screen perhaps but that doesn't absolve you from keeping your eyes on the road and avoiding the pedestrian that's right in front of you, you know? And if you had a warning come up saying there's a pedestrian right in front of you that probably wouldn't be very helpful, you know? You've still got to keep your mind on the job.'

Legal expert (interview 21)

Theme 4: Training

Some participants described the user-training programme as inadequate. These participants have had no formal training in using ePMR systems. Those who were fortunate enough to be trained said that the training was organised by their employers or delivered by system vendors when the system was first installed in the pharmacy. Other forms of training mentioned by participants include self-learning through trial and error; experiential knowledge gained from using other systems, the system operating manual and the system's the help function, and shadowing or learning from other users within or outside the pharmacy chain. They mentioned that training is reinforced by using the system regularly in practice.

There was repeated criticism of the quality of the training received by users. Participants said that they did not receive any specific training in alert management. They said that they use their clinical judgement and follow the guidance provided in their pharmacy organisation's standard operating procedures (SOPs).

'In all my time as a pharmacist, I have been shown the ropes…once and that was only because I happen to be working in a pharmacy when the software engineer turned up to change the systems over… and then I had a half hour training session on how the new system was different from the old and how to use the new system. Other than that, it's a case of sink or swim when you arrive in the morning.'

Pharmacist (interview 03)

Some participants said that the idea of mandatory training is good but it is better if training is recommended not mandated. They opined that if trainees do not put the knowledge gained into practice early on after the training, they may forget what they were trained on. In addition, trainees may not follow the training they received.

Time pressure, lack of protected training time and lack of a dedicated ePMR system for training were highlighted by participants as some of the factors preventing users from learning to use ePMR systems during work hours. It was suggested that installing electronic training modules on ePMR systems, making help facilities contextual and providing on-demand web-based training might help users become more proficient in using ePMR systems. It was proposed that training in the basic operation of various ePMR systems, human factors and risk management should be offered as part of future undergraduate training programmes.

Participants suggested that system vendors should provide the initial training because they designed and know how the data in the system was implemented and how the system could be used effectively. As part of that training, users should be informed about what the system can or cannot do.

> *'So, the system developer is taking the data and they're implementing it in a particular way and there's…more than one way of implementing these things. The training needs to reflect the way it's been implemented.'*
>
> Drug database vendor (interview 22)

System vendors stated that they offer an initial and on-demand training to users, face-to-face or via online video, onsite or offsite. Training materials and information are also available electronically and via paper guides, quick reference guides, operating manuals, release notes and the helpdesk.

4.4.2 Technology context

The technology context is reflected in participants' opinions about ePMR systems, safety features and alerts in areas, such as evaluation of systems by users, facilitators of the usefulness of ePMR systems and factors inhibiting the usefulness and development of ePMR systems. Also in concepts, such as desirable features and improvements in ePMR systems, perceptions about current safety alerts, alert implementation, alert display, alert management and severity levels, and professional autonomy and control.

Theme 1: Evaluation of systems by users

Some superintendent pharmacists of pharmacy companies reported that evaluation of the safety performance of ePMR systems in their organisations was sometimes reactive not proactive. They mentioned that they had no formal means of evaluating the performance of ePMR systems in their organisations. Rather, they use informal means such as insights obtained from incident investigations and feedback from dispensing staff and information technology (IT) experts.

A few of the superintendent pharmacists also said that the choice of systems on the market is limited and pharmacy owners often find it difficult to switch to a different supplier, so there is no impetus to carry out performance evaluation of ePMR systems prior to or after purchasing a system. They also pointed out that there have been no major incidents involving ePMR systems to warrant performance evaluation of ePMR systems

> *'We have a couple of pharmacists in the group who are…they're techie, they're into IT and they're interested in that side of the business…I rely on them a lot to advise me on how they're getting along…I mean at the moment I suppose we're very reactive rather than proactive in the respect of analysing whether the system is delivering our needs. We only really do anything about it after an event's happened…We don't have any way of formally doing that.'*
>
> Superintendent pharmacist (interview 07)

Theme 2: Facilitators of the usefulness of ePMR systems

Participants agreed that none of the current ePMR systems could be considered an ideal ePMR system because individual user requirements vary. However, they suggested characteristics they would expect an ideal ePMR system to have. These characteristics fall into two categories: structural and functional (please see appendix C.6 for facilitators of ePMR systems' usefulness suggested by participants).

The structural category is characterised by a fast, intuitive and efficient system, quick and legible information recall, user friendliness, uncluttered interface and ability to integrate with other clinical systems. The system should be modular, lightweight, interoperable; tailorable to the level of expertise of the user, use unified dose codes and comply with industry standards. It should provide referenced, evidence-based information; use colours, icons and text appropriately, possess tools to enable the system to learn and should be updated regularly.

> *'…an ideal PMR system would be where pharmacy is fully integrated into the rest of the primary care IT [Information Technology] structure, which predominantly would be the sharing of care records…a system that therefore knows the full entire record of the patient…'*
>
> System vendor (interview 27)

The functional category is characterised by in-built safety features and contextualised alerts, an intelligent and short pick list, and ability to minimise risks, such as the risk of selecting the wrong product. Additionally, the system should be able to generate automatic and on-demand reports, manage stock efficiently, record and manage clinical practice, capture the right record and the right amount of information.

> *'*Well *something which would have built-in safety features. That we could minimise the risk of selecting the incorrect product. It would be supporting, full of knowledge base for the end user. So would have lots of subtle…breaks in the system, which would identify possible errors. So it would be aware of common errors and would already be anticipating that pharmacists could make an error and then should be…and if somebody was to select that kind of product or use the system that way, I think I would expect it to highlight that and say, 'Do you really want to do this?'*
>
> Health care policy maker (interview 18)

Theme 3: Factors inhibiting the usefulness and development of ePMR systems

Participants were asked if they were aware of any factors inhibiting the usefulness of ePMR systems. In response, they highlighted several factors that they believed were making ePMR systems less useful than they could be (please see appendix C.7 for the inhibitors of ePMR systems' usefulness and development suggested by participants). One of the participants suggested that there is a misconception that repeat prescriptions are safe, so system operators often ignore safety warnings when dispensing repeat medications. It was also emphasised that sometimes, the fear of being blamed for medication incidents prevents users from trusting the decision support information presented by systems. One participant reported that system vendors often use terms and conditions to absolve themselves of liabilities in case of any software malfunction or inadequacy.

Furthermore, users expected the electronic prescription service (EPS) to be faster but some participants complained that this was not the case. For this reason, they said they often revert to processing medication orders manually. It was also highlighted that drug doses on electronic prescriptions were not translating properly in some ePMR systems. Lack of audit trail, copies of dispensed prescriptions and appropriate tools for recording clinical encounters and interventions also make the systems less useful as a safety tool and for dispensing. Participants said that they expected barcode scanning and checking of medications to be in widespread use because the required tool is already available. However, they expressed disappointment that this was not the case.

> *'…at the end of the day, the biggest numbers of errors that (I perceive) happen in pharmacy are people picking the wrong drugs and the barcode scanner stops you doing it.'*
>
> Superintendent pharmacist (interview 05)

Participants also highlighted several issues that are facing the development of ePMR systems. For example, system vendors and drug database vendors said that there is limited budget for developing ePMR systems. One of the drug database vendors also highlighted that legacy ePMR systems are incapable of handling the level of sophistication required by modern decision support systems. Historical medication records also present compatibility problems for newer computing architecture and standards for clinical terms, such as the Systematised Nomenclature of Medicine – Clinical Terms (SNOMED CT), they said. In addition, participants pointed out that failure to state the expected characteristics of an ideal ePMR system by relevant stakeholders and lack of foresight on the part of system suppliers are hindering development.

Theme 4: Desirable features and improvements in electronic patient medication record systems

Participants who use ePMR systems were asked to name other safety features they would like in ePMR systems to support them in their professional practice (please see appendix C.8 for the desirable features and improvements in electronic patient medication record systems advocated by participants). They suggested safety features to highlight large dose increases, similar patient records, drug-disease interaction, active dose checking and drugs. They also suggested features to highlight indications for prescribed doses, doses that lack corresponding indications, loading doses, unlicensed doses, paediatric doses and products that have previously been implicated in adverse drug events for patients. Hard stop alerts were suggested to prevent users from rushing through alerts when dispensing medications that are likely to harm patients. One participant suggested making such alerts audible if the responsible pharmacist is not the one receiving or reviewing the alert. However, this suggestion was not widely supported by the other participants.

Non-safety features that participants would like to see in the systems include features for printing compliance charts and medication administration records for ambulatory patients. In addition, features for getting product recall information into ePMR systems in real-time and sending electronic feedback to general practice surgeries about high risk alerts that were picked-up in the pharmacy were suggested. A feature for electronically recording and reporting patient specific errors and adverse events was also proposed.

Other improvements suggested by participants include presentation of the most important information at the top of the screen and only relevant information in alerts; correct identification of patients with vital details displayed throughout the dispensing process and standardisation of dosage syntax. In addition, they mentioned that repeat prescriptions should be differentiated in prescription queues, patients' medication histories should be displayed onscreen during the dispensing process and security of ePMR systems and data should be improved. Unique and universal login for pharmacy professionals, a central repository for alerts, medicines optimisation information and direct access to evidence-based resources were advocated.

Theme 5: Perceptions about current safety alerts

Participants suggested that pharmacists should acknowledge major alerts. They described the characteristics of their ideal alert: relevant to the patient context and flashes immediately if the potential risk of harm to the patient is significant. The colour of such an alert should match the urgency of the situation being warned about. The alert should be prominently displayed with severity levels based on a traffic light approach. It should fire at an appropriate time relative to the action that is taking place and be tailorable to the knowledge and expertise of individual users. It should inform the user what it is about, give concise information and briefly suggest a range of remedial actions that might be appropriate to take. The alert should have no scroll bar and should signpost the user to referential information if required, ask the user for management action, give the user the option to print the alert or review later and be auditable.

> *'…there could be a review of which warnings were presented at the point of labelling because you might have one person labelling and then another person actually checking, but obviously if the labeller has overridden a warning, the checker won't know.'*
>
> Health care policy maker (interview 18)

Pharmacy professionals mostly mentioned drug-drug interaction checkers when asked to name the safety features in ePMR systems. One participant reported that safety features in ePMR systems usually provide '*negative*' alerts such as drug interaction and adverse reaction alerts. She advocated introducing what she described as contextual and '*positive*' alert types, such as alerts to remind pharmacists to offer extra counselling to patients around weight, diet and other public health issues.

Participants' views about current alerts in practice were mixed. Some said they find alerts helpful in practice. One participant was keen to point out that alerts often remind him of important clinical information that he had forgotten about because of working primarily in a management role over the years. Some participants said that they have no expectation of alerts and do not rely on them.

> *'…the buck stops with me in terms of safety of any medication handed out…and you know, I'm not in a position to…say you know, I relied on the PMR, that's why XY and Z happened or that's why I missed XY and Z.'*
>
> Pharmacist (interview 03)

According to other participants, an alert could be a hindrance. For example, alerts suggesting monitoring of clinical parameters that are not normally carried out in community pharmacies were described as unhelpful.

> *'…our system would say that if someone's on a strong opiate, they should be prescribed a laxative. It doesn't help. I'm not a prescriber.'*
>
> Superintendent pharmacist (interview 10)

One participant said that although warnings can be a hindrance, he keeps them active in the system for training purposes.

Theme 6: Alert implementation and severity levels

Participants pointed out that differences exist in the levels of severity of alerts implemented in current ePMR systems and these differences often prevent effective management of alerts. One of the database vendors ascribed the differences to the data, the data structure and implementation in the system.

> *'…take drug interaction for instance…you could have 2…3…4…different levels of severity attached to the information itself…How that is handled by the system is a completely separate issue…The important thing is that those different levels are identified within the dataset…'*
>
> Drug database vendor (interview 22)

It was highlighted that the levels of severity of alerts in ePMR systems were not a priority for many pharmacy companies in the past because pharmacy companies simply wanted management systems. However, large pharmacy companies have developed their own criteria for determining the levels of severity of alerts that should be implemented in the ePMR systems used in their pharmacies.

> *'…when we came to thinking about safety alerts, the position we found was there was no expected norm. There was no agreed level of warnings in particular that that should be in the PMR [Patient Medication Record] system. So as a rule of thumb, we simply said, well, it ought to – it ought to flag up all the ones that are in the BNF [British National Formulary].'*
>
> Legal expert (interview 21)

System suppliers said that they often enforce display of all alerts to users even though they appreciate that it can lead to over-alerting, alert fatigue and alert bypass. They reported that they find it difficult to establish what the right information is from a community pharmacy perspective. They expressed difficulty in balancing the level of clinical knowledge and professional experience of potential users within alerts. They also highlighted that the implicit nature of the clinical information used for alert content development presents implementation challenges because of the difficulty in

determining the net effect of interactions between multiple ingredient products. Therefore, for clinical safety and legal reasons, they decided to display all alerts to users to ensure that they do not miss important alerts. Some participants disagreed with this approach urging that enforcement should only be at the level of alerts that users need to act on.

> *'Workflow is one the biggest issues so it's about getting the right information to the right person at the right time. Understanding who is the right person, is difficult because we don't actually know the person in that role. We don't know their level of ability, their level of knowledge, their level of familiarity with the patient, the level of familiarity with the drug that they're prescribing or dispensing. Taking all of those unknowns means that you have to err on the side of caution and do you then say well that's down to the user to filter out what they know and don't know…'*
>
> Drug database vendor (interview 25)

Participants suggested solutions to over-alerting, including customisation, giving users control of alerts and suppressing alerts for a limited time. Customisation was criticised as having the potential to lead to multi-tiered systems if custom features are not rolled out to other ePMR systems. Customisation was highlighted as best suited for speciality areas in secondary care than primary care. To address the problems of over-alerting in primary care, participants suggested contextualisation and adoption of strategies to improve alert specificity.

> *'I think the issue in primary care wouldn't be solved by customisation because the issue is the business of how well are we looking into the…patient record…how specifically is the medicines information in the patient context being put together…that wouldn't differ from practice to practice for any reason at all.'*
>
> Drug database vendor (interview 24)

System vendors pointed out that it is extremely difficult to achieve a balance of alerts that would not result in over-alerting when implementing alerts. One of the system vendors said that they implemented alert suppression in their system to reduce over-alerting. When a user gets an alert, that user has the option to suppress the alert so that it is no longer displayed for the medication and patient involved. Those who were not privy to the decision to suppress the alert will subsequently see a flag displayed onscreen indicating that there is a supressed alert in the specific patient's medication record.

One participant opined that alerts are not too many and users should not be allowed to suppress or switch off alerts under any circumstance.

> *'I just think that's a mistake waiting to happen…because no patient is the same. So there may be the odd freak occurrence where an interaction that you ordinarily let slide, in one particular instance you may not and if it's not being highlighted, then there is the potential to miss that.'*
>
> Superintendent pharmacist (interview 06)

The potential danger in displaying all alerts as pop-ups was highlighted by some participants. They suggested that users involuntarily become familiar with such alerts, and might begin to see them as part of the dispensing routine or a hurdle to overcome when dispensing medications. One system vendor's solution to this problem involves displaying alerts in a corner of the computer screen. However, the participant from this vendor company agreed with other participants that it is best to present alerts about serious harm to patients as pop-ups for effectiveness.

> *'…we know from experience, people don't read the information in the side corner of the screen…they'll only see it if it's flashed in front of their faces.'*
>
> System vendor (interview 30)

Participants reported that some alerts were poorly implemented. For example, the NPSA alert for safer use of oral methotrexate that triggers for every patient to whom the medication is dispensed irrespective of the dosage regimen. One participant said that a dosage check alert should not flag if both the dose and frequency of administration of methotrexate are correct.

Theme 7: Professional autonomy and control

Safety features are included in ePMR systems to help prevent potential clinical hazards and harm to patients. One of the legal experts highlighted a reason why pharmacists may choose not to accept alert recommendations.

> *'…Is a computer system better than an individual pharmacist? Because sometimes yes and sometimes no. Sometimes the pharmacist or a doctor for that matter can look at it and say, "Well, I've got this patient in front of me and they're on this, this, this and this." They shouldn't be standing, you know, but they are. So you know the interaction is not important.'*
>
> Legal expert (interview 21)

Some participants rejected the notion of a default alert configuration for users. They opined that the responsible pharmacist should be able to decide the right level of alert to set in the system. One participant observed that:

> *'…the older pharmacists who've built up the knowledge over the years do run their systems on the lower level alerts. The younger pharmacists, they set the systems to alert them a lot more…'*
>
> Superintendent pharmacist (interview 07)

Some vendor companies allow users to set a host of non-clinical preferences in the system such as the number of prescription labels to print and whether alerts should be displayed onscreen or printed to label. Users are not allowed to add or modify any clinical functionality in the system. One of the vendor companies allows users to add missing products to the drug database but such products do not take part in any safety check conducted automatically by the system.

> *'Anything clinical we force, anything commercial they can do whatever they like.'*
>
> System vendor (interview 30)

The use of individual user profiles was suggested as a way to give users control of alerts they would like to see when working on ePMR systems. It was highlighted that such an approach would require a common framework to succeed. Additionally, it has the potential to make user preferences for alerting profiled and available wherever a pharmacist is working, irrespective of the ePMR system that is used. User differences and lack of knowledge about users' level of expertise, however, make implementation of alert control by users a difficult task for system vendors.

Theme 8: Alert display and management

The challenge of presenting alert information intelligently and at an appropriate time in the workflow was emphasised by the system and drug database vendors. It was posited that serious alerts such as alerts about '*never events*' should flash up onscreen immediately the drug product is selected.

> *'…clearly, the most severe things that you don't do this, sort of situations, need to be in your face but there's actually not very many of those…the other things, I don't think it's a question of say they shouldn't be there…the challenge is how you present the information.'*
>
> Drug database vendor (interview 22)

Participants noted that alerts should be managed in a consistent manner. However, they reported that although alert management in some community pharmacies is guided by the standard operating procedure (SOP), this may not be done consistently even within the same pharmacy. Alert response may involve a quick scan of an alert for signal words, reading and evaluating the alert for relevance and importance to identify the most appropriate management option, including whether to act on or ignore the alert. Participants said they usually base alert management decisions on their clinical knowledge, training, experience, information in evidence-based literature and professional judgement. Practicing pharmacists who participated in the study

reported that they pay attention to alerts highlighted as '*major*' by ePMR systems or warnings generated by high risk medications, antibiotics, new medicines and medications with narrow therapeutic window.

Practicing pharmacy professionals said that they regularly encounter insignificant alerts in practice, which they ignore. Such alerts include those emanating from drug interactions and co-prescriptions, with no evidence of having caused any harm to the patients involved in the past. For example, an alert suggesting that a patient may become hypotensive because of doubling or concomitant use of blood pressure medications that are commonly combined is often encountered and ignored. Counselling information presented as alerts and alerts generated by repeat prescriptions where there have been no apparent changes in the patient's circumstances are also ignored.

Other reasons cited for ignoring alerts are inadequate alert sensitivity and alert information, excessive workload, display of alerts in an inconspicuous area of the screen, multiple alerts about the same hazard, spurious alerts and familiarity with alerts. Participants also highlighted that recognising specific alert wording in insignificant alerts can cause users to behave automatically towards alerts. In addition, deferring all alerts until the end of the dispensing process with no warning about serious risks of harm to patients, constant alert pop-up, mixing of non-clinical and clinical information in alerts were all implicated in alert bypass. Likewise, the need to double-click alerts or scroll through alerts to read the full alert text, duplication of alerts, lack of a cut-off date for historical medication records involved in alert generation, all encourage users to ignore alerts (please see appendix C.9 for the list of inhibitors of alert usefulness suggested by participants).

One of the pharmacists said that she ignores an alert if she checks a reference source such as the British National Formulary (BNF) and there is no supporting information there about the alert. Another participant explained that she scans alerts presented onscreen very quickly, but ignores them when busy, as she believes that the prescriber would have checked that any prescribed medication is safe for the patient before issuing the prescription.

> *'To be honest with you [laughs], some of them… you sort of glance through it quickly and then you just have to carry on if you are really in a hurry. You do read but if you are not reading very carefully, you probably just go, you know, say well…it's an alert but the doctor has prescribed it so I just…carry on, they are probably aware of these alerts anyway before prescribing.'*
>
> Pharmacist (interview 02)

One of the superintendent pharmacists offered an alternative view of the alert bypass situation. He suggested that there are reasons why pharmacy professionals might ignore some alerts. He emphasised that this should be based on appropriate evidence and pharmacists' professional judgment.

> *'…they've already built into their own practice how to deal with the consequence of that alert. Whether it's through routine counselling for patients regarding a specific molecule or in their experience that the alert is there because perhaps a professional publication…the BNF [British National Formulary] has suggested that that alert should be there, but the reality of practice is one where actually that alert has very little meaning. So something about making sure that the PMR [Patient Medication Record] systems reflect the formal and professional publications that come out. So there's something that actually goes back to those publications rather than the PMR systems about making sure that they are appropriate themselves. I think there's also something there about a pharmacist using their own professional discretion and judgment to say whether or not that alert is of such significance that they need to do something about it. So I can imagine that there'll be a number of standard alerts that pharmacists would now routinely, not ignore, but have accommodated within their practice, that they therefore would cancel those alerts.'*
>
> Superintendent pharmacist (interview 08)

Another pharmacist explained how he has been managing alerts. He said that the pharmacy staff members sometimes print alerts on blank prescription labels for him to review when conducting the final prescription checks. They can also call him to review alerts onscreen if the pharmacy is quiet. However, if he had evaluated an alert

for a patient under the same circumstances in the past, then the dispenser is allowed to ignore the alert without informing him, in accordance with the pharmacy's SOP. The following quote captures a different approach to alert management offered by another pharmacist:

> *'I don't actually read them although I insist that if somebody is dispensing for me, if a warning comes up, they need to print it because it's my job to make a decision whether the interaction is significant or not.'*
>
> Pharmacist (interview 01)

One participant highlighted the potential danger associated with printing alerts on blank prescription labels. It was suggested that occasionally, these alerts might be placed in the prescription bag for patients to read, with no further action being taken, he said.

> *'I think having a list of…labels with twenty-four different types of interactions, basically gets people to take their eye off the ball.'*
>
> Legal expert (interview 20)

One of the pharmacists also mentioned that the ePMR system he uses could be set to request a passcode to get past some alerts, if the dispenser is not a pharmacist. However, there is a drawback.

> *'The technicians soon pick up the password, the pharmacist is busy and put that through which is why …coming out with dispensing label has become important to us. If it isn't the pharmacist that's seeing the notification, there needs to be some way of that being communicated to the person doing the pharmaceutical check.'*
>
> Superintendent pharmacist (interview 10)

Participants advocated making alert review a part of the pharmaceutical review process if truly, pharmacists should review all alerts. They said this is because the person who is generating the prescription labels may not be a pharmacist. It was highlighted that this might mean displaying all alerts in a separate window so as not to slow other processes down.

4.4.3 Organisational context

The organisational context uncovers participants' perceptions about the influence of standardisation and regulations on ePMR systems in community pharmacy practice. It also captures participants' views about the pharmacy work environment, organisational safety policies, their impact on practice, ePMR systems' use and development.

Theme 1: Current standards and regulations

Participants noted that there were no formal stakeholder agreed minimum specifications or standard for ePMR systems, their safety features and alerts. Although standards were set for Electronic Prescription Service (EPS), other aspects of the functionality of ePMR systems were excluded. One reason for this as suggested by one of the participants was that pharmacy contractors might want their system to operate in a certain way.

According to one of the legal experts, ePMR systems are already being regulated, through the Medicines Act 1968 amended in 2009, which imposed a legal duty on responsible pharmacists to ensure safe and effective running of any pharmacy under their control. The National Health Service Pharmaceutical Services Regulations 2005 contain the terms of service, including the clinical governance requirements. In addition, the code of ethics provided by the former Royal Pharmaceutical Society and supplemented by standards and guidance, sets out the principles that pharmacy professionals must follow. However, there were concerns that community pharmacists were possibly less aware of the various acts and regulations including the clinical governance requirements. It was suggested that targeted Continuing Professional Development (CPD) in particular subjects such as clinical governance and risk management once every 3 years might help to address this.

> *'...the approach of the General Pharmaceutical Council is to lay down some basic standards and give a certain amount of guidance but broadly it's approach is that it will let pharmacy owners and pharmacists decide for themselves how they are going to comply with standards. That's a rather hands-off approach but if pharmacists fall so far short of the standard that is laid down by the GPhC [General Pharmaceutical Council], they may find that they face fitness to practice proceedings...'*
>
> Legal expert (interview 19)

Participants acknowledged awareness of some standards around ePMR systems' interaction with the NHS EPS, basic requirements of data protection, patient confidentiality and professional standards. None of them knew of any standard or regulation for ePMR systems, their safety features and alerts. The dispensers said that they were aware of the existence of SOPs and the information governance (IG) policy. One locum pharmacist said that although he had heard about IG, he did not know much about it.

Participants unanimously agreed that there should be stakeholder agreed minimum specifications for ePMR systems and alerts, asserting that without these, pharmacy owners face a hurdle in selecting the best ePMR systems to support community pharmacy practice. They suggested that some features and functionality should be common to all ePMR systems with the option to purchase other modules as and when required. It was suggested that perhaps stakeholders, such as pharmacy professional bodies and risk-management organisations could produce an industry standard ePMR system or have kite mark certification to identify ePMR systems with appropriate functionality and features.

> *'...there should be standards around how that appears on the screen, how it's checked, a core data set would be a boon...it's not really a vibrant market in terms of moving from one supplier to the next. Without a core data set, moving from one supplier to the next is a nail-biting process.'*
>
> Superintendent pharmacist (interview 10)

Some of the participants posited that provision of standards would facilitate interoperability and seamless exchange of information between ePMR systems and other clinical systems. It was suggested that standards should be agreed on a national scale, excluding the software interface. This they said is to maintain each ePMR system's uniqueness and vendor innovation. One argument that was put forward against standardisation by one of the participants was that it might be costly to standardise ePMR systems in their current state of maturity.

It was suggested that there is currently no impetus to standardise ePMR systems and alerts nationally. Some participants posited that change of government and the political landscape are partly responsible for this. For example, the previous government aimed to centralise health information nationally for local use whereas the current government favoured localisation.

> *'...instead of trying to set standards at the centre and saying everybody must meet these standards, they intend to set a few key principles which are very simple to meet apparently and then it's up to you as to how you do it and make it work for you locally.'*
>
> Legal expert (interview 21)

Theme 2: Common safety alert module

Participants' opinions about a common safety alert module for ePMR systems ranged from positive to negative. Some mentioned that it would be useful as a central reference resource such as the NHS Dictionary of Medicines and Devices (dm+d). Another suggested advantage is that it would be familiar to users wherever they go because it is common. Nevertheless, participants suggested it might not suit every user because of the tendency to aim at the lowest common denominator. One participant was extremely negative about the idea suggesting that it could lead to replication of bugs in the software program across all the systems.

> *'That's not a good idea at all. I think that's a terrible idea...It's not a very clever move to have a consolidated database because then you've got a bug for a product which is now across all your pharmacies rather than it being in a smaller group of pharmacies.'*

System vendor (interview 29)

Instead of a common safety alert module, some participants suggested a common approach to alert presentation. They advocated setting up an authoritative body to work out alerts that should be presented to users when dispensing medications, such as alerts about medications with narrow therapeutic window. This is in addition to users being able to tailor the system and alerts to their level of expertise. For example, pre-registration pharmacists may be shown all alerts while experienced pharmacists get only the alerts that they have chosen to see. Both options however, should be auditable and traceable.

Theme 3: Leadership and support

Superintendent pharmacists of some of the participating pharmacy organisations explained how their organisations support pharmacists to practise safely and ensure safety of medications. They said that they focus attention on medications that evidence suggests are prone to cause errors and harm, and work closely with system vendors to highlight such medications in ePMR systems.

> *'We have a particular focus on molecules that we've identified as being sensitive. So we work with our system suppliers to make sure that the appropriate warnings present themselves and that may require some particular tailoring…We'll be reflecting on our practice and our insights. We'll be using our insights from near-misses and dispensing errors for example to identify where we would want a particular focus…and we've got the opportunity to do that. We also have a PMR [Patient Medication Record] system, which allows us to locally bespoke what warnings look like. So we can change some of the parameters which allow the warnings to come up in a specific way.'*
>
> Superintendent pharmacist (interview 08)

The EPS project was cited as an example of how pharmacy as a profession is failing to provide leadership in community pharmacy IT initiatives. One participant said that the government was guilty of two things. Firstly, allowing people with little or no expertise in scoping the project requirements. Secondly, using non-disclosure agreements, which prevented stakeholders from sharing ideas and information that could have benefited the project and the development of ePMR systems. It was suggested that because of this, ePMR system vendors got a completed but inadequate specification.

> '*They are responsible for what happened to the way that EPS occurred because what they did is, the government divided and conquered and we were not involved at a necessary level. You can't exclude a software house on something like this and therefore we have PSNC [Pharmaceutical Services Negotiating Committee], Royal Pharmaceutical Society and other august bodies getting involved with the Department of Health to specify what was required and that was the user group, the user group which I've never heard of before were actually obliged to sign non-disclosure agreements. So how can that be a listening exercise when the people that are scoping out the requirements who are not qualified by the way to scope out those requirements, then can't talk to the software people?*'
>
> System vendor (interview 27)

One participant representing one of the drug database vendors reported that his organisation has the expertise and the knowledge to help system suppliers to make good use of the organisation's decision support modules in ePMR systems. However, he suggested that system suppliers have been reluctant to take advantage of this due to commercial sensitivity, competition and the fear that their intellectual property rights may be violated.

> *'There's a wealth of things in our data…there is not one system out there that takes all the functionality within our data and sometimes when you do speak to a vendor you find that they're coding something but they haven't even used your data to help them enable it.'*
>
> Drug database vendor (interview 25)

Theme 4: Safety climate

Participants declared that due to increasing prescription volume and clinical service provision, one computer terminal is no longer adequate in today's community pharmacy environment for effectual discharge of pharmacists' professional duties and clinical services. It was suggested that '*blame*' culture still exists in community pharmacy practice setting and is preventing users from being open and honest about errors, jeopardising potential opportunities to learn from such errors. Participants declared that potential error points should be addressed to prevent any untoward event before, rather than after an event.

> *'I don't think people learn from being prosecuted or being made the subject of disciplinary proceedings because things have gone wrong. That's just something that happens after the event...there's a great deal of concern about pharmacists who are made into criminals when they made dispensing errors and I think that's a damaging thing. The historic approach of treating in that way has been damaging. For example, because one aspect of training involves learning from the use of error logs and near miss logs and I have seen pharmacists who were brought before a disciplinary committee because they recorded errors in an error log and that obviously would discourage people from being honest and open about mistakes.'*
>
> Legal expert (interview 19)

Theme 5: Choice of system

Participating superintendent pharmacists of pharmacy companies also reported that there is no official guidance to use in selecting an effective ePMR system. Superintendents of large-chain pharmacies reported that they drew up formal requirements for ePMR systems and safety features in-house before choosing the ePMR system their companies were using. Others based their selection on various criteria: safety, good relationship with the vendor, positive user experiences, vendor's ability to innovate and the speed of response to issues raised by users, user recommendations and the corporate needs of user organisations.

Homegrown System

A homegrown system could be the solution where specific features required by a pharmacy company are not available in a commercial system. This was highlighted as a way to exercise a significant degree of control over the ePMR system than may be possible with any commercially available system. It was also suggested that large-chain pharmacy companies with many branches sometimes opt for homegrown systems on the basis that it would be cheaper than purchasing a system from a commercial vendor.

Theme 6: Pharmacy funding structure

Some of the pharmacy professionals reported that it is becoming increasing difficult to maintain an appropriate level of safety in some community pharmacies. They suggested that increasing volume of prescriptions not matched by a corresponding funding structure to allow a reasonable level of staffing is to blame. Additionally, reduction in funding related to supply of medicines has resulted in pharmacists spending more time in getting more products out rather than ensuring safety and correctness of the products. They said that this invariably puts emphasis on community pharmacy as a retail business rather than as a clinical safety checkpoint.

> *'I think one of our underlying issues still is the increasing volume of prescriptions, which means that more and more, we have…high-frequency work in pharmacies and we probably haven't got, actually, funding structure underlying that to allow pharmacy owners to have sufficient staffing or resources in place to always help to do that in a considered way so that you've got as a pharmacist, time to stop and think, "Right, we've got a problem here that we've spotted…How are we going to deal with it working with the patient and the GP [General Practitioner]?" So I think a lot of safety problems possibly get missed…or get spotted, but they're not able to see them through in perhaps a way they'd wish to as good professionals because of the constant flow of prescriptions coming in.'*
>
> Health care policy maker (interview 15)

4.5 Discussion

This study records the perceptions of stakeholders, including the experiences of practicing pharmacy professionals about ePMR systems that are used in community pharmacies in England, in terms of their functionality and ability to alert users about clinical hazards and errors at the point of dispensing.

Pharmacists' professional role

Increasing number of drugs and complexity of medication regimens significantly raise the potential for errors and harm to patients, necessitating a shift in focus on pharmacists' role, from being largely product-centred to patient-centred (Heikkila et al., 2006). Using the information contained in ePMR systems for conducting clinical checks has the potential to highlight errors and prevent harm from getting to patients. Failure to use the information inappropriately places emphasis on dispensing of products rather than patient safety. This does not suggest in any way that pharmacists should rely completely on ePMR systems. They are free to exercise professional judgement as and when necessary. Currently, the extent to which the information in ePMR systems is used to conduct safety checks in community pharmacies is not clear.

Training

The role of training is to help pharmacy professionals understand how ePMR systems function, what they are designed to do, what they cannot do and how to use them. This would prevent users from creating unnecessary '*workaround*' that could jeopardise patient safety. Training has the potential to facilitate correct and optimal use of the system, including proper alert management in a consistent manner (Humphries et al., 2007; Raebel et al., 2007b; Mansour et al., 2010; Bhardwaja et al., 2011). Reference to safety features as security features, perhaps was due to limited understanding of the safety features in the systems and what they are designed to do. Appropriate user training would help to rectify this apparent knowledge gap.

Those who require training may find it difficult to obtain. Findings from this study indicate that training of pharmacy professionals in ePMR system use is typically unstructured. Migrant pharmacists often miss training organised by

system vendors due to the nature of their work. The use of live ePMR systems for training purposes may also be restricted in order not to corrupt the system (Fisher, 2006). These suggest that other training modes should be explored to give pharmacy professionals, especially migrant pharmacists, more options for training outside of the traditional face-to-face or classroom mode training. Results from a study that was conducted in Canada by Ellaway et al. (2014), highlight the importance of context and learner autonomy in training and supports the request by some participants for non-traditional modes of training, such as online and via mobile devices.

Training to improve individual pharmacy professional's culture of safety, competence in operating ePMR systems, human factors, alert and risk management are essential to patient safety. This could be incorporated into the undergraduate, postgraduate, on-the-job training and CPD programmes available to pharmacy professionals. Training should be continuous and available as required, not just when a new system is installed in the pharmacy. There are concerns that technologies such as ePMR systems can cause new risks for errors (Grimsmo, 2006; Strom and Schinnar, 2011). However, adequate training can help users to identify potential ePMR system-induced errors in practice.

Mandatory training of pharmacy professionals in ePMR system operation, including alert management with refresher training at regular intervals have the potential to improve patient safety and care quality. The reasons given by participants who rejected the idea of mandatory training include trainees not following what they learned in training and forgetting what they learned if the knowledge gained during training is not put into practice immediately. These reasons are untenable and are perhaps, due to lack of understanding of what mandatory training is and how to implement it. The UK Royal College of Nursing (2009) described mandatory training as training that is determined by an organisation as essential for its safe and efficient running, to reduce organisational risks and comply with government policies and guidelines. It is one of the regulatory requirements in high safety reliability organisations such as commercial aviation where airline pilots are expected to complete a certain number of simulator training sessions at pre-specified intervals for safety reasons (Graf et al., 2012).

Regulation 9 of the Provision and Use of Work Equipment Regulations 1998 (Health and Safety Commission, 2008) states that every employer shall ensure that all persons who use work equipment, including those who supervise or manage the use of work equipment have received adequate training. This includes training in the methods that may be adopted when using the work equipment, any risks that such use may entail and precautions to be taken. It highlights that training needs are likely to be greatest on recruitment. It also notes that skills decline if they are not used regularly so, refresher training should be provided if necessary. Mandatory and refresher training in subjects, such as ePMR system use, alert management, human factors, risk management and clinical decision making should be introduced in community pharmacy to help bridge the gap between pharmacists' expected role and actual practice performance (Sheridan et al., 2011).

Learning through reflection

Technologies such as ePMR systems can help improve medication safety and it has been suggested that human interaction, including regular reflections, plays an important role in its success (Santell, 2006). The process of reflection has been described as a conscious and a constant action (Taylor, 2010), useful in preventing medication errors in practice (Schön, 1991). However, the role of both reflective pathways in preventing medication errors in community pharmacy practice has received little mention in the literature (Pezzolesi et al., 2013). The extent to which pharmacy professionals employ reflection in practice, use their own judgement in clinical decision-making and the impact on patient safety are indeterminate. An understanding of these issues may help uncover new opportunities for preventing errors and safeguarding patients.

Data access and quality

Data in current ePMR systems are predominantly medication record data. This facilitates drug-drug interaction checks and is perhaps the reason why pharmacy professionals seemed to be more aware of safety features around drug-drug interactions more than other safety features. Integrating ePMR systems with other clinical systems allows patients' clinical data to be linked with electronic medication

record data, thereby providing context for alerts. This has been shown to be beneficial in reducing the amount of spurious alerts displayed to clinicians (Sittig et al., 2006; Duke and Bolchini, 2011; Jung et al., 2012; Horsky et al., 2013). However, challenges may arise due to differences in system hardware and software capabilities, issues around interoperability, patient confidentiality and liability. All of these would need to be considered carefully to ensure the success of any programme aimed at reducing non-contextual and clinically insignificant alerts in ePMR systems. One ePMR system vendor, Rx Systems now links pharmacies that are using Rx Systems' ProScript software with general practices that are using the EMIS Web clinical management system. This initiative provides those pharmacies with the opportunity to securely access patients' clinical data in the general practice computer system to support safer dispensing (Egton Medical Information Systems Limited, 2014). However, there are issues around the allowances of general practices and the consent model to allow the records to be seen by pharmacists.

Availability of some safety features suggested by participants, the quality of alerts and advice based on alerts are dependent on having appropriate and high-quality data in the system. For example, a feature for alerting about drug-age suitability requires that the correct age of the patient be recorded in the system. At present, the quality of data in ePMR systems and their impact on safety is unknown. Pharmacy professionals should be encouraged to complete patient details and other ePMR data accurately, including updating existing records as and when new information becomes available. Introduction of a set of quality indicators similar to those in the Quality and Outcomes Framework (QOF) for general practice surgeries could help raise the quality of data in ePMR systems and facilitate development of other safety features for the benefit of patients (British Medical Association, 2014). Systems should be capable of warning users where checks have not been performed due to lack of appropriate data.

The suggestion that prescribers should annotate prescriptions with information about decisions they have made to avoid unnecessary call-backs corroborates the results of the study by Johnson et al. (2010). The study found that the number of callbacks to doctors increased where necessary and decreased in other situations when alerts and override comments were appended to electronic prescriptions generated by one electronic prescribing system. Implementing such a solution in English community

pharmacies could help pharmacists understand prescribers' decisions better and prevent delays in medication therapies.

System development and evaluation

The identified facilitators and inhibitors of ePMR and alert usefulness present system vendors with rich data about desirable areas to focus improvements in ePMR systems, in support of current and future clinical practice. For example, alerts presented to pharmacy staff should be those they can deal with in the pharmacy, not alerts that only the prescriber or other clinicians need to act on. In addition, future system development should incorporate ways for users to recall warnings in context or virtually step through a dispensing scenario. This would avoid the need for pharmacy staff to re-create dispensing scenarios to understand the context in which alerts were initially presented, a situation participants suggested is currently the case. It is not clear, if alerts in ePMR systems are tracked and whether the information obtained from the exercise is used in subsequent development of ePMR systems. This sort of audit is useful to provide essential data about the use of ePMR systems and users' alert management behaviour to aid individual system development.

From the findings of this study, it appears that the decision regarding the type of safety features that should be in ePMR systems and alerts to present to users rests mostly with the system vendors. However, a pharmacy organisation may request specific features and alerts to be added. Similar to the findings from two US studies by Shah et al. (2006) and Horsky et al. (2013), part of the findings from this study include a proposal by participants that only high severity alerts should appear as interruptive dialog box and less severe warnings should appear unobtrusively without any explicit requirement to respond. With no specifications for alerts, this may be difficult to achieve. Research is required to establish what is appropriate in the context of community pharmacies to avoid compromising patient safety. Evaluation of ePMR systems should be systematic and coordinated to ensure that findings and lessons learned are shared among stakeholders in the interest of patient safety. Reliance on feedback from pharmacists with information technology (IT) skills as a means of evaluating ePMR systems demonstrates a poor organisational safety culture and should be avoided.

Safety alerts

Practicing community pharmacy professionals reported that they automatically behave towards alerts on a regular basis, such as ignoring or overriding alerts with or without any valid reason. They cited lack of appropriate clinical knowledge, poor safety culture, lack of alert context and displaying alerts that community pharmacy professionals have no authority to act on in the pharmacy as some of the reasons for overriding alerts. For example, alert about monitoring serum creatinine level of a drug perhaps is best presented to health care professionals with access to the relevant patient's clinical data. These findings agree with the findings from other studies that have shown that there are several valid reasons why users of pharmacy systems may override or ignore alerts (Murphy et al., 2004; Buurma et al., 2006; Slight et al., 2013). Constant exposure to certain types of alerts and multiple alerts over a long period can desensitise users to such alerts. To avoid this, Wogalter et al. (2002) suggested that multiple warnings should be presented on a rotating basis to ensure that an individual's exposure to a specific warning stimulus will be less frequent, therefore, habituation is less likely to occur.

Even though practicing pharmacy professionals who participated in this study gave several reasons for ignoring alerts, perhaps the alerts they encountered in community pharmacy practice were also poorly designed or they were consciously or unconsciously demonstrating lack of a culture of safety. It has been suggested that alert design incorporating human factor principles based on evidence could help promote compliance with alerts (Wogalter et al., 1997). Evidence from other studies also highlights links between signal words in alerts and other attention getting features (iconic features, such as colour and font size). In the case of signal words, the word '*Deadly*' is more attention getting than the word '*Note*'. Signal words are useful in gaining the observer's initial attention, but provide little information on their own. It has been suggested that there should be a clear distinction between the attention-getting features and the informational contents of alerts because they both play different roles in the alerting process (Edworthy and Adams, 1996a; Edworthy, 1998). Innovative hazard matching with iconic features and colours have also been recommended in order to prevent habituation from using only signal words in alerts

(Hellier et al., 2000b). The use of signal words in alerts displayed on ePMR systems and the impact on pharmacy professionals should be investigated.

It was suggested that some pharmacies have alert management policies in their SOPs, but it is not clear if this is the case across all community pharmacies in England. The apparent lack of a formally agreed alert management policy in community pharmacies suggests that alert management may be inconsistent across pharmacies, systems and pharmacy professionals. Studies have shown that there is disparity between the severity levels given by reference resources and drug databases (Abarca et al., 2004; Martins et al., 2011). This can lead to variation in the display and subsequent management of alerts. Increasing numbers of new medications and complexity of therapy, make such a policy necessary, to ensure consistency of response to alerts and to prevent delays in initiating medication treatment. If the pharmacist is to check all alerts and prescriptions clinically, perhaps both the pharmaceutical check and alert review process should be separated from the labelling process if the pharmacist is not the one dispensing. Nevertheless, further research is required, to investigate the effectiveness and safety impact of this approach in comparison with other approaches, such as flashing alerts immediately a signal is detected.

System vendors gave reasons why they sometimes choose to display all alerts to users even though there is no evidence that this approach is effective. Presenting all alerts to pharmacists may not be a problem in low-volume dispensing pharmacies on the short term, but could lead to habituation on the long term. In high volume dispensing pharmacies, time pressure and various other competing factors could prevent users from paying attention to alerts. In such situations, users might find alerts, which give information they need to act on and alert presented in context more useful than those that do not.

Displaying all alerts to users or to a corner of the screen as suggested by some system vendors potentially makes it more likely for users to ignore or miss alerts. A better approach would be, first, to work out the most important alerts that users need to see and action, and second, to work through the rest of the alerts to eliminate non-clinically significant alerts. The mention of different approaches for displaying alerts,

including presenting important alerts as pop-ups and displaying other alerts unobtrusively suggest that there is no '*one size fits all*' way to display alerts. It is therefore important to identify and set out best and promising practices for displaying alerts at the point of dispensing.

If alerts are suppressed in the system, users should be duly informed and the alerts should be traceable. It is important for pharmacists to know about changes to patients' clinical situations that could cause a suppressed alert to become redundant. Patients should also be encouraged to inform pharmacists about changes in their circumstances that may warrant cancellation of any suppressed alert. It would be expected that a suppressed alert would be cancelled automatically if new information becomes available. It has been suggested that failure to inform system operators that there are suppressed alerts in the system could result in the system vendor being legally culpable of negligence if harm occurs to patients that could have been prevented (van der Sijs et al., 2008). Currently, it is not clear which systems are able to suppress alerts and whether the function is used, how widespread the practice is and what the impact is on safety. The suggested '*positive*' alerts such as '*this patient might benefit from extra counselling around weight or diet*' need to be presented intelligently and in context to be useful. This could be presented as counselling information to minimise the potential to increase alert burden, leading to over-alerting and automatic alert bypass.

Professional autonomy and control

One challenge regarding displaying alerts effectively is how to ensure compliance with alerts and avoid over-alerting and automatic behaviour towards alerts at the same time. To address this issue, participants put forward various arguments in favour of and against giving users control of alerts, from a community pharmacy perspective. However, no evidence was found in the literature to suggest that giving control of alerts to users would lead to better outcomes for patients or to allow a recommendation to be made. It is difficult to say what unintended consequences might result from such an approach. Current arrangements where users could add products to the drug database, but such products are exempt from checks conducted automatically by the system, creates safety gaps with potential for errors, and harm to patients. Instead, there should be facility on ePMR systems for communicating

requests to system vendors, which can be included in future updates and rolled out to other sites.

Standards and regulations

The concerns that were raised about community pharmacists' awareness of regulations, including clinical governance requirements could be addressed through continuing education and professional development. A central repository for the regulations and standards advocated by participants would help to ease pharmacy professionals' access to those resources. One question that may be asked, however, is how the service would be paid for. This should be discussed and agreed by stakeholders.

System vendors are having to develop their own specifications in-house because there is no formally agreed specifications for ePMR systems and alerts. Pharmacy owners have also highlighted lack of minimum specifications for ePMR systems as an issue when attempting to select ePMR systems for their pharmacies. An authoritative body should therefore, work out specifications for ePMR systems and alerts, which are fit for purpose and for current and future community pharmacy practice. Any agreed specification would require regular update and could serve as a benchmark for new systems.

Common safety alert module versus common approach to alert presentation

Potential benefits cited by proponents of a common safety alert module if set by an authoritative body are, trust in the information provided and adoption by stakeholders as a central repository for safety information. The same authoritative body should also recommend absolute alerts that should be presented to users. Regular update and sign off by the same authoritative body could help assure reliability of the information contained in the repository.

The main arguments against a common safety alert module are user differences and the potential for software programming deficiencies to be replicated across systems. Instead, a common approach for presenting alerts was suggested. In order to achieve success of a common approach for presenting alerts, minimum specifications are required for ePMR systems, their safety features and alerts based on available

evidence and backed by regular evaluation to ensure that the systems are meeting patient safety goals. However, further research is required to determine the impact of both approaches.

Organisational influences

Patient safety and best practices should be high on the agenda of pharmacy organisations with management providing leadership (Reason, 2000). The assertion that current ePMR systems do not need to be evaluated demonstrates a lack of safety leadership or full appreciation of the role of community pharmacies in ensuring medication safety. The level and quality of safety leadership in community pharmacy practice is also unclear.

As part of the previous government's programme to modernise the NHS, a national information strategy was adopted for local implementation to enable NHS professionals to have the information they need to help patients receive the best possible care and play their part in improving the public health (Department of Health and NHS Executive, 1998). However, the present government chose a different approach of having local solutions that could easily be used to meet the needs of the local population (Department of Health, 2012). The impact of changing political priorities and health policies on the ability of health care organisations to reduce errors and maintain patient safety is not clear. Further research is required to understand the impact of both approaches on clinical services and patient safety.

The spending cuts being imposed across the NHS also affect pharmacies contracted by the NHS. Pharmacies try to mitigate the impact of the cuts by generating extra funds through other means, such as increasing the number of prescription items they dispense in order to sustain their business. Additionally, the assertion that the NHS is only interested in the clinical aspects of ePMR systems, hence the apparent lack of interest in its overall development is not quite true given the contributions of the NHS to community pharmacy IT initiatives, such as the EPS. Pharmacy contractors who operate Release 1 or Release 2 of the service are entitled to a monthly allowance of £200 per calendar month from NHS England for each month that they are able to operate the service, subject to conditions detailed in the NHS England and Wales Drug Tariff (Department of Health et al., 2014). This amount may not be sufficient to

guarantee continuous development of ePMR systems due to the enormous cost implications of developing and maintaining such clinical systems. The apparent lack of evidence demonstrating the usefulness and effectiveness of ePMR systems in achieving the NHS's clinical goals may also be contributing to the problem.

Strengths and limitations

One of the strengths of this study is that all the participants in the sampling frame participated in the study. The study focused mainly on expert stakeholders with knowledge of ePMR system functionality and community pharmacy practice. Their knowledge and experiences of the topic of enquiry allowed a broad and detailed representation of stakeholder perspectives to emerge. Patients and other health care professionals were not included in the study and only 13 out of the 30 participants were frontline users of ePMR systems. It is therefore possible that other perspectives about ePMR systems, their safety features and alerts exist, which are yet to be fully explored.

Data analysis in this study was done using Framework approach, based upon a well-structured interview framework. An in-depth grounded theory approach was also a possibility but was not taken for two major reasons. First, grounded theory approach is mainly employed in theory development whereas the main aim of this study was to understand the perceptions of stakeholders about ePMR systems' functionality focusing on safety features and alerts. Secondly, grounded theory approach involves interviewing continuously to the point at which no new theme emerges. This was not a feasible approach to take in a study like this due to limited resources.

Reflexivity and interviews

Participants were made aware of my status as a qualified pharmacist at the time they were invited to participate in the study or at the beginning of the study. One advantage of this is my understanding of some of the issues being explored. This enabled me to explore the topic of interest in greater depth by asking appropriate focused and follow-on questions. Conversely, this may be seen as having the potential to influence participants' behaviour or responses, thereby introducing unnecessary bias into the study and as such, a disadvantage. However, a researcher with no prior experience of the processes within a community pharmacy may require some in-situ observations and training to ask focused questions and achieve the level of

participant engagement attained in this study, although may have little preconceptions.

I do not think that my status as a qualified community pharmacist influenced participants' behaviour or responses in a negative way. Rather, I think that my position as a practising community pharmacist made pharmacy professionals more able to share with me the issues they considered extremely important to them in practice, but which they thought that the health care policy makers were not taking cognisance of. This was because they saw this study as an opportunity to voice their opinions about ePMR systems and alerts. Many suggested off record, that as a colleague, they believed that I had a good understanding of the issues facing them daily in community pharmacy practice setting. Even the non-pharmacist and non-practicing pharmacist participants responded freely about medication safety issues in community pharmacy practice setting, which they felt that practising pharmacy professionals may not know about.

My understanding of the issues participants talked about came from reading the interview transcripts several times and listening to the audio recordings of the interviews. For each interview, I documented my reflections shortly after each interview session. This helped me to identify issues that I needed to investigate further. It also added depth to my analytical thinking. For each interview, I prepared a summary of the key points to take forward using a word processor and a few keywords to facilitate easy retrieval of the main ideas. I updated the notes I made about issues raised by participants, wrote about what I learned from the interviews and the ideas generated through the process. In some cases and where useful, I diagrammatically captured the issues described by participants or discussed during the interview sessions. My professional experience and research skills acquired through training helped me to explore the relevant issues on the subject of ePMR systems and alerts. Additionally, they enabled me to ask appropriate follow-on questions to further examine many of the issues that were raised by participants. My notes provided insights into the wider implications of what I heard during the interviews and have been important sources of ideas during data analysis and the thesis writing process.

I learned to use Framework analytical technique (Ritchie et al., 2013) shortly before I began analysing the qualitative interview data. This experience was challenging, however, it made data retrieval and cross analysis of findings within participant-groups and across cases easier. I discussed key findings from the interviews with my supervisors and recorded the points from those discussions in the project notebook. I found this very helpful in understanding the issues that were important to participants and in identifying areas for further investigation to gain a better understanding of the topic being explored.

Implications for policy

This study provides potentially useful evidence to support the development of ePMR systems and medication-safety improvement efforts. It shows that communication and collaboration among stakeholders need to improve. It is also a reminder that acquiring ePMR systems for use in community pharmacy practice setting is just the beginning of the process to ensure safety of medications in practice. It is clear that to ensure reliability and effectiveness, there has to be a robust structure for evaluating ePMR systems, their safety features and alerts. Safety is not an intrinsic feature of any system. It reflects what a system does, which is dynamic and may have different effect in different situations. Such potential variability and inadequacies suggest that regular monitoring and evaluation of ePMR systems should be done to enhance their effectiveness. It is vital to identify areas for immediate action and what needs to be done to bring any failing system up to speed to ensure that such a system performs as expected in terms of patient safety outcomes.

This study highlights the need to standardise certain aspects of ePMR systems. For example, the disparate levels of severity of alerts and alert information presented to users could benefit from standardisation. This would ensure consistency of information presented across the systems and reliability of the systems' performance. Where standardisation is unsuitable perhaps due to varying local requirements, concerted effort should be made to harmonise ePMR systems, including their safety functionality to ensure that users receive clear and actionable messages where required, irrespective of the system being used. The possibility of developing a repository of high quality evidence, which ePMR systems could link to, should also be

explored to further support pharmacy professionals in making informed and evidence-based decisions in practice.

Implications for practice

Pharmacists need to be well acquainted with the demands of their role as a safeguard for patients and to ensure that their knowledge and skills are up to date. Coupled with using ePMR systems integrated with functional safety features, the additive impact helps to ensure that potential errors and clinical hazards are caught at the dispensing stage of the MUP. However, it is important to address the concerns expressed by participants about the safety functionality of ePMR systems, their safety features and alerts to continue to support users in practice and protect patients.

Innovative training methods and opportunities should be sought and training in ePMR system use, alert management, human factors, risk management and clinical decision-making incorporated into future pharmacy training curriculum. This would help pharmacists to gain a full appreciation of their impact in practice and perhaps generate a culture of problem solving in those areas.

Further research

Although this study provides some insight into stakeholder perspectives about ePMR system functionality, it also highlights some gaps in this subject area. It identifies opportunities for improving the effectiveness of ePMR systems, through education and training of pharmacy professionals in all aspects of ePMR system operation. Areas of importance are risk management, ergonomics, standardisation and regulation of ePMR systems, stakeholder collaboration, safety culture and safety climate.

It is important to work out critical alerts that should be presented to pharmacy professionals and ensure compliance with them. In addition, the best way to present alerts to users of ePMR systems and appropriate alert wordings should be investigated. This will help to ensure that alerts are effective and that users do not miss important alerts. Innovative and unobtrusive ways of presenting insignificant alerts and alerts that other clinicians other than pharmacists need to action should be sought, if such alerts are to be presented at the point of dispensing at all.

Currently, there is no formal alert management policy in community pharmacies. It is not clear if users are truly managing alerts in line with company approved SOPs and whether the SOPs are fit for purpose. Results from one study suggest that non-compliance with guidelines for management of drug-drug interaction alerts is common in community pharmacies (Buurma et al., 2007). The study by Slight et al. (2013) highlighted inconsistencies in the way clinicians managed alerts. The inconsistencies include failure to monitor as recommended, reporting that patients had taken the interacting medications together in the past, but usually with no confirmatory evidence, overriding important alerts presented in practice even when relatively few false positive alerts are displayed. The prevalence of such practices in English community pharmacies is not known and should be investigated. It would seem appropriate for alert management to be consistent across systems, in the interest of patient safety.

4.6 Conclusions

This chapter sought to understand the perspectives of stakeholders about ePMR systems, their safety features and alerts from an end user perspective of design and functionality. Towards this end, semi-structured interviews were carried out with a wide array of pharmacy professionals, health care policy makers, legal experts, drug database vendors and system vendors. Findings from the study were consolidated into three different contexts based on the themes that emerged from the study: the user context, the technology context and the organisational context.

Findings from this study indicate considerable differences in user perceptions about safety alerts at the point of dispensing. While the majority of participants felt that ePMR systems and safety alerts are useful, they opined that clinical judgement must take absolute pre-eminence in the course of medication dispensing. The low rate of alert acceptance and compliance was attributed to several factors such as lack of agreement about the levels of severity of alerts, lack of standardisation of alerts and absence of alert management guidance.

Pharmacists have a duty of care towards patients and pharmacy patrons and must ensure that they are competent and know the ePMR systems they are using, including what the systems can and cannot do. As such, it is important for stakeholders to determine the critical alerts that should be presented to users during order entry and for vendors to form a common platform through which these alerts can be presented to pharmacy professionals regardless of the ePMR system being used. It is also important to know how the systems perform in practice to identify areas where improvements are necessary.

Chapter 5

Assessing electronic patient medication record systems in community pharmacy practice setting: A simulated observational test

5.1 Introduction

In the previous chapter, stakeholder perspectives on electronic patient medication record (ePMR) systems' functionality were explored, focusing on safety features and alerts. The study in this chapter aims to evaluate the ability of ePMR systems used in community pharmacies in England to detect (and alert users to) a sample of clinically hazardous interactions, contraindications and other problems during pharmacy order entry (POE). In this study, systems that have been approved by the National Health Service (NHS) in England were examined. To achieve approval, all these systems have to be capable of using Electronic Prescription Service (EPS) Release 2 (R2) (Pharmaceutical Services Negotiating Committee, 2014).

5.2 Aim

This study aimed to assess the performance of electronic patient medication record (ePMR) systems in community pharmacy practice setting. The study addressed the research question, 'How do electronic patient medication record systems perform at the point of pharmacy order entry?'

5.3 Methods

This study was the first part of an ethnographically informed observational study exploring the use of ePMR systems and alerts in community pharmacy practice setting in England (please see chapter 6 for the second part). It was intended to test the performance of the ePMR systems that were being used in the eight community pharmacies that agreed to take part in the ethnographically informed observational study.

Firstly, community pharmacies in the Nottinghamshire area of England were approached. The pharmacies were invited, with permission from their superintendent pharmacists, by post or telephone, to participate in the observational study. There were seven EPS R2 approved ePMR systems at the time of this study in August 2012. Five of the systems were available in the pharmacies where observations took place. An extra ePMR system was identified and this system was tested in a demonstration setting. This sample represented all six ePMR systems available in community pharmacies in England in August 2012. The vendor of the seventh system confirmed that the system had just been approved and was yet to be deployed in any pharmacy in the Nottinghamshire area. Direct on-site observational data were collected between September 2012 and November 2012. The ePMR systems have been labelled: S1 – S6 to preserve ePMR system and vendor anonymity.

Test scenarios

Pre-specified scenarios against which the ePMR systems were to be evaluated were to test prompting of clinically important events or the spurious alerting of non-clinically important events. The scenarios were intended to be illustrative, not exhaustive. They were devised based on consensus agreement between a GP (TA) and two community pharmacists (OO and MB) at an initial meeting, following a review of primary literature; guidance from the British National Formulary (BNF) 63 (British Medical Association and Royal Pharmaceutical Society, 2012) and Summary of Product Characteristics (SPCs). Some of the scenarios were adapted from previous studies described elsewhere (Fernando et al., 2004; Saverno et al., 2011). After the initial discussion, scenarios were developed by OO, these were iterated over a further two meetings until consensus agreement was reached.

The scenarios included appropriate alerts when contraindicated drugs or hazardous drug-drug combinations were entered into the ePMR systems. The twenty-eight scenarios were used to check for spurious alerts, drug-drug interactions and other hazardous situations where evidence exists that an ePMR system should alert the user about potential errors and harm during order entry. These scenarios included various patient demographics and conditions such as hypertension, asthma and rheumatoid arthritis. Some of the scenarios were specifically chosen to refer to generic names and some to brand names to establish if the ePMR system is able to notify users about potential clinical hazards when medications are prescribed for patients by both their generic and brand names.

Table 5.1. Clinical scenarios involving hazardous co-prescriptions and interactions

Test	Dispensing scenario (Alert Expected = yes)	Rationale
A. Drug Interactions		
A1	Sildenafil prescribed to a patient who is also receiving a nitrate	Sildenafil significantly enhances hypotensive effect of nitrates - avoid concomitant use
A2	Ciprofloxacin prescribed to a patient who is taking ciclosporin	Increased risk of nephrotoxicity when quinolones are given with ciclosporin
A3	Clarithromycin prescribed to a patient who is taking digoxin	Macrolides increase plasma concentration of digoxin - increased risk of toxicity
A4	Erythromycin prescribed to a patient who is taking simvastatin with no evidence that the patient has been advised to stop the simvastatin whilst taking the antibiotic	Increased risk of myopathy when simvastatin is given with erythromycin
A5	Ibuprofen prescribed to a patient who is taking lithium carbonate	Excretion of lithium reduced by NSAIDs – increased risk of toxicity
A6	Verapamil prescribed to a patient who is taking atenolol	Taking verapamil with beta-blocker may lead to severe hypotension and heart failure
A7	Naproxen prescribed to a patient who is taking warfarin	Anticoagulant effect of coumarins possibly enhanced by NSAIDs
A8	Tagamet prescribed to a patient who is taking warfarin	Metabolism of coumarins inhibited by cimetidine, the active ingredient in Tagamet leading to enhanced anticoagulant effect
A9	Fluvastatin prescribed to a patient who is taking warfarin	Fluvastatin enhances anticoagulant effect of coumarins
A10	Microgynon prescribed to a patient who is on carbamazepine	Carbamazepine accelerates the metabolism of oestrogens - reduced contraceptive effect
A11	St John's Wort prescribed to a patient who is taking fluoxetine	Increased serotonergic effects when fluoxetine is given with St John's Wort – avoid concomitant use
A12	Tramacet prescribed to a patient who is taking paracetamol	Tramacet contains tramadol and paracetamol - duplication of paracetamol and increased risk of paracetamol toxicity

Table 5.2. Clinical scenarios in relation to drug-allergies, contraindications, inappropriate doses, drug-route suitability, high dose initiation of medicines and significant dose increase

Test	Dispensing scenario tested (Alert expected = Yes)	Rationale
B. Drug Allergy		
B1	Fluarix vaccine prescribed to a patient with egg allergy	Summary of Product Characteristics (SPC) – Contraindicated British National Formulary (BNF) - Individuals with a history of egg allergy can be immunised with either an egg free influenza vaccine, if available or an influenza vaccine with an ovalbumin content less that 120 nanograms/mL (facilities should be available to treat anaphylaxis). Fluarix's ovalbumin content is less than 100 nanograms/mL
B2	Phenoxymethylpenicillin prescribed to a patient with penicillin allergy	Contraindicated
C. Contraindications (including age, gender and condition)		
C1	Aspirin 300mg tablet to be taken every six hours when required (112 tablets) prescribed to a child of 14 years	Contraindicated in children less than 16 years - Reye's syndrome. Guidance increased from 12 years old in 2003 (Medicines and Healthcare Products Regulatory Agency, 2003)
C2	Acrivastine 8mg capsule to be taken three times daily (84 capsules) prescribed to an elderly patient of 70 years	Contraindicated in patients over 65 - may be more sensitive to side effects especially drowsiness
C3	Finasteride prescribed to a female patient	Finasteride is not indicated for use in women or children
C4	Methotrexate prescribed in pregnancy	Contraindicated
C5	Propranolol 10mg tablet to be taken four times daily (112 tablets) prescribed to a patient with asthma who is on salbutamol	Beta-blockers, including those considered to be cardio selective (e.g. Propranolol), should usually be avoided in patients with a history of asthma or bronchospasm

D. Dose check		
D1	Diclofenac sodium 50mg tablet to be taken four times daily (112 tablets)	The daily dose of 200mg is more than the maximum daily dose of 75-150mg in 2-3 divided doses recommended by the BNF for oral intake
D2	Methotrexate 2.5mg tablets, 15mg to be taken daily (42 tablets)	Methotrexate dose is once weekly
E. Drug-route check		
E1	Timolol eye drop prescribed to a patient with asthma who is on salbutamol	BNF states that beta-blockers, even those with apparent cardio-selectivity should not be used in patients with asthma or a history of obstructive airways disease, unless no alternative treatment is available. In such cases the risk of inducing bronchospasm should be appreciated and appropriate precautions taken
F. High dose initiation of medicines and significant dose increase		
F1	MST Continus 100mg tablets prescribed to a patient who had 10mg recorded in the ePMR system	Significant dose increase
F2	Morphine sulphate solution 20mg/ml, 5ml to be taken every 4-6 hours when required by an opiate naïve patient	High dose initiation

Table 5.3. Clinical scenarios where an alert would not be expected

Test	Dispensing scenario (Alert expected = NO)	Rationale
G1	Pravastatin prescribed to a patient who is already taking warfarin	Unlike some statins, pravastatin is not known to affect the effect of anticoagulants. This scenario checks if interactions are picked up at drug class, product level or both
G2	Amoxicillin prescribed to a patient who is on Microgynon	Current recommendation - no additional contraceptive precautions are required when combined oral contraceptives (COCs) are used with non-enzyme inducing antibiotics unless diarrhoea or vomiting occurs (Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit, 2011)
G3	Atenolol prescribed to a patient who is already taking amlodipine	Calcium-channel blocker and beta-blocker combination may be used to treat high blood pressure or to relieve angina pain when either drug alone proves inadequate
G4*	Atenolol 75mg to be taken once daily for 28 days	Requires dispensing of 25mg and 50mg tablets as the 75mg product is not commercially available. Maximum daily dose can be up to 200mg depending on the condition being treated

* Drug-doubling

Rationale for the test scenarios

Table 5.1 to Table 5.3 shows the clinical rationale for each of the scenarios tested. The scenarios in Table 5.1 and Table 5.2 are potentially hazardous based on the clinical rationale outlined above and should trigger an alert in the ePMR system. The first set of tests, described in Table 5.1 was designed to test the performance of ePMR systems with respect to checking drug-drug interactions and hazardous co-prescriptions. The second set described in Table 5.2 was designed to test information that could have been provided either from the prescription or from the patient medication record without recourse directly to the GP. The third set described in Table 5.3 looked at the potential for over-alerting. The scenarios should not trigger alerts. These include circumstances where other drugs in the class have clinically significant interactions but the test drug does not or because of concomitant use being downgraded due to new evidence. Allergies and pregnancy data are not routinely communicated directly on prescriptions. Nevertheless, pharmacists may be

aware of this information directly from the patient and would expect to receive appropriate alerts if the information was recorded in the ePMR system.

Test process

One researcher (OO) visited each participating pharmacy at a mutually convenient time to collect relevant data about the performance of the pharmacy's ePMR system. The simulated test was conducted in each pharmacy over a period of two days (not necessarily consecutively) to allow for scenarios requiring historical medications to be entered on the second day. A member of the pharmacy staff entered the dummy patient data and the scenarios into the ePMR system while the researcher stood nearby and observed. All scenarios were tested on each of the systems once. In the scenarios employed, the dosage instructions were created using the ePMR system's dose codes and so it was expected that the ePMR system would be capable of recognising an error. Data were recorded on pre-designed data extraction sheets. Where a scenario required a historical medication record for an assessment, entry of any '*newly-prescribed*' medication was done at least one day after the initial entry of the '*historical*' medication. The response of the ePMR system was recorded as '*yes*' where an alert was generated or '*no*' if the ePMR system did not produce an alert. A '*correct*' response was recorded if an alert was presented onscreen when an alert was expected or an alert was not displayed onscreen when it was not expected. The study was reviewed by the University of Nottingham Medical School Research Ethics Committee and was given a favourable opinion. National Health Service (NHS) research and development permission was obtained from Nottinghamshire Health care NHS Trust.

5.4 Findings

Five unique ePMR systems licenced for EPS R2 in England were tested in the eight participating pharmacies with a sixth ePMR system assessed in a demonstration setting. All the six ePMR systems assessed had safety features in them, alerting users about potential hazardous situations. Four of the eight participating pharmacies were using the same ePMR system (System S2) at the time of the assessment; the system responses observed in all four sites were the same. No system produced the anticipated responses for all of the 28 scenarios tested. Alerts were displayed in a pop-up window (two systems); in a fixed area for messages (one system); on a separate screen (one system) or as a dual warning in both a pop-up window and in a fixed message area (two systems).

Table 5.4. Hazardous co-prescriptions and interactions - alert responses by electronic Patient Medication Record systems (alert generated = Yes, no alert generated = NO)

Test	Dispensing scenario tested	Electronic Patient Medication Record System					
		S1	**S2**	**S3**	**S4**	**S5**	**S6**
A. Drug Interactions							
A1	Sildenafil prescribed to a patient who is also receiving a nitrate	Yes	Yes	Yes	Yes	Yes	Yes
A2	Ciprofloxacin prescribed to a patient who is taking ciclosporin	Yes	Yes	Yes	Yes	Yes	Yes
A3	Clarithromycin prescribed to a patient who is taking digoxin	**NO**	**NO**	Yes	Yes	Yes	Yes
A4	Erythromycin prescribed to a patient who is taking simvastatin with no evidence that the patient has been advised to stop the simvastatin whilst taking the antibiotic	Yes	Yes	Yes	Yes	Yes	Yes
A5	Ibuprofen prescribed to a patient who is taking lithium carbonate	Yes	Yes	Yes	Yes	Yes	Yes
A6	Verapamil prescribed to a patient who is taking atenolol	Yes	Yes	Yes	Yes	Yes	Yes
A7	Naproxen prescribed to a patient who is taking warfarin	Yes	Yes	Yes	Yes	Yes	Yes
A8	Tagamet prescribed to a patient who is taking warfarin	Yes	Yes	Yes	Yes	Yes	Yes
A9	Fluvastatin prescribed to a patient who is taking warfarin	Yes	Yes	Yes	Yes	Yes	Yes
A10	Microgynon prescribed to a patient who is on carbamazepine	Yes	Yes	Yes	Yes	Yes	Yes
A11	St. John's Wort prescribed to a patient who is taking fluoxetine	Yes	Yes	Yes	Yes	Yes	**NO**
A12	Tramacet prescribed to a patient who is already taking paracetamol	Yes	**NO**	**NO**	Yes	Yes	Yes

The systems correctly identified the majority of hazardous co-prescriptions and drug-drug interactions (Table 5.4). Two of the ePMR systems identified all the 12 interactions that were assessed in this category. Systems S1 and S2 failed to highlight the potential for digoxin toxicity when co-prescribed with clarithromycin. Systems S2 and S3 failed to notify the user about potential hazards from coincident prescribing of paracetamol when generic paracetamol and Tramacet (a product containing tramadol and paracetamol) were prescribed for the same patient on subsequent days. System S6 did not highlight the clinically significant interaction between fluoxetine and St John's Wort. Further investigation of the settings for S6 highlighted that St John's Wort drug name was not mapped to a physical product.

Table 5.5. Responses by electronic Patient Medication Record systems in relation to drug-allergies, contraindications, inappropriate doses, drug-route suitability, high dose initiation of medicines and significant dose increase (alert generated = Yes, no alert generated = NO)

Test	Dispensing scenario tested	Electronic Patient Medication Record System					
		S1	S2	S3	S4	S5	S6
B	**Drug Allergy**						
B1	Fluarix vaccine prescribed to a patient with egg allergy	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**
B2	Phenoxymethylpenicillin prescribed to a patient with penicillin allergy	**NO**	Yes	**NO**	**NO**	**NO**	Yes
C	**Contraindications (including age, gender and condition)**						
C1	Aspirin prescribed to a child of 14 years	**NO**	**NO**	Yes	Yes	**NO**	**NO**
C2	Acrivastine prescribed to an elderly patient of 70 years	**NO**	**NO**	**NO**	Yes	**NO**	**NO**
C3	Finasteride prescribed to a female patient	**NO**	**NO**	**NO**	Yes	**NO**	**NO**
C4	Methotrexate prescribed in pregnancy	**NO**	**NO**	**NO**	Yes	Yes	**NO**
C5	Propranolol prescribed to a patient with asthma who is on salbutamol	**NO**	Yes	Yes	Yes	Yes	Yes
D	**Dose check**						
D1	Diclofenac tablets prescribed above the maximum daily dose recommended by the British National Formulary	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**
D2	Methotrexate prescribed on a daily basis	Yes	Yes	**NO**	Yes	Yes	Yes
E	**Drug-route check**						
E1	Timolol eye drop prescribed to a patient with asthma who is on salbutamol	**NO**	**NO**	Yes	**NO**	Yes	**NO**
F	**High dose initiation of medicines and significant dose increase**						
F1	MST Continus 100mg tablets prescribed to a patient who had 10mg tablets recorded in the ePMR system	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**
F2	Morphine sulphate concentrated oral solution prescribed to an opiate naïve patient	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**

Table 5.5 shows the ability of the ePMR systems to highlight drug-allergy issues, contraindications, inappropriate doses, drug-route suitability, issues with high dose initiation of medicines and significant dose increase assessment.

None of the systems produced an alert for all the scenarios. System S4 produced the most alerts (for four of the twelve scenarios), with system S1 only providing an alert in one of the scenarios. None of the systems identified the potential allergy to Fluarix and only S2 and S6 provided an alert to the penicillin sensitivity. Further investigation of the systems showed that in S4 and S5, drug allergy must be recorded per product for allergy checking to take place. With respect to checking for contraindications because of age, gender or co-morbidity a wide range of system responses were observed. S4 successfully alerted for all of the scenarios presented, S1 did not alert for any of the scenarios and the other systems alerted in less than half of the scenarios. Systems S1, S2 and S5 informed about non-suitability of aspirin use (C1) in a child of 14 years of age by recording the information on the prescription label or in the message area irrespective of the age of the patient. S3 did both. It was not possible to record in S6 that a patient was pregnant (C4).

None of the systems identified the overdose of diclofenac in D1. Five of the six systems provided a warning about the use of methotrexate (D2) however, the alert was provided irrespective of the frequency regimen of methotrexate - weekly or daily. None of the ePMR systems appeared to check the dosing frequency entered. The alerts displayed in four of the ePMR systems were based on the National Patient Safety Agency (NPSA) directive regarding weekly dosing of oral methotrexate (National Patient Safety Agency, 2006). In S4, the weekly regimen was advised in the counselling section of the ePMR software; however, this was contrary to the specific alert layout recommendations of the NPSA. No alert was provided by S3.

Scenario E1 was similar to C5; beta-adrenoceptor blocking drugs (in this case, timolol eye drops) should not be used in asthmatic patients (even when administered as eye drops). Unlike C5 where five of the systems correctly alerted the user, for E1 four of the systems failed to warn the dispenser about the potential for harm. Scenarios F1 and F2 were concerned with instances where patients should be started on a low dose of the medication or have doses changed gradually. None of the six systems tested provided any warning when presented with these scenarios.

Table 5.6. Responses by electronic Patient Medication Record systems in clinical scenarios where an alert would not be expected (alert generated = YES, no alert generated = No)

Test	Dispensing scenario tested	Electronic Patient Medication Record System					
		S1	**S2**	**S3**	**S4**	**S5**	**S6**
G1	Pravastatin prescribed to a patient who is already taking warfarin to investigate whether ePMR alerts are attached to individual drugs or whether they are applied at the class level	No	No	**YES**	No	**YES**	No
G2	Amoxicillin prescribed to a patient who is on Microgynon to see if systems are being updated in line with more recently updated guidance	**YES**	No	**YES**	No	No	**YES**
G3	Atenolol prescribed to a patient who is already taking amlodipine	No	No	**YES**	No	**YES**	**YES**
G4*	Atenolol 75mg (25mg + 50mg) once daily [28-day treatment]	No	No	No	**YES**	No	No

*Drug-doubling

Table 5.6 shows the results when systems were tested to assess whether unnecessary alerts were generated. Many statins interact with warfarin; however, pravastatin has been shown not to interact. In G1, four of the systems correctly showed no alert, however systems S3 and S5 incorrectly produced alerts. The scenario G2 involving the combined oral contraceptive (COC) Microgynon and the antibiotic amoxicillin was included to assess if new guidance had been implemented to no longer warn against concomitant non-enzyme inducing antibiotic use with COCs (Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit, 2011). Three ePMR systems presented an alert contrary to the revised guidance. Scenario G3 looked at the co-prescribing of two anti-hypertensive drugs, a very common and usually appropriate practice in patients with high blood pressure. Three of the systems produced alerts about the use of two similar medicines while three did not. The prescribing of two strengths of the same medicine to achieve a dose not available as a single tablet was tested in G4. Five of the systems appropriately produced no alert.

5.5 Discussion

The results suggest that current ePMR systems have some deficiencies with respect to highlighting clinical hazards such as drug-drug interactions, co-prescriptions, allergies, contraindications and inappropriate dosing. Although some progress has been made in the development of ePMR systems over the years, there is still a long way to go in bringing the systems up to the level of performance that is now required in clinical practice.

The tests described in Table 5.1 assessed the performance of ePMR systems with respect to checking drug-drug interactions and hazardous co-prescriptions. All of the medicines a patient receives from a pharmacy are recorded in the ePMR system so the information is generally readily available to perform these safety checks. However, this is only the case when patients use the same pharmacy. There would appear to be some cases where known drug-drug interactions are not warned against. If pharmacists rely on the ePMR system to identify these hazardous events, then this is a concern for patient safety. This study was not designed to identify the reasoning behind these events being missed and further work would be needed to understand why this was the case.

Pharmacists are considered to be experts in medicines and as well as being aware of specific drug interactions, they are also required to ensure medicines are used safely based on key parameters such as allergies, co-morbidities, issues associated with age and gender of the patient. Often the pharmacist has available only the information presented on the prescription and in the ePMR system, along with the information provided by the patient to perform the necessary safety checks. Research has shown that without broad attention, users of ePMR systems may fail to notice things onscreen or from one view to the next ('*inattentional blindness*'). This suggests that users perceive and remember only the things and details that they deliberately focus on when using the system, missing other concurrently presented information (Simons and Chabris, 1999). The ePMR systems had highly variable performance when checking for issues other than drug-drug interactions. In many cases, few or none of the systems identified the potentially hazardous prescribing. Inattentional blindness may result in users not being aware of the varying performance of the system if they are only on the lookout for drug-drug interaction information.

In the tests relating to information that could have been provided either from the prescription or from the patient medication record, some of the systems tested were unable to record the required information such as allergy status, thus preventing appropriate checks being made by the ePMR system. In one instance, allergies could be recorded but these were required to be identified against each medicine, for example, a patient with a penicillin allergy would require an allergy marker being placed against each type of penicillin-based medicine (of which at least six are routinely used in general practice in England). Where allergies could be recorded, none of the systems identified the potential issues with Fluarix vaccine.

The responses to items prescribed inappropriately to patients based on their age were commonly absent with only one system correctly identifying both hazardous events. All computer generated prescriptions now include both the age and date of birth, which can also be easily verified by the patient at the point of dispensing. With this availability, it is surprising that the facility for the ePMR system to verify appropriateness based on age is not generally present.

The tests showed that the alert for oral methotrexate appeared irrespective of the frequency entered on the label potentially allowing hazardous daily dosing to be overlooked as this warning appeared whether the frequency was correct or not. There was no alert in S3 perhaps due to oversight, lack of awareness of the existence of the NPSA recommendation, or other reasons best known to the pharmacy software vendor company.

In relation to prescribing of morphine, none of the systems alerted to the hazardous practice of initial prescribing of high dose of medicines to patients or making sudden increases in dose. Given the potential for opioids such as morphine sulphate to cause harm to patients (Cousins et al., 2011), high initiation dose and sudden dose increase should alert the user of the system to enable appropriate collaborative management of this potential clinical hazard to take place between the pharmacist and the prescriber and where relevant, in conjunction with the patient.

It has been reported that alert fatigue can occur when excessive alerts are presented, potentially resulting in important alerts being ignored by the end user (Horn, 2006; Kesselheim et al., 2011). In the tests to check the potential for over-alerting, two of the six systems in test G1 triggered unnecessary alerts suggesting that some systems generate alerts at the drug class level rather than individual drug level, which may lead to an over-presentation of warnings. Three of the six systems in test G2 provided unnecessary warnings about the use of Microgynon with amoxicillin. This suggests that some systems are not updated in a timely fashion when new guidance becomes available.

Implications for policy

The results of this study have shown that all of the ePMR systems have inadequacies and do not always produce the same alerts. Given that the ePMR system is intended to be a core element of the service provision in pharmacy, then it would seem appropriate for the information to be consistent across systems. At present, there is no core specification for the types and content of safety features in ePMR systems in England and there is an urgent need to produce one.

In addition, a minimum specification for the data that should be recorded in ePMR systems should be set to facilitate appropriate safety checks being made. For example, the date of birth should be recorded in the system every time a new patient is added to the system. If the allergy status is known, this should also be entered or '*no known allergy*' entered in the system if the patient has no known allergy. Ideally, this information should be pulled into ePMR systems from appropriate hospital or primary care information systems.

Facilities for verifying appropriateness of medications based on age should be included in ePMR systems where necessary. In addition, the frequency of medications entered into the systems should be used in calculating the total dose of prescribed medications whenever the information is available and where possible, to avoid hazardous doses being overlooked. In some cases, this would require prescribers to include the indications for prescribed medications along with prescriptions. High initiation doses, sudden dose increases and loading doses should alert ePMR system users in order to continue to protect patients from related hazards. Users should be informed where an alert might be expected but due to updated evidence, this is no longer the case.

It is important to integrate ePMR systems with other clinical systems for access to patients' clinical data. This would provide context for alerts and enable wider adherence and safety checks to be conducted. However, this would require careful consideration and agreement by pharmacists as to the level of responsibilities they are willing to accept professionally.

In the interest of patient safety, it would also be helpful for software vendors and knowledgebase creators to work together to explore ways of cutting down on unnecessary alerts. Moreover, it would be helpful to create an online repository for existing evidence used in alerts and any relevant and agreed recommendations for reference purposes, to provide vendors and users with access to the data used in ePMR systems and alerts.

Implications for practice

Based on the results from this study it is important that pharmacy professionals understand the capabilities of the systems they use in practice, including their strengths and weaknesses. They need to continue to use multiple methods to ensure safety of medications at the point of dispensing. Users need to improve the quality of data recording in ePMR systems to enable the software to take advantage of modern computing architecture and programming to help reduce or in some cases, eliminate false, irrelevant or non-contextual alerts.

Minimum specifications and standards are required for ePMR systems. With no core specification and standard system response, it falls to the clinical knowledge of the pharmacist to ensure that all of the items they dispense are clinically appropriate and safe. Many pharmacists work in one pharmacy, but some work in different pharmacies providing cover for days off and holidays. As these systems provide different responses to clinical situations, the pharmacists need to be fully aware of how the ePMR systems they are using will respond, if at all, in any given situation. Provision of feedback loops in ePMR systems would enable system vendors to gather important data about their system's performance in practice. This would provide focus for the necessary improvements to be made in ePMR systems to improve patients' clinical outcomes.

Strengths and limitations

Strengths

One of the strengths of this study is that six of the seven EPS R2 approved ePMR systems in August 2012 were tested. Five were available in practice and one was supplied by the system vendor. These represent almost complete coverage of systems used in community pharmacies in England. This study provides a picture of the ability of ePMR systems and their safety features in their current state of maturity, to pick up potential clinical hazards and medication errors during pharmacy order entry. It is the first assessment of its type to look at the safety aspects of ePMR systems approved for EPS R2 in community pharmacy setting in England.

Limitations

This study was an assessment of the ability of the systems to inform users about potentially hazardous situations during order entry. It provides information about the current state of maturity of the systems. However, there are limitations that should be considered when interpreting the results obtained in this study.

A more in-depth and rigorous approach such as a Delphi panel could have been used to reach consensus about appropriate scenarios to include in the study. However, the limited project period did not permit the use of such a technique. As such, the selected scenarios were based on available evidence and consensus between my supervisors and me. Other criteria that were used are clinical importance, frequency of use in practice, alerting potential and tendency to cause harm to patients.

It is worthy of note that some of the scenarios used in the assessment may, on occasion, be violated for specific patients. For example, when treatment is started by a specialist consultant in secondary care for continuation in primary care. It was not the intention of this study to allow for these situations thereby focusing on more routine prescribing in general practice.

Using separate patient profiles for each scenario prevented unnecessary alerts from being generated by non-targeted drug combinations. However, this may not be a true reflection of what happens in practice. In the real world, other medications prescribed to patients could have caused the systems to generate additional alerts. It is also possible that the performance of systems that produced spurious alerts was due to older software versions. Perhaps updates were yet to be applied to those systems at the time of the study.

Further research

The assessment was not conducted as a specific test of the sensitivity or specificity of the systems as the underlying algorithms were not reviewed. Cases where therapeutic moieties were not mapped to physical products or the reasoning behind missed events were also not investigated. Further research would be needed to address these issues and to explore how other clinical data about patients such as allergy and laboratory data can be used for real time checks conducted by ePMR systems.

Further research is also warranted to look at how pharmacy professionals respond to safety alerts and how they perceive them in practice. Likewise, an investigation of the opportunities to improve pharmacy professionals' ability to detect drug interactions and other clinical hazards to prevent iatrogenic harms to patients.

5.6 Conclusions

This study is a preliminary step in identifying opportunities for improving the functionality of ePMR systems used in community pharmacies focusing on patient safety. This could lead to a new era of ePMR systems that are capable of making effective use of the full range of available patient data. It would also help in providing contextual alerts and reducing over-alerting and alert bypass.

The performance of the ePMR systems tested was variable and sub-optimal. Findings from this study suggest the need for minimum specifications, standardisation and harmonisation of ePMR systems to ensure consistency of performance. It is essential that the deficiencies identified with respect to highlighting clinical hazards, such as dangerous co-prescriptions and inappropriate dosing are addressed. Exploiting the capabilities of modern technologies offers enormous prospects for achieving these goals. For example, coupling other clinical information systems with ePMR systems, including access to details of medications dispensed to patients in other pharmacies, could help improve the quality and effectiveness of clinical decision support in ePMR systems.

In order to achieve patient safety goals in community pharmacy, a multifaceted strategy is required at every stage of the medication use process, including focused training of pharmacists in human errors, risk management, alert management, decision-making and communication.

Chapter 6

Understanding how pharmacists and pharmacy staff use electronic patient medication record systems and manage alerts during the dispensing process

6.1 Introduction

Evidence from the literature and findings from the qualitative interviews in chapter 4 indicates that users of electronic patient medication record (ePMR) systems ignore alerts. The study in this chapter explores how pharmacists and pharmacy staff use ePMR systems and manage alerts during the dispensing process. It has been suggested that safety alerts are useful in identifying adverse drug events and preventing clinical hazards and harm to patients (Amsden, 2002; Buurma et al., 2006). However, research has also highlighted the potential for new, unintended errors arising from the use of technology including system interface design problems, such as pick lists that cause juxtaposition errors (Ash et al., 2004; Campbell et al., 2006).

Alerts and alert management in computerised prescriber order entry systems have been studied in both primary and secondary care, both in the UK and abroad (Sittig et al., 2006; Avery et al., 2007; van der Sijs et al., 2009; Zwart-Van Rijkom et al., 2009; Yeh et al., 2013). In community pharmacies, studies of safety alerts and alert management have focused mainly on drug interaction alerts with limited emphasis on other forms of safety alerts (Desiraju and Murphy, 2003; Colon et al., 2004; Murphy et al., 2004; Buurma et al., 2006; Murphy et al., 2006; Indermitte et al., 2007b; Malone et al., 2007).

However, there is no information about community pharmacy professionals' alert management behaviour in England. No evidence was found in the literature about computerised safety alert designs and their influence on pharmacy professionals' decision to take cognisance of or ignore alerts. This study addresses the aforementioned gaps. The methods of investigation, findings, discussion and conclusions are presented in the sections below.

6.2 Aim

The aim of this study was to understand the use of ePMR systems, management of safety alerts and alert-response practices by pharmacy professionals via direct participant observations in community pharmacy practice setting. The main research question was, 'How do pharmacists and pharmacy staff use ePMR systems and manage alerts during the dispensing process?' This question was expanded as follows:

1. How do pharmacy professionals manage safety alerts presented to them in practice?
    a. What are the reasons why users might ignore alerts in practice?
2. What alert design features do users find useful in practice?
3. What are the inhibitors of alert usefulness?

6.3 Methods

This study was an ethnographically informed, direct observational study exploring the use of ePMR systems and alert management in community pharmacy setting.

Ownership structure of community pharmacies

Pharmacy organisations in England vary in size and number. For the purpose of this research, the following classifications were used: independent (one pharmacy), small chain (2-4 pharmacies), medium chain (5-25 pharmacies) and large chain (over 25 pharmacies) (Bradley et al., 2013).

Criteria for selecting pharmacies and pharmacy professionals

Inclusion criteria:

- All the pharmacies in the Nottinghamshire County PCT and Nottingham City PCT in England
- The pharmacists, pre-registration pharmacists and dispensers in the pharmacies mentioned above, with a minimum of three months experience of using ePMR systems and regular involvement in the prescription dispensing process

Exclusion criterion:

- Pharmacy professionals who participated in the previous study presented in chapter 4 in this thesis, which explored the views and perceptions of stakeholders about ePMR systems, their safety features and alerts were excluded

Sampling and recruitment

Community pharmacies in Nottinghamshire, England were contacted either by post or by telephone and invited to participate in the study with permission from their superintendent pharmacists. A prospective sample of 148 pharmacies were approached with the intention of recruiting a purposeful sample of 8-12 pharmacies based on their ownership structure (see section 6.3 - Ownership structure of community pharmacies), to ensure that various sizes and types of pharmacies were included in the study. In addition, to gain coverage across a range of different ePMR systems that were licensed for electronic prescription service release 2 (EPS R2) and were being used in community pharmacies in England at the time of the study.

Eight (8) pharmacies volunteered to participate in the study. The eight pharmacies covered five out of the six ePMR systems that were available in community pharmacies in England in August 2012, so it was decided to include all of the eight pharmacies in the study. These included one independent pharmacy, two small chain pharmacies, two medium chain pharmacies and three large chain pharmacies. Each of the eight participating pharmacies was assigned a study code from P1 to P8.

Description of participants

Individual participants were pharmacists and pharmacy professionals from the eight pharmacies that agreed to participate in the study. In total, 17 pharmacy professionals took part in the study. Each participant was assigned an identification code based on the participant's professional designation and the pharmacy code, for example, '*Locum Pharmacist, Pharmacy P7.*'

The research observer

As the primary researcher, I conducted the observations, interviews and data analysis under the guidance of my supervisors. I am a practicing pharmacist and I have received training in research methodologies and techniques.

Participant information sheet and consent form

Prior to the observations, participants received a letter of introduction (please see appendix D.1 for a copy of the letter of invitation) describing the study and its aim. Participants were also sent an information sheet (please see appendix D.2 for a copy of the participant information sheet) and were encouraged to ask questions about any aspect of the study that was not clear to them. They were free to withdraw from the study at any time without prejudice. All participants completed the consent form to signify their intention to participate in the study (please see appendix D.3 for a copy of the consent form).

Pharmacy observations

Direct on-site observations took place in the eight community pharmacies that agreed to participate in the study at a mutually convenient time. Three or four 30-minute observational sessions were conducted over a period of three days. The three days were spread over a period of four weeks or as a single block depending on the requirements of the pharmacy and participants. A period of 30 minutes was chosen to strike a balance with being present for sufficient amount of time to observe a meaningful amount of prescription dispensing episodes, whilst not creating undue burden on participants. As much as possible, observations were conducted at different times of the day in the pharmacies (please see appendix D.6 for the schedule of observations conducted in the participating pharmacies). The

observations were relatively unstructured and attempt was made to record all that occurred during each 30-minute observational period (please see appendix D.4 for a copy of the observation schedule and guidance notes). I observed from a short distance to gain a clear view of the ePMR system screen, but moved closer to participants if my attention was called to an alert on the computer screen or to clarify an observed phenomenon, pattern or behaviour. Some participants talked to me or made comments voluntarily, to point my attention to potentially relevant issues about the study. Recording of observational data was done manually using a pre-designed data collection form.

The interview process

Participants were asked to clarify any unusual behaviour at the end of each period of observation. In total, 17 participants were interviewed. The interviews included the follow-up interviews with participants to clarify any observed individual or system behaviour where required. A short semi-structured interview was also conducted with each of the responsible pharmacists of the eight community pharmacies where observations took place. This was to obtain information about the characteristics and capabilities of the ePMR systems being used in the pharmacies.

Researcher's position

Participants were fully aware that they were being observed. During the period of the observations, I openly took notes but did not participate in any of the activities or discussions within the pharmacy, other than when asking participants questions about an observed behaviour or occurrence. Manual note taking was used to capture the interview data because it was less obtrusive than audio recording or filming participants using a video camera. At the end of each day, I went over the notes to ensure that I captured the observed activities correctly and that all the relevant details had been recorded accurately and completely. Each note was typed and stored electronically in readiness for analysis.

Analytical approach

The observational and interview data were read several times and analysed thematically, using the technique of constant comparison for identifying emerging themes and Framework approach for cross-analysing the data (Ritchie et al., 2013).

This Framework built on the Framework used for analysing the data from the exploratory study (chapter 4). Content analysis of the interview data was done to identify desirable features and improvements suggested by participants.

The performance of specific safety features such as those based on drug interaction and allergy checking were also observed on the different ePMR systems. If an alert was presented onscreen when it was expected or an alert was not displayed onscreen when it was not expected, a correct response was recorded. The design and presentation features of alerts onscreen that could influence users' alert acceptance behaviour were also recorded. Descriptive statistics were used to describe some of the performance assessment data obtained from this study (see chapter 5).

Information about the characteristics of ePMR systems' user interfaces and alerts were obtained from the responsible pharmacists or through observations but confirmed with the responsible pharmacists. The parameters used were selected based on the findings from the literature (chapter 3), the qualitative interviews with stakeholders (chapter 4) and the performance assessment study (chapter 5). Summary of the findings about ePMR systems' user interfaces and alerts are presented in Table 6.2 and Table 6.3 respectively for comparative purposes. The data were anonymised and kept in the location designated for secure storage of research artefacts by the University of Nottingham.

Ethical approval, NHS permission and confidentiality

Ethical approval was obtained from the University of Nottingham Medical School Research Ethics Committee and NHS permission was obtained from Nottinghamshire Health care NHS Trust. The names of the pharmacies have been anonymised P1-P8 and the ePMR systems S1 – S5 (see section 5.3) to preserve the anonymity of the pharmacies, the ePMR system and system suppliers. Copies of the confidentiality agreement between the researcher and the pharmacy, and the poster displayed in the pharmacy during the observational sessions can be found in appendix D.7 and appendix D.8 respectively.

6.4 Findings

Five unique ePMR systems licensed for electronic prescription service release 2 (EPS R2) in England were in use in the eight pharmacies that took part in the study. Out of the eight participating pharmacies, four were using the same ePMR system (S2). The responses of these four systems observed in all four sites were the same (see section 5.4). Findings from the observations are presented first, followed by findings from the reflective interviews that followed the observations. The findings are arranged under relevant themes derived from the Framework analysis (see section 2.6) of the data obtained from this study. The details of the pharmacies and participants are provided in Table 6.1.

Table 6.1. Details of pharmacies and participants in the observational study

Case study	P1	P2	P3	P4	P5	P6	P7	P8	Total
Ownership Type	LC	MC	SC	SC	LC	I	LC	MC	
ePMR system code	S1	S2	S3	S2	S4	S2	S5	S2	
Number of computer terminals	2	3	2	2	2*	1	1	2**	
Total number of pharmacy professionals observed and interviewed	**1**	**2**	**1**	**3**	**2**	**1**	**4**	**3**	**17**
Pharmacists	1	1	1	1	1	1	1	1	8
Locum pharmacists	0	0	0	0	0	0	0	2	2
Pre-registration pharmacists	0	0	0	1	1	0	0	1	3
Dispensers	0	1	0	1	0	0	1	1	4

Ownership types: Independent (I) - one pharmacy, Small chain (SC) - 2-4 pharmacies, Medium chain (MC) - 5-25 pharmacies, and Large chain (LC) - over 25 pharmacies

* One of these two terminals was located in the consultation room for recording clinical services but was not enabled for dispensing.

** One of these two terminals was located in the consultation room for recording clinical services; was enabled for dispensing, but had no label printer attached.

6.4.1 Findings from the observations

Location of computer terminals in the pharmacy

Pharmacies P5, P6 and P7 had one terminal each. Pharmacies P1, P3, P4 and P8 had two terminals each while pharmacy P2 had three terminals. Two of the terminals in Pharmacy P1 were in the dispensary. One was close to the electronic tills while the second terminal was located close to the water sink where reconstitution of liquid preparations was carried out. The terminal that was close to the tills was used more heavily than the one close to the sink, which was seldom used (see Figure 6.1 for an example layout of a community pharmacy where observations were conducted). Pharmacy P5 had an extra computer in the consultation room. In pharmacy P8, there were two terminals – one in the dispensary and one in the consultation room. The second system was only used for clinical services such as medicines use reviews (MURs). The terminal in the consultation room had no prescription label printer attached to it.

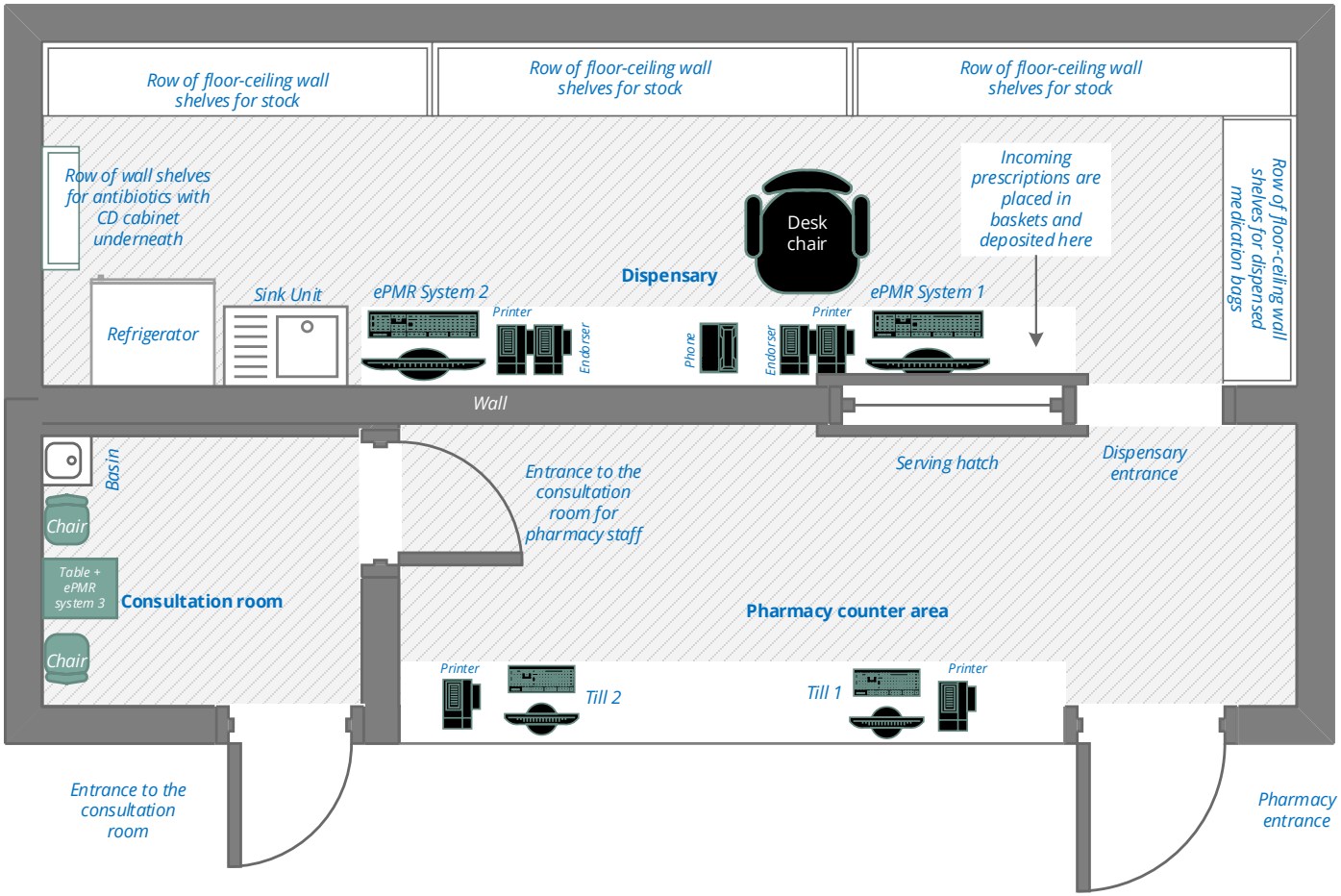


Figure 6.1. Example layout of a community pharmacy where observations were conducted

Note: Figure not drawn to scale.

System operation by pharmacy professionals

Pharmacists may or may not be involved in the order entry process or operation of the ePMR system. Pharmacists' involvement in the order entry process appeared to be dependent on choice, staff availability and the established work pattern in the respective pharmacy. For example, pharmacists including locum pharmacists were more likely to operate the system when working in the dispensary alone or without support.

In pharmacies P4, P5 and P8, the pharmacists did not operate the ePMR system at all during the period of observations. In pharmacy P4, the pharmacist mostly attended to customers with queries and performed pharmacist-led services, such as medicines use reviews. The dispensing staff members did all the dispensing tasks and the pharmacist conducted the final prescription checks. The pharmacist in pharmacy P3 did order entry and prescription label generation herself. She then passed the prescriptions and labels to the dispenser to assemble the items. She also handed out the completed prescriptions herself after conducting the final prescription checks.

The user interface

The layout of the user interface for dispensing was different on all the systems. The user interface of systems S2 and S3 looked busy with many windows and texts. For example, system S2's user interface was divided into six sections for patient medication record, prescription label, product prices and stock details, endorsement information, British National Formulary (BNF) product classification information and an information box which was sometimes used for displaying alert information. The user interfaces of systems S1, S4 and S5 appeared less busy than the user interfaces of the other two systems (S2 and S3). System S5 had the set of uses of the ePMR system neatly organised into menus and tabs on the user interface.

Table 6.2. Some observed characteristics of the user interfaces of electronic patient medication record systems

Item	Feature	Electronic Patient Medication Record System				
		S1	S2	S3	S4	S5
1	List of active safety features displayed onscreen or at the top of the screen	No	No	No	Yes	No
2	Dispensing was done on a single screen	No	No	Yes	No	No
3	Patient details displayed throughout the dispensing process	No	No	Yes	No	No
4	Prescription form type indicated onscreen (1- Form colour, 2-Short code, 3- Icon, 4- Label background takes the prescription form colour)	1, 2	1,2	4	2	2,3
5	Historical medication record displayed during dispensing	Yes	Yes	No	No	No
6	Partial-drug name search possible	Yes[1]	Yes[1]	Yes	Yes[1]	Yes
7	Pick list is shortened as the name of a product is typed into the search box	Yes	Yes	No	Yes	No
8	Possible to free-type dosage instructions	Yes	Yes	Yes	Yes	Yes
9	Facility for recording interventions while dispensing is available	No	Yes	No	Yes	No
10	System displayed dispensed items and endorsement information onscreen on or before label is printed	Yes	Yes	Yes	Yes	Yes

1. System automatically searched for the drug name; search result reduced as more characters of the drug name is typed into the search box

On system S3, dispensing and selection of products were done on one screen, with no pop-up window. On this system, the details of the patient being dispensed to were displayed at the top of the screen throughout the dispensing process. The prescription form type was displayed onscreen (system S1) as coloured labels (system S3) or coloured icons (system S5) if this option was selected at the beginning of the dispensing process. Other windows such as product selection window do pop up onscreen and may cover part or all of the main dispensing screen on systems S1, S2, S4 and S5. For example, it was observed that system S1 displayed pieces of information from the British National Formulary and other advisory information onscreen after a medication has been selected from the pick list. However, I noticed that the pharmacist who operated the system swiftly moved past that screen.

It was observed that systems S1 and S2 displayed the historical medication record on the right-hand and left-hand side of the screen respectively during the dispensing process. Some users were seen reviewing prescription orders together with patients' historical medication records, to ensure that patients' profiles were correct and up to date. Systems S3, S4 and S5 did not display the historical medication record onscreen for the system operators to see. Instead, users had to access the medication records if they required the information. Consequently, pharmacy professionals who were using those systems often did not review patients' historical medication records before or during the dispensing process.

Systems S1, S2, S3 and S4 narrowed down the product pick list as the name of a product was being typed into the product search box. On systems S3 and S5, the system operator had to type in the first few characters of the name of the product being searched for in the search box and hit the enter button on the keyboard to get relevant products to show up. It was therefore not possible to predict the length of the pick list on systems S3 and S5. The only way to avoid a long pick list on these two systems was to constrain the search result by typing in more characters of the name of the product in the search box or by including in the search, the formulation type with or without the strength of the product being searched for. The medication pick list on systems S1, S2 and S4 appeared automatically once the user begins to type in the medication search box. They also narrowed down the search results as more characters of the product name were typed into the product search box. In system S5,

the user had to type in a few characters of the product name sequentially and correctly and then press enter on the keyboard to get anything to come up.

Facility for recording interventions was observed on systems S2, S4 and S5 but it was not used during the observations. All the systems had facilities for recording patient notes but this was not done consistently across the pharmacies. Notes were displayed to the person operating the system on accessing the relevant patient record. In some cases, the information boxes created by ePMR system suppliers for note-taking were being used for recording clinical information, such as allergies. None of the systems required the system operator to record the reason for ignoring alerts.

All the systems displayed the dispensed prescription information and relevant endorsements onscreen either as the user dispensed (systems S1 and S4) or before the labels were printed (systems S2, S3 and S5). This was an opportunity for the system operator to check the correctness and accuracy of the dispensing.

System S4 did not allow prescription labels for items in the '*selected list scheme*' (SLS) of the National Health Service (NHS) to print if the user forgot to tick the box designated for confirming that such items can be prescribed under the NHS.

System S5 displayed alerts in an integrated alert box. However, non-clinical information was mixed with clinical alert information in the alert box. Often, the non-clinical information was presented first. For example, system S5 displayed the following information in sequence in a simulated dispensing of Microgynon 30 tablets to a woman who was already taking carbamazepine. First, 'Press Ctrl+B to show brands, including branded generics and Ctrl+G to show generics.' Second, 'Microgynon effects reduced/abolished by Carbamazepine. Bleeding, pill failure possible…' Third, 'Endorsement (1 X 63).'

Design and presentation of alerts

All the systems had safety features in them but only system S4 displayed a list of the safety features that were active on the system at the top of the screen (see Table 6.2). The safety features listed onscreen were based on contra-indications, allergy, drug-drug interactions, duplicate therapy, drug doubling, warnings and precautions.

Table 6.3. Some observed characteristics of alerts on electronic patient medication record systems

Item	Feature	Electronic Patient Medication Record System				
		S1	**S2**	**S3**	**S4**	**S5**
1	Alert display (1- pop-up, 2- alert box, 3- pop-up and alert box, 4- separate screen)	1	1 or 3	2	4	2 or 3[1]
2	Possible to print alert	Yes	Yes	Yes	No	No
3	Hard stop alert observed	No	No	No	No	Yes[2]
4	Scroll bar[3] (vertical) observed in alert box	No	Yes	No	No	No
5	Colour used in alerts (alert text/alert background) (1- Black/White, 2- Red/White, 3- White/Red, 4- Black/Yellow, 5- Black/Red, 6- White/Green, 7- Black/Light yellow)	1	2 or 3	1, 4 or 5	6	7
6	Alert wraps onto multiple lines	Yes	Yes	Yes	Yes	No
7	Alert management advice observed in alerts	Not observed	Irregular	Irregular	Irregular	Irregular
8	Alert severity level implied (1- Minor/Medium/Severe and coloured icons 2- Possible major or serious/ minor interaction 3- Coloured alert background 4- Star rating)	1	2	3	4	Unclear

1. Only seen during the dispensing of methotrexate 2. Hard stop alert prevented users from completing the prescription order entry until they had intervened 3. This is a graphical control element for scrolling continuous lines of text.

Safety alerts were displayed on a separate screen (system S4) in a pop-up window (system S1), an alert box at the bottom of the screen (system S3) or a combination of both pop-up window and alert box (system S2 and S5) (see Figure 6.2 for a sample representation of alerts observed on the ePMR systems). The alert information in the pop-up window was sometimes duplicated in the alert box at the bottom of the screen on system S2 (see Figure 6.2, alert display 3). On systems S1, S2 and S3, alerts could be printed on prescription labels but this option was not observed on systems S4 and S5. A hard-stop alert was observed on system S5 during the dispensing process. The system operator cannot ignore the alert and must decide between two options: '*Proceed*' or '*Do not proceed.*' No other system exhibited a hard stop alert during the rest of the period of observations.

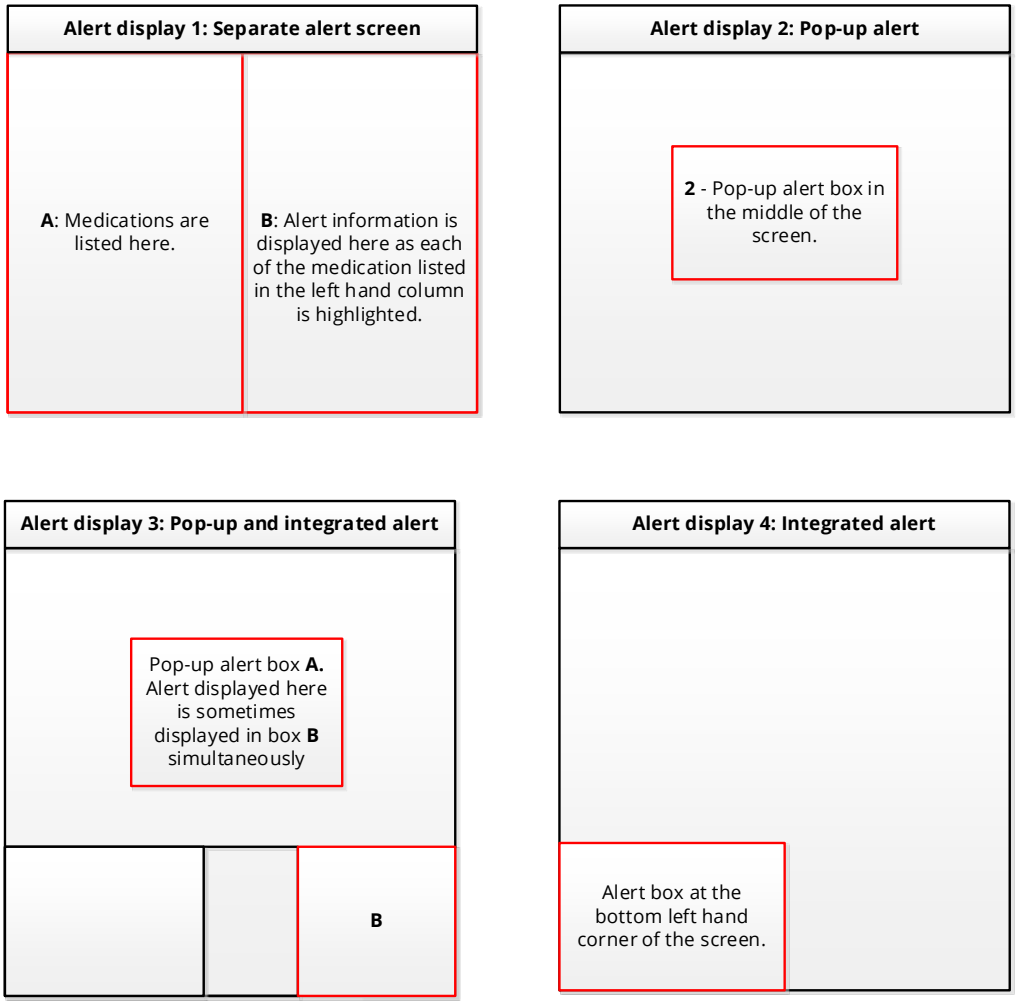


Figure 6.2. Sample representation of alert presentation on the observed electronic patient medication record systems

Level of danger

Alert severity levels in the systems were not clear. It was observed that system S4 displayed three-star (3*) as the level of severity of drug-drug interactions on the system but with no indication about what the three-star signified. It was not clear how many levels there were, how many were featured in system S4 and the significance of each level. System S1 used words such as '*minor*, *medium* and *severe*' in relation to potential interactions presumably indicating three levels of severity. System S2 indicated two possible levels of severity with the terms '*minor interaction*' and '*possible major or serious interaction*.' System S1 used words, colours and symbols to denote the levels of severity of alerts. For example, yellow triangle for minor interactions, blue triangle for medium interaction and red triangle for severe interaction.

Signal words

Signal words used in alerts varied considerably. There was lack of consistency in the use of signal words and the way alert information was written. In system S2, some signal words and terms were capitalised or displayed in normal text. Additionally, the signal words used in drug interaction alerts were different from those used in other warnings. Examples of these signal words and terms are 'POSSIBLE MAJOR OR SERIOUS INTERACTION' (used in drug interaction alerts), 'ATTENTION' and 'Warning' (used in other alerts). For drug interactions, system S3 used signal words or terms such as, 'High risk. Avoid', 'High risk. May need to avoid combination,' 'Moderate risk. Monitor,' 'Moderate risk. May need to avoid combination,' 'Be aware' and 'Potential risk. Monitor,' 'Potential risk. May need to avoid combination.' It was not clear what signal words were used in systems S4 and S5, but terms such as 'contraindicated,' 'dosage risk' and 'increased risk' were observed in some alerts.

Colour

Some of the systems separated drug interaction messages from other warnings. For example, system S3 displayed drug interaction messages in a tabbed box labelled 'Interacts' while other warnings were displayed in another tabbed box labelled as 'warnings' (black text on a white background). The alert messages in system S3 were also divided into several pieces and displayed in sequence from the severe (black text on a red background) to the less severe (black text on a yellow background). Navigation through the alerts was by using the arrow keys on the computer keyboard. This was different from system S2 where alerts that were marked as '*major drug interactions*' were displayed as red text on a white background and those marked as '*minor drug interactions*' were displayed as black text on a white background. Other warnings were displayed as white text on a red background. In pharmacy P5, the pharmacy company colours were prominent in the design of the ePMR system software used in system S4. Alerts were displayed as white text on a green background.

Alert management

The systems mostly identified that there were problems but offered little or no management advice. Users appeared to have a tacit understanding of how best to manage the alerts they received, such as ignoring them. Additionally, dispensing staff members may notify the responsible pharmacist if new medicines are involved. However, the pharmacists and pharmacy professionals I observed mostly cast a quick glance at or completely ignored alerts. Pharmacy professionals ignored alerts regardless of whether alerts were graded in the system or not. It was easy for them to do so either by pressing the enter key or a designated function key on the computer keyboard to continue with the dispensing process. I noticed that dispensing staff in pharmacies P2 and P4 who were using system S2 did not call the responsible pharmacists' attention to any alert during the period of observations, even those suggesting serious clinical hazards. They also did not print alerts for pharmacists to review during the final prescription checking process. In pharmacy P4, the dispenser did not call the pharmacist to any of the alerts that flagged on the system including those warning about '*possible or serious drug interactions*' ('*red text*' alerts) throughout the period of observations at the site.

Hazard management advice was observed occasionally in the systems. For example, when St Johns Wort was prescribed to a patient who was already taking Fluoxetine, system S5 warned about, '*Possible increased 5HT levels, increased effects and incidence of adverse effects with Fluoxetine + St Johns Wort OAD (Kira). CSM advises stop St Johns Wort OAD (Kira). Tell patient*.' However, such management advice was infrequent.

6.4.2 Findings from the interviews

Location of computer terminals in the pharmacy

The pharmacist in Pharmacy P5 confirmed in a follow-up interview that the extra computer located in the consultation room did not have any ePMR software installed. In pharmacy P8 where the second terminal in the consultation room was being used for clinical services, such as medicines use reviews (MURs), the pre-registration pharmacist explained that this occurred about four times a day.

System operation by pharmacy professionals

The pharmacists who did not operate the system in pharmacies P4, P5 and P8 said that they prefer to work that way when they have dispensing help. This is to free up time for checking prescriptions, conducting clinical services and attending to other professional and administrative duties.

The pharmacist in pharmacy P3 said in an interview that she prefers to do order entry and prescription label generation herself. She said that this gives her the opportunity to validate the prescription and do order entry simultaneously. The dispenser then assembles the items before the pharmacist does her final checks and hands over the bagged prescriptions to the patient, carer or pharmacy patron. The pharmacist commented that handing out the dispensed prescription bag herself also gives her an extra opportunity to check the accuracy of the dispensing and to have any necessary communication with the patient or the person who is collecting the prescription.

Views expressed about ePMR systems by participants

Participants expressed mixed views about ePMR systems' performance during the individual interviews.

Positive views expressed about ePMR systems by participants

Positive views expressed by participants during the interviews include highlighting of products that are not allowed on the National Health Service by system S1. Users of system S2 said that they find signposting to various features and functions useful when learning to use the system or after a period of absence from practice. One superintendent pharmacist said that he chose system S2 because of the functional similarity between the care home module in system S2 and the previous system that the pharmacy used, which was made by the same supplier. He suggested that it made dispensing to care home patients less time consuming because fewer mistakes were being made when generating the medication administration record sheets. The pharmacist in Pharmacy P3 expressed liking for system S3 because in her opinion, electronic transfer of prescriptions on the system '*is very quick.*' In addition, dispensing of medications is done on a single screen thus enabling users to avoid potential errors that could result from having multiple windows open simultaneously.

Negative views expressed about ePMR systems by participants

Participants expressed concerns about various aspects of the functionality of ePMR systems. For example, users complained about failure of some systems to remember previous user actions, failure to split labels for multiple packs automatically and computer glitches. Users of system S2 disliked not being able to go back or step through the order entry process. Users of system S4 complained about having to delete a completed prescription to correct mistakes. One user of system S2 believed that he developed repetitive strain injury because of redundant keystrokes in the dispensing process. An example is the need to press the enter button twice to start dispensing a new prescription after selecting the appropriate patient profile. He suggested that such redundant keystrokes should be eliminated because they could create accessibility problems for disabled people.

All the users of system S2 complained about the need to exit the standard dispensing screen to access the electronic prescription service. They described the experience as frustrating when processing electronic and paper prescriptions simultaneously, coupled with the need to login to the server each time. Some users of systems S2 and S4 said that they often find processing prescriptions manually quicker than using the electronic prescription service (EPS). They described the EPS as slow (system S2) and the steps involved in dispensing electronic prescriptions as long-winded (system S4).

Design and presentation of alerts

The responsible pharmacists of participating pharmacies were asked various questions about alerts (please see appendix D.5 for a copy of the report and data collection form containing the questions). They believed that no category or drug interaction alert level was suppressed or turned off in the systems. Five of them said that it was not possible to highlight serious error-prone situations, such as look-alike names in the ePMR systems they were using. The other three pharmacists said they did not know if this was possible. None of the pharmacists had seen tall-man letters, such as hydrOXYzine and hydrALAzine used to differentiate between look-alike drug name pairs in the systems they were using. They also stated that it was not possible for them to change the font size or colour of the product names in the systems to highlight look-alike drug name pairs. None of the pharmacists knew if the systems they were using could provide reports of drug alerts overridden or ignored by users.

Furthermore, five of the responsible pharmacists (one user of system S1 and four users of system S2) suggested that alerts with little or no clinical significance regularly appeared onscreen during the dispensing process. Only two pharmacists in pharmacy P4 and P8 who both used system S2 said that they had seen spurious alerts in the system. Participants also complained about verbose alerts; lack of alert context, alert management guidance, levels of severity, appropriate signal words and consistency of alert information provided across systems. One participant suggested that:

> *'...many of the alerts are generic, like they are trying to cover everything.'*
>
> Pharmacist, Pharmacy P1

In system S4, all alerts were aggregated to a separate screen at the end of the order entry process. The pharmacist and pre-registration pharmacist who were using this system in pharmacy P5 opined that failure to highlight clinical hazards to users during the dispensing process could lead to important alerts being missed. They also commented that displaying alerts as white text on a green background on system S4 erroneously signifies that it is safe to dispense the related prescription. However, they said that they know from experience that this may not be true because alerts about serious clinical hazards are also displayed in the same way. They also highlighted that the colours were similar to the colours of their natural work environment, thus making it difficult for them to recognise important alerts among multiple alerts. An entry in my field notes captured the opinion of one user about alerts on system S4.

> *'They are not obvious so sometimes when you are in a rush, you don't even know they are there.'*
>
> Pre-registration pharmacist, Pharmacy P5

When asked, users of system S4 were unable to confirm the level of danger implied by the three star (3*) displayed alongside drug-drug interactions at the top of the screen.

Alert management

The pre-registration pharmacist in pharmacy P4 said that if there is a '*red*' alert on system S2 and the medication involved is new, then she would call the pharmacist or print the alert for the pharmacist to assess during the final checking process. The pharmacist confirmed this in a subsequent interview. In pharmacy P8 where system S2 was being used, the dispenser said that she and her colleagues were taught to notify the pharmacist about '*red text*' alerts (possible or serious drug interactions) but to ignore '*black text*' ones (minor drug interactions). She noted however that even with the '*red*' coloured alerts, the pharmacist would often tell them to continue with the dispensing process. The pharmacist in pharmacy P4 suggested that his staff had been trained to flag up problems and potential clinical hazards promptly when operating the ePMR system.

The responsible pharmacist in pharmacy P5 who used system S4 was astounded that users can ignore alerts about serious harm to patients in system S4 but cannot dispense items in the NHS SLS category without ticking the box provided to acknowledge that such items can be prescribed on the NHS.

Reasons for accepting or ignoring alerts

Participants suggested various factors, which facilitate alert acceptance: new alert or new medication, patient is visiting the pharmacy for the first time, the person operating the system has not seen the alert before or for some time, or the patient's circumstances have changed, for example, the patient had been hospitalised.

Some of the reasons given by participants for ignoring alerts include alert generation by repeat medications that a patient is already taking without any obvious problems or alert has been authorised previously and there has been no change in the patient's circumstance. Non-clinical alerts, which are presented to users to remind them to re-order stock for monitored dosage systems, check the validity of Schedule 2 drugs or suitability of a pharmacy service, such as the new medicine service (NMS) when a patient does not meet the criteria for the service, are ignored. In addition, National Patient Safety Agency (NPSA) alert for opioids (system S1) that flags when dispensing opioid-containing products irrespective of the strength, multi-step alerts and multiple alerts about the same thing are disregarded.

Desirable features and improvements

During the interviews, participants suggested new features they would like to see in ePMR systems. Examples include safety features based on dose checking, significant jump in dose, allergy checking and excessive doses. One participant proposed a fast and intelligent search engine on every screen of ePMR systems.

Participants would like to see improvements in the mapping of virtual therapeutic moieties to products, performance of electronic prescription service, the ordering system and resolution of technical issues related to ePMR systems. In addition, they would like to be able to review alerts presented during order entry in context and see only relevant features onscreen when dispensing.

Training

Participants were asked how they learnt to use the system observed in the pharmacy in which they were working. They said they learned through training offered by system suppliers, by shadowing other users or through self-learning such as reading manuals, using the help feature on the systems and following onscreen signposting where available. One locum pharmacist said:

> *'When it is quiet, I try to explore every functionality in the system.'*
>
> Locum pharmacist, Pharmacy P7

When asked if they had any training needs, they suggested that vendors should provide video tutorials and how-to guides that users can access on-demand. Users of system S4 in pharmacy P5 suggested that the software module should be installed on the system in training or demonstration mode. These users highlighted that employees of pharmacy P5 have access to the company's online training facility, in addition to classroom and onsite training. However, they are required to login with their employee number. This was identified as an issue for locum pharmacists because they are self-employed and are not issued employee numbers.

Relations with customers

The pharmacist in pharmacy P3 suggested that the rapport between the pharmacy and the supplier of system S3 was excellent. In her opinion, the system vendor responded to queries and resolved any technical problem the pharmacy had promptly. However, the pharmacists in pharmacies P6 and P8, who both used system S2, had a different opinion about the supplier of system S2. They said that slow response rate, poor issue resolution rate, long helpdesk call waiting times and the increased telephone bills associated with such calls often discourage them from calling to give feedback or ask for help about system S2. They suggested putting a feedback button or link directly on ePMR systems for reporting issues directly to system suppliers.

The pharmacist in pharmacy P8 suggested that pharmacy organisations should work together more to solve problems they encounter in practice especially getting system suppliers to respond to queries and improve ePMR systems. She expressed the opinion that commercial sensitivity and competition is preventing pharmacies from collaborating in any meaningful way. She also emphasised the need to improve communication between pharmacies and surgeries. She perceives that general practice receptionists often do not appreciate the significance of the issue they seek to discuss and sometimes prevent queries raised by pharmacy professionals from reaching the appropriate clinician or prescriber.

6.5 Discussion

This observational study provides an account of how pharmacists and pharmacy staff use ePMR systems and manage alerts during the dispensing process in eight community pharmacies in Nottingham, in the East Midlands of England.

Principal findings

The pharmacies where observations took place all had at least one ePMR system and up to three terminals. The extra terminals were often underused because they were located far from the general dispensing area or due to lack of all the required tools and resources, such as a label printer. Operation of ePMR systems by pharmacists

during order entry and dispensing seemed to depend on personal choice, staff availability and the workflow adopted in the respective pharmacy.

All the systems had safety features in them but only one system (S4) displayed a list of the safety features that were active on the system at the top of the screen. Safety alerts were displayed on a separate screen (system S4), in a pop-up window (system S1), in an alert box at the bottom of the screen (system S3) or as a combination of both pop-up window and alert box (system S2 and S5) (see Figure 6.2). The alert information in the pop-up window was sometimes duplicated in a box at the bottom of the screen on system S2 (see Figure 6.2, alert display 3). The level of hazard implied was represented in most systems with colours, icons, texts or a combination of these. One system (S4) used star rating instead of colours, icons and text with three (3*) displayed next to drug interactions but with no indication of the levels of the star rating in the system and their significance. Whilst the study did not consider different visual abilities, such as colour blindness and astigmatism, it was noted that some alerts were presented on red or green backgrounds, as red texts or capital letters. This could make it difficult for affected users to read alerts.

The user interface

To support practice effectively, the user interface should be simple enough to facilitate the ease of use and access to the required functions and features without causing user mistakes or errors. The reason why the electronic prescription service module was separated from the rest of the dispensing module on system S2 is unclear. It is difficult to determine the impact of this separation on safety because this is not currently evaluated in community pharmacy practice. The study conducted by Franklin et al. (2014) in England, which looked at electronic transfer of prescriptions between general practices and pharmacies, found that the prevalence of content errors and enhancements were similar across all prescription types – electronic and non-electronic. In a US-based study, a computerised prescriber order entry (CPOE) system facilitated 22 different types of medication error risks, one of which was user interface displays that prevented a coherent view of patients' medications (Koppel et al., 2005).

Where other windows open on top of the main dispensing window during the dispensing process, there is the possibility for error to occur. For example, during the order entry process on systems S1, S2, S4 and S5, other windows such as the product selection window, alert window and drug information window may open on top of the main dispensing window. Important patient details, such as allergy status, date of birth and any other unique identifier should be displayed consistently in the windows that open up onscreen to ensure that the individual being dispensed to is correctly identified throughout the dispensing process. Previous research has highlighted the possibility of making a juxtaposition error when selecting from a pick list, such as when selecting a patient name adjacent to the intended name. It has been suggested that in such a situation, the system should provide adequate feedback on who was selected. For example, by displaying the selected name in large letters on the screen (Campbell et al., 2006).

Shortening the product pick list observed on systems S1, S2 and S4 has the potential to help prevent errors of commission. Research findings from a US based study indicate that partial drug name search functions can help reduce the requirement to search through drop-down menus thereby increasing efficiency and reducing errors (Devine et al., 2014). Selection of medications in another study conducted in Canada by Zwarenstein et al. (2007) was done using an error minimising menu-based pick list. All of these strategies offer potentials to minimise errors by ensuring that the right patient or product is selected and should be considered for inclusion in all ePMR systems.

Pharmacists should conduct clinical checks based on a full knowledge of patients' historical medication record to avoid any latent condition that could lead to medication errors. Conversely, a patient's historical medication record is to be reviewed as part of the prescription validation and clinical checking process, then the record should be available to the system operator during order entry or at the appropriate time during the clinical checking process. This might involve a re-design of some of the user interfaces on ePMR systems. However, it would help ensure that safety checking of prescribed medications by pharmacists is done with full knowledge of the medications that the patient is taking. It would also help ensure that pharmacy

professionals do not rely on the system alone to flag potential clinical hazards or their clinical knowledge to recognise potential clinical hazards.

Design and presentation of alerts

The rationale for the design of display 3 (see Figure 6.2) that was seen on system S2 where alert information was displayed simultaneously in a pop-up and an integrated alert box is unclear. This type of display confuses and can lead to errors or cause users to ignore alerts. One study that compared the impact of pop-up and non-pop-up alerts on prescribing error rates of junior doctors found that participants exposed to both types of alerts were less likely to make a prescribing error than those who were not shown an alert. However, the error rate with non-pop-up alerts was 3.6 times higher than with pop-up alerts (95 percent CI 1.88 to 7.04) (Scott et al., 2011). These findings support the need to alert pharmacists about potential errors and harm to patients and present alerts that pharmacists must act on as pop-ups.

Colour

Available evidence suggests that alert noticeability can be enhanced by using a variety of design characteristics, including adding a distinctive colour or a pictorial symbol, using a larger font or increasing the contrast between the warning message and its surroundings (Wogalter and Mayhorn, 2005). Wogalter (2006) recorded that red colour expresses greater hazard than yellow or orange, which are not substantially different from each other. Blue and green colour generally express less or no hazard. This supports the opinions of system S4 users that alerts displayed as white text on green background suggest to them that no hazard exists. Therefore, where colour is used in warnings, it should reflect the hazard level implied by the warning.

Signal words

There seemed to be no systematic approach to the use of signal words in alerts in ePMR systems. Several authors have explored the use of signal words to quantify hazard implied by a warning (Adams and Edworthy, 1995; Hellier and Edworthy, 2006; Hellier et al., 2006). Findings from the study by Hellier et al. (2000b) indicate that signal words can be used to match the hazard inherent in a situation and that implied by the accompanying warning. However, research is required to determine the specific signal words that should be used (Hellier et al., 2000a). It has also been

suggested that some phonetic features could make a signal word sound less urgent, so the authors of the particular study advised that signal words containing such phonetic features should be avoided (Van den Bos et al., 2005). The extent to which these recommendations are employed in the design of alerts in ePMR systems is unknown but findings from this study suggest that this should be prioritised in the development of safety alerts in ePMR systems.

Separating drug interactions from other warnings and labelling as 'interacts' (system S3) should be avoided. It suggests a lack of understanding of what qualifies as a warning in the context professional practice or an unnecessary attempt to elevate drug interactions above other clinical hazards. This could confuse users or lead to misinterpretation of warning messages and the urgency of the hazard being conveyed.

Alert management

The social environment of practice also affects alert management. Pharmacy staff members may copy how pharmacists manage alerts and do the same. For example, if a dispenser had seen the pharmacist override alerts or had been told to ignore serious alerts in the past that dispenser may begin to behave similarly towards alerts without the pharmacist's knowledge or consideration for the clinical and legal implications. The infrequent alert management guidance offered by ePMR systems contrasts with the recommendation that alerts should be accompanied by management alternatives, detailed information and management options (Ko et al., 2007).

A hard stop alert such as the one seen on system S5 is useful for forcing the system operator to slow down and assess the risk of harm implied by the alert. By ticking a designated box (system S4), users were able to acknowledge that the prescribing requirements for items listed in the NHS SLS were met. However, they were prevented from completing the dispensing process if they did not tick the box. This suggests a focus on ePMR systems as a revenue-loss prevention tool in system S4 rather than as a medication safety tool. This may be unintended but it is difficult to believe otherwise because users were able to get past serious clinical hazard alerts without anything stopping them from doing so. In a study of practitioners' views on

electronic drug–drug interaction alerts, pharmacists expressed preference for making override of lethal interactions more difficult (Ko et al., 2007). However, it has been suggested that such could result in delayed treatment (Strom et al., 2009). Therefore, careful consideration should be given to its use in ePMR systems so as not to delay treatment or exasperate users.

Pharmacists' mentioned that they sometimes work alone in the dispensary. This would be a cause for concern if the staffing level is inadequate, as it could compromise safety. There is a minimum dispensing staff level in hours per week that is recommended for community pharmacies based on the number of prescription items dispensed per month (Department of Health et al., 2014). Further research is required to establish the level of compliance with the guideline or its impact on safety in community pharmacy environment.

Training

There is an obvious mismatch between the alert management instructions pharmacists said they gave to their dispensing staff and the actual management of alerts by those dispensing staff. It is not clear how dispensing members of staff are expected to manage alerts competently without the requisite training. For example, how they are to assess an alert indicating the potential for tramadol to induce seizures when co-prescribed with serotonergic medicines. These situations, including ignoring alerts on the basis that the pharmacist had ignored the same alerts in the past, all suggest absence of a culture of safety and warrants appropriate training and provision of alert management guidance to help pharmacy professionals manage alerts safely.

Reflexivity

As the field researcher, I tried to establish a good rapport with the pharmacy professionals first before beginning observations and taking notes. This was to encourage participants to get to know me, relax and feel comfortable with the observational process. Participants were aware of my professional background as a qualified and practicing community pharmacist. I perceive that I interfered very little with their activities and my presence was not distractive.They seemed to be comfortable with having me observe some aspect of their daily practice perhaps

because they felt that as a community pharmacist, I understood the challenges they faced in promoting medication and patient safety in practice.

Observations involved watching community pharmacy staff in their everyday situations. No patient identifiable information was recorded and any information observed was treated in the strictest confidence in line with professional and research codes of practice. I might have missed some observational clues or failed to record other useful information about the topic of interest when some of the pharmacies became busy. Likewise, it was also possible that selective perception on my part influenced the amount and type of data collected or that my presence in the pharmacy affected the observations in ways that I was not aware of.

Strengths

One of the strengths of this study is that it is the first study of its type to seek to understand, how pharmacists and pharmacy staff in community pharmacy setting in England manage computerised alerts during the dispensing process. This study also covered five of the seven ePMR systems approved for EPS R2 in community pharmacies in England in August 2012, providing a substantial coverage of the systems used in community pharmacies in England. One of the two remaining systems was yet to be in operation in any of the pharmacies in the Nottinghamshire area at the time of the study, according to the system vendor. The other system was not available in any of the pharmacies that agreed to participate in the study.

Participants were aware of the researcher's status and they knew that they were being observed. They were also aware that their superintendent pharmacists had given permission for the study to be conducted in the pharmacy, so they were willing to engage freely in the study without inhibition.

Limitations

This study was limited to the use of ePMR systems and alert management behaviour of community pharmacy professionals during the period of observations. Some of the pharmacies where observations took place allowed me to visit at times they found convenient, which were usually very quiet times. During those times, the staff support level was usually at the barest minimum. Perhaps there were other directly or

indirectly related variables that I could have observed but I was unable to given the limited time spent onsite.

I noticed that some participants seemed to pay more attention to alerts perhaps because of their awareness of being observed - the '*Hawthorne effect*' (Macefield, 2007; Westbrook et al., 2008). Both pharmacists and pharmacy support staff called my attention to specific alerts displayed onscreen during the dispensing process. These were mostly alerts that participants had encountered in the past but which they considered as poorly designed or insignificant. I did not notice the same attention by pharmacy support staff members in terms of reporting alerts to the responsible pharmacists. I also perceived that my presence as an observer in the pharmacy caused participants not to rush through alerts on occasion but to consider them carefully. Some participants also called on their colleagues to ask about specific situations they had encountered in the past where they felt that specific alerts require improvements. This was perhaps because they perceived the study as an opportunity to contribute to such improvements, but not necessarily because I was observing them.

There was lack of interest by many pharmacy owners in participating in the study. Reasons cited include involvement in previous or other on-going research, time constraints and inability to accommodate a researcher on site. Some pharmacy owners also cited '*too many invitations*' to participate in research studies as the reason for declining the invitation to participate in this study even though evidence suggests that research involvement by community pharmacies is minimal (Saini et al., 2006; Armour et al., 2007). In some cases, no explanation was given.

Implications for policy

Many policy implications have emerged from the findings of this study one of which is the need to set minimum specifications for ePMR systems. This will provide pharmacy owners with a set of criteria for choosing appropriate ePMR systems. It will also help to increase competition between vendors of ePMR systems as they would need to justify why pharmacy organisations should purchase their system. It can also drive innovation in the industry because system vendors would have to improve their

systems continually and include other add-on features beyond the minimum set in the specifications to remain attractive to purchasers in the marketplace.

Standardisation of ePMR systems will also help to assure the quality and consistency of performance of the systems. This will help the mobile workforce to know what to expect of any new ePMR system they encounter in the course of their professional duties. However, care must be taken to only standardise where necessary. In addition, the standards must be fit for purpose and updated regularly to prevent poor and out-of-date standards from driving down performance and efficiency.

A central repository for knowledge information such as alerts, evidence-bases, standards, laws, regulations and user-training resources should be created and shared with vendors, pharmacy organisations and pharmacy professionals (Shah et al., 2006). A competent authority should define the most important alerts that should be presented to pharmacists and pharmacy staff. System suppliers should be encouraged to implement these in their systems, ensuring that such alerts cannot be ignored or cancelled easily.

Facility should be made available for users to record the management of serious alerts and this information should be used in evaluating the effectiveness of alerts and in developing ePMR systems. Quality recording of interventions and clinical data, such as allergies in ePMR systems is also required to enable relevant safety checks to be made if the functionality exists.

System suppliers should be encouraged to make use of existing research evidence when designing systems and alerts, including using appropriate signal words, colours, icons and font sizes. System design should include display of patient details and other important information about patients in a conspicuous area of the screen throughout the dispensing process. To improve the systems, an effective audit trail and functionality for identifying and reporting redundant alerts and hazards should be developed.

Implications for practice

Findings from this study suggest that there is the need to maximise the use of computer terminals available in community pharmacies for order entry and clinical services. There is also no all-purpose approach to ensuring alerts on ePMR systems are effective. It is essential to give pharmacists options about how they would like alerts displayed to them and identify the alerts that pharmacy staff are allowed to deal with.

Open user groups should be established to include frontline users to support identification of issues with individual systems and to support system suppliers in their development work. There is the need to provide opportunities for on-demand ePMR system training to improve pharmacy professionals' competency. The opportunity to learn by doing and to reflect on effective strategies in a professional group setting could be helpful in building users' capacity and increasing resilience.

Communication between all stakeholders including surgery-pharmacy and vendor-pharmacy communication needs to be improved in the interest of safety. Establishing a multi-disciplinary partnership between health care professionals involved in patient care in primary care should be explored to achieve this purpose in the interest of patient safety. Pharmacists' training should also include risk management and human factors.

Further research

At present, alerts are presented in a pop-up window, a message area, on a separate screen or as a combination of both pop-up window and alert box. Further work is warranted to establish their effectiveness and how they can best support practice.

Further work is also necessary to investigate and establish the specific words, colours and icons that should be used in safety alerts and when they should be used. There is currently no consensus on when a hard stop alert is appropriate in practice. This should be determined in the interest of patient safety.

Ways to maximise the potentials of ePMR systems beyond their current use for medication dispensing and occasional use for pharmacy services should be sought. This should include exploration of aspects of the functionality of ePMR systems that can strengthen patient safety and help ensure that community pharmacy practice is free of avoidable errors.

6.6 Conclusions

In conclusion, it is clear that ePMR systems and alerts have inadequacies, which limit the support they are able to give to community pharmacy practitioners' efforts to ensure medication safety.

The findings of this study suggest that pharmacy professionals should be trained in risk management, informatics, human factors, clinical decision-making, alert management and all aspects of ePMR system operation. This would enable them to become more familiar with alert management standards and develop a culture of safety. In addition, system vendors should be provided with appropriate guidance to help them design enhanced and effective ePMR systems and alerts. The design of the user interface should enhance pharmacy professionals' access to all the required functions and should not introduce errors into the dispensing process.

Stakeholders also need to work out aspects of the systems that can benefit from standardisation and harmonisation, such as alert severity levels and hazard alerts that should be shown to users. In addition, improved training of community pharmacy professionals in ePMR system use and alert management would facilitate prompt detection and prevention of errors and safer management of alerts in community pharmacies.

Chapter 7

Discussion, future work and conclusions

7.1 Introduction

The main reasons for implementing ePMR systems are to increase the efficiency of the dispensing process, provide relevant data for management decision making and improve patient safety by preventing medication errors, clinical hazards and adverse drug events. The studies presented in this thesis aimed to gain understanding of ePMR systems' functionality focusing on safety features and alerts. This aim was fourfold: firstly, to review the literature systematically for evidence of the effectiveness of safety features and alerts in electronic patient medication record systems at the point of pharmacy order entry (POE). The data obtained from this study, which were presented in chapter 3, have been published (Ojeleye et al., 2013). Secondly, to establish baseline understanding of electronic patient medication record systems' functionality focusing on safety features and alerts through individual qualitative interviews. Thirdly, to assess ePMR systems' performance using simulated scenario observational tests. The data obtained from this study, which were presented in chapter 5, have also been published (Ojeleye et al., 2014). Finally, to understand how community pharmacists and pharmacy staff use electronic patient medication record systems and manage alerts during the dispensing process, through observations in community pharmacy practice setting.

In this chapter, I attempt to draw out from the research findings, answers to the research questions posed in chapters 3, 4, 5 and 6. This is followed by recommendations emanating from the studies, my reflections on the adopted methodology and my personal views of the research. As a final point, this chapter will conclude with details of potential areas of investigation stimulated by this research and my final remarks.

7.2 Answers to the research questions raised in this research

The studies presented in this thesis sought to answer the research questions posed. The research questions and subsequent findings, which can be found in chapters 3, 4, 5 and 6 are drawn together in this section.

What is the evidence for the effectiveness of safety alerts in electronic patient medication record systems at the point of pharmacy order entry?
Key findings: *Alerts identified clinical hazards based on drug-drug, drug-laboratory, drug-pregnancy and drug-age (see Table 3.3) safety features but there were problems of false alerts and inconsistent management of alerts.*

A systematic review of the literature was conducted to explore existing evidence at the time of the review in March 2012 (chapter 3). Five relevant studies were identified each of which showed that alerts in ePMR systems led to reductions in dispensing of critically interacting drugs; contraindicated drugs based on age or pregnancy; adverse drug events related to hyperkalaemia and medication errors. The studies confirmed that ePMR systems have the potential to improve patient safety and reduce the risks that may arise from prescribed medicines, by processing personal and clinical information along with medication records to provide patient specific advice.

All the studies were from the US. None was from community pharmacy. In four studies, alerts prevented the prescription label from being printed until the pharmacist had actively intervened to determine whether the prescription should be dispensed or whether to contact the prescriber (Humphries et al., 2007; Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011). A decision support guide was

printed for the pharmacist in lieu of alerts in one study (Bhardwaja et al., 2011). In the study by Mansour et al. (2010), a pop-up screen appeared onscreen to warn pharmacists about patients' last reported potassium level including a reminder about where to document the response to the alert. Although some of the studies mentioned how pharmacists handled the specific alerts in the studies, there was no in-depth discussion of alert management by pharmacists in general. It was not clear if the way those pharmacists handled alerts was a true reflection of everyday practice and whether there were facilitators and barriers to the usefulness of the safety alerts. Pharmacists were allowed to override alerts if the reason for the override was explained and the action documented. While the interventions had a positive effect on the primary outcomes in the identified studies, there were instances of false alerts and discrepancies in alert management. Problems of false-positive alerts appeared to be prevalent (Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011). One of the studies was terminated early because of false-positive alerts (Raebel et al., 2007a).

The report of a study conducted in Brazil to evaluate the impact of a locally developed drug-drug interaction screening system before and after implementation was published after the systematic review that was reported in chapter 3. The study measured the proportion of patients that were co-prescribed two interacting drugs. The drug-drug interaction screening system that was evaluated in the study also appeared to decrease the average number of events per patient and the risk of co-dispensing interacting drugs (Moura et al., 2012).

How do participants view pharmacists' role in the medication use process?
Key findings: *Participants suggested that pharmacists owe patients and pharmacy patrons a duty of care. Pharmacists are also expected to be competent and punctilious.*

Semi-structured interview technique was used to explore the views of participants including pharmacy professionals, health care policy makers, legal experts, drug database vendors and system vendors about the role of pharmacists in the medication use process in section 4.4.1. Participants emphasised that pharmacists are expected to safeguard patients and the public from harm while using pharmacy services or while in the care of pharmacists and that this may sometimes require them to use their professional judgement.

In addition, pharmacists are expected to be competent professionally. For example, they should be proficient enough to know what the system they are using can or cannot do, what safety features there are in the system and how to use them effectively. It was suggested that any inefficient use of ePMR systems could result in missed opportunities to uncover potential patient safety issues and save time on repetitive tasks.

Some participants argued that it is more important to be conscientious when dispensing medications. They highlighted that it is useful to get alerts about clinical hazards during the dispensing process; however, operators of ePMR systems should also reflect regularly on the tasks involved rather than relying on ePMR systems and alerts to ensure that medications are dispensed safely. It was suggested that the clinical checks conducted by pharmacists should involve analysis of patients' medication record data but participants noted that this may not always be the case. The role of pharmacists as highlighted tallies with their primary role of preventing iatrogenic harm and helping patients to make best use of their medicines (Kelly and Rucker, 2006).

How do pharmacy owners choose the electronic patient medication record system to use in their pharmacies?

Key finding: *There is no formal guidance for selecting ePMR systems.*

Superintendent pharmacists of pharmacy companies reported that they were not aware of any official guidance or criteria for selecting ePMR systems to use in their pharmacies. Superintendents pharmacists of large-chain pharmacies reported that they drew up formal requirements for ePMR systems and safety features in-house (section 4.4.3). Other pharmacy owners based their selection on various criteria, such as the corporate needs of their organisations, safety, a cordial relationship with the vendor, vendor's ability to innovate, efficient helpdesk response time and recommendations of other users. It was highlighted that a homegrown system may be preferred where specific features required by a pharmacy company are not available in a commercial system. This approach may also be used to gain control of the functionality of a system and how it is used than may be possible with any

commercially available system. Additionally, it may be cheaper than purchasing a system from a commercial vendor.

A set of requirements for ePMR systems that are used in England is required to support pharmacy professionals in complying with the standards of community pharmacy practice. For example, the State of Washington in the US stipulated in the Washington Administrative Code chapter 246-875 on pharmacy patient medication record systems, the minimum required information in an ePMR system maintained by all pharmacies and other sites where dispensing of medications takes place (Washington State Legislature, 1992). In Canada, a working group set up by the National Association of Pharmacy Regulatory Authorities produced a set of requirements to instruct pharmacy professionals, pharmacy owners, system vendors and developers about the required minimum functionality for systems used in pharmacy practice in Canada (National Association of Pharmacy Regulatory Authorities, 2013).

How do users learn to use ePMR systems?

Key findings: *Training is fragmented; formal training is not widespread and there is no evidence of alert management training being offered to users.*

Some practicing pharmacists who participated in the exploratory study said that they did not receive any formal training on how to operate ePMR systems. Those who were fortunate to receive formal training said it was organised by their employers or delivered by the system vendor when the system was first installed in the pharmacy. Participants said they did not receive any specific training in alert management.

Some participants suggested that training should be recommended but not mandated (section 4.4.1). The reasons cited are that trainees may fail to follow what they learned or they may forget what they learned in training if they do not put the knowledge gained into practice immediately. However, the potential benefits of mandatory training such as safety, efficiency, risk reduction and ensuring pharmacists' compliance with policies and guidelines outweigh the reasons not to mandate training. Mandatory training can help ensure that users of multiple ePMR systems, those returning to practice and those who need refresher training receive

appropriate training and are able to use ePMR systems competently. Participants suggested that vendors should take the lead and offer the initial training because as the designer of the system, they know how to use the system effectively. As part of that training, users should be informed about what the system can or cannot do.

System vendors reported that they offer initial and on-demand training to users face-to-face or online via video, onsite or offsite. They also mentioned that training materials and information are made available via electronic and paper guides, quick reference guides, operating manuals, release notes, onscreen signposting where available and through the helpdesk. However, findings from the interviews suggest that this may not be as widespread as the system vendors suggested. It is possible that training is available but some pharmacists do not know about it or know how to access it. Other forms of training mentioned by participants include self-learning and shadowing or learning from other users within and outside the pharmacy chain. Participants suggested that training is reinforced by using the system regularly in practice although time constraints impede the opportunity to learn during working hours. Users of ePMR systems also asked for video tutorials and visual how-to guides they can access on-demand.

Participants who took part in the observations (section 6.4.1) confirmed in follow-up interviews (section 6.4.2), some of the assertions by those who participated in the exploratory study. These participants said they learned through training offered by system suppliers, by shadowing other users and through self-learning.

What are the perceptions of participants regarding alerts in community pharmacy practice setting?

Key finding: *Participants expressed mixed views about safety alerts in ePMR systems suggesting that alerts can be helpful or a hindrance. Users of ePMR systems said they get many non-contextual and insignificant alerts in practice, which encourage automatic behaviour towards alerts.*

An alert can be helpful or a hindrance according to participants (section 4.4.2). For example, an alert presented in the pharmacy but which requires the attention of another healthcare professional was considered unhelpful. Practicing community

pharmacy professionals said that they get many clinically insignificant alerts, which they ignore, such as alerts suggesting that some medications that are commonly combined to treat high blood pressure could lead to lower blood pressure. One participant reported that safety alerts in ePMR systems are usually '*negative*' alerts such as drug interaction alerts. This participant advocated introducing what she described as contextual, '*positive*' alert types, such as alerts to remind pharmacists to offer extra counselling to patients around weight, diet and other public health issues. However, poor implementation of such '*positive*' alert types could lead to over-alerting.

The effectiveness of the different alert display modes - separate screen, pop-up window, alert box at the bottom of the screen or a combination of both pop-up window and alert box (see Figure 6.2) has not been discussed previously in the literature. Findings from the observations suggest that constant pop-up alerts annoy users. Alerts displayed in a box at the bottom of the screen can easily be overlooked. Nevertheless, it appears that pop-up alerts are the most appropriate where there is significant threat to patient safety. Alert box would be useful for displaying alerts unobtrusively particularly when there is absolutely no risk of harm to patients. Displaying all alerts in a separate window could support pharmacists who are mainly involved in the dispensing process at the clinical checking stage to conduct a holistic check of the safety and suitability of medications for patients. However, delaying all alerts until the end of the dispensing process, with no warnings about serious risk of harm to patients could lead to errors or irritate users if they have to cancel the entire prescription for safety reasons.

In addition, the practice of printing alert information on blank prescription labels (section 4.4.2) was seldom mentioned in the literature. However, it has the potential to help pharmacists avoid missing important alerts when someone else operates the system. A study conducted in the US reported that on occasion, the medication alert triggered the printing of a decision support guide for the pharmacist in lieu of the prescription label (Bhardwaja et al., 2011).

What are the opinions of participants regarding a common safety alert module?
Key findings: *Some participants suggested a common approach to alert presentation rather than a common safety alert module.*

Participants' opinions about a common safety alert module for ePMR systems varied (section 4.4.3). There was no agreement about whether this should be implemented in ePMR systems or not. Some participants said it would be useful as a central reference resource and may be familiar to users wherever they go because it is common. An example of such a tool is the '*G-Standaard*' drug database, produced by the Royal Dutch Association for the Advancement of Pharmacy, a professional and trade association for pharmacists in the Netherlands. The G-Standaard supports various processes such as prescribing, dispensing, ordering and decision support, including safety assessment of medications. It is used by all interest groups in healthcare in the Netherlands, including the government, health insurers, manufacturers, pharmacists, physicians and wholesalers (Royal Dutch Association for the Advancement of Pharmacy, 2014). The tendency to aim at the lowest common denominator was highlighted as a barrier against its suitability for all users. One participant was extremely critical of the idea suggesting that it could lead to replication of programming errors across all systems.

Instead of a common safety alert module, some participants suggested a common approach to alert presentation but with an authoritative body determining the alerts that should be presented to users and how such alerts should be presented during the dispensing process. An example is the NHS Common User Interface (CUI) Programme, a joint patient safety initiative between Microsoft and the National Health Service (NHS) in England (Microsoft Corporation, 2010). The CUI programme developed a range of standards and guidance relating to the design of user interfaces for clinical computing system. The core objectives of the programme included improving patient safety and reducing training costs. There is currently no evidence in the literature regarding the effectiveness of any of the two approaches suggested by participants. Further research is required to establish their impact on safety.

What are the opinions of pharmacy professionals about alert categorisation?

Key findings: *Participants pointed out that differences exist in the levels of alert severity implemented across ePMR systems. They suggested that these differences create difficulties for practicing pharmacists in managing safety alerts effectively. Some participants favoured a traffic light approach to alert display, based on alert severity levels.*

Observations showed disparity of alert severity levels across systems (section 6.4.1). Alert severity level was implied with words, colours and symbols. For example, in one system (S1), yellow triangle was used to represent minor interactions, blue triangle for medium interactions and red triangle for severe interactions. It was not clear how many levels there were in some of the systems. Comparative studies conducted in Australia, Brazil and the US showed variation in the level of agreement among commonly used drug interaction compendia. In addition, the drug interactions classified as major in one compendium may not be included in other compendia (Abarca et al., 2004; Vitry, 2007; Martins et al., 2011). The effect of these disparities on the quality of alerts in ePMR systems is currently unknown.

Participants suggested that the differences in the levels of severity of alerts implemented in ePMR systems prevent effective management of alerts (section 4.4.2). It was emphasised that the different levels of alert severity should be identified within the dataset. With no guidance about the appropriate levels of severity, large pharmacy companies developed their own criteria for determining the levels of alert severity to implement in the ePMR systems used in their pharmacies, based mostly on the information in the BNF.

Some practicing pharmacy professionals complained that they get too many warning messages during the dispensing process. This is similar to the finding by Avery et al. (2003) in their study of general practice computer systems in the UK. A significant number of other users were not bothered. Users also expressed preferences for how they would like alerts presented. There were those who preferred to leave all alerts active in the system and presented to users for legal reasons and for training purposes. Others supported pharmacists making a professional judgement on how best to deal with alerts.

How are ePMR systems evaluated by users?

Key findings: *There is no formal evaluation process for ePMR systems.*

Some superintendent pharmacists reported that evaluation of the safety performance of ePMR systems in their organisations was sometimes reactive not proactive (section 4.4.2). They evaluated ePMR systems informally through insights obtained from incident investigations and feedback from dispensing staff and information technology (IT) experts. They highlighted that there have been no major clinical incidents involving ePMR systems. Additionally, there is a limited choice of ePMR systems on the market, hence, no impetus to carry out performance evaluation of systems before or after purchase.

An example tool for assessing the safety of medication practices including the safety functionality of ePMR systems in community pharmacy is provided by the Institute for Safe Medication Practices in the US. The aim is to identify opportunities for improvement and offer a basis for comparison with demographically similar community pharmacies in the US (Institute for Safe Medication Practices, 2001). The National Reporting and Learning System (NRLS) service of the NPSA is a voluntary scheme for reporting patient safety incidents and collating the information centrally, to identify trends and learn from them. It is not known what the company policies and practices are at the individual and organisational level in terms of reporting to the NRLS and how useful the NRLS is with respect to the development of ePMR systems. It is also not clear if root cause analysis of errors is done and the ePMR system is evaluated if implicated. How the lessons learned are shared to improve practice is also not known. However, it is expected that a pharmacy organisation involved in an error will put necessary structures in place to prevent such an error from happening again.

Are participants aware of any standards and regulations governing the operation and administration of ePMR systems and alerts?

Key findings: *Participants were not aware of any bespoke standards or regulations governing the operation and administration of ePMR systems and alerts.*

Participants showed awareness of some standards around ePMR systems' interaction with the National Health Service (NHS) Electronic Prescription Service (EPS), basic requirements of data protection and confidentiality and professional standards, standard operating procedures (SOPs) and the information governance (IG) policy (section 4.4.3). They were not aware of any stakeholder agreed minimum specifications or standards for ePMR systems, their safety features and alerts. They highlighted that standards were set for EPS but other aspects of ePMR system's functionality were excluded.

It was suggested that ePMR systems are already being regulated through the Medicines Act 1968 amended in 2008 (Department of Health, 2008), which imposed a legal duty on responsible pharmacists to ensure safe and effective running of any pharmacy under their control. Also by the NHS Pharmaceutical Services Regulations 2005 (Department of Health, 2005), which contain the terms of services, including clinical governance requirements, the code of ethics supplemented by standards, guidance, and professional requirements set out by the former Royal Pharmaceutical Society.

How do ePMR systems perform in community pharmacy practice setting?

Key findings: *The performance of the ePMR systems that were tested was variable and sub-optimal.*

A simulated observational test was conducted to answer this question. No system produced the anticipated responses for all of the 28 scenarios tested (section 5.4). The ePMR systems had highly variable performance when checking for issues other than drug-drug interactions. Some of the systems tested were unable to record the required information such as allergy status, thus preventing appropriate checks from being made by the systems. The responses to items prescribed inappropriately to patients based on their age were commonly absent. Studies conducted in Spain

(Cremades et al., 2009), Switzerland (Indermitte et al., 2007a) and the US (Hazlet et al., 2001; Saverno et al., 2011) have also reported sub-optimal performance by ePMR systems.

What account do pharmacy professionals give about how they manage alerts presented to them in practice?

Key findings: *Participants accounts of how they manage alerts, obtained from individual interviews (sections 4.4.2 and 6.4.2) and observations (section 6.4.1) indicate that alert management is inconsistent across pharmacies and systems. Pharmacy professionals regularly ignored alerts and dispensing staff members often fail to inform pharmacists about serious alerts. There is no formal alert management policy or guidance for community pharmacy professionals.*

During the interviews, participants said they usually base alert management decisions on their clinical knowledge, training, experience, information in evidence-based literature and professional judgement. Practicing pharmacy professionals' accounts of how they manage alerts varied (Section 4.4.2). Some mentioned that they manage alerts according to the pharmacy company's SOP. However, findings from the observational study did not support this. For example, some pharmacy organisations advise their dispensing staff to inform the pharmacist about alerts but this was not done on several occasions during the period of observations.

Observations showed that ePMR system operators' responses to alert often involve scanning alerts for signal words, reading and evaluating alerts to identify the best management options, including whether to act on or ignore alerts. Practicing pharmacy professionals said that they encounter clinically insignificant alerts regularly, which they usually ignore. Some suggested that they pay attention to alerts highlighted by the system as '*major*' and warnings generated by high risk medications, antibiotics, new medicines and medications with narrow therapeutic window. Observations showed that some pharmacy professionals did not take notice of alerts.

From the observations (section 6.4.1), users appeared to have some implicit rules for managing alerts. Many alerts were ignored even those suggesting potentially serious harm to patients. Dispensing staff members sometimes notified pharmacists about

medications that were new for patients, if the medications were involved in alerts or for counselling. Hazard management information was observed infrequently in the systems. Observations also indicated that some dispensing staff members did not inform the responsible pharmacists about alerts or print alerts for pharmacists to review during the final prescription checks as suggested during the interviews. Alert management also appeared to be influenced by the social environment of practice. Some dispensers imitated the alert response behaviour of the pharmacists they worked with. Some also ignored alerts that they had been instructed to ignore in the past, sometimes without regard for the context.

What are the reasons why users might ignore alerts in practice?

Key findings: *Participants gave several reasons for ignoring alerts, some clearly signifying lack of a culture of discipline and safety.*

Reasons given by practicing pharmacy professionals for ignoring alerts include clinical insignificance, familiarity with alerts, alert generation by repeat prescriptions and presentation of counselling information as alerts (section 5.4.2). Other reasons cited include inadequate alert sensitivity, excessive workload, inadequate alert information and appearance of alerts in non-conspicuous area of the screen. They also highlighted that multiple alerts about the same hazard, spurious alerts, easy alert bypass and recognition of an insignificant alert or specific alert wording in a list of multiple alerts all encourage automatic behaviour towards alerts. In addition, deferring all alerts until the end of the dispensing process with no warnings about serious risk of harm to patients, constant pop-up alerts, mixing of non-clinical and clinical information in alert windows were also implicated. Likewise, the need to double-click alerts or scroll to read the full alert text, lack of a cut-off date for historical medication records involved in alert generation were all highlighted as encouraging users to ignore alerts.

In the follow-up interviews conducted after the observations (section 6.4.2), participants mentioned several reasons for ignoring alerts, some of which were similar to those offered by participants in the exploratory study. These include lack of alert management advice and alert generation by repeat medications where the patient has had no problems with the medications in the past or the alerts have been authorised previously. Non-clinical alerts, non-contextual alerts, multi-step alerts and

multiple alerts about the same thing are also ignored. Many of the reasons cited by practicing pharmacy professionals for ignoring alerts have also been documented in the literature. Examples are alert generation by prescription refills and discontinued medications, false alerts and insignificant alerts (Murphy et al., 2004; Raebel et al., 2007a; Raebel et al., 2007b; Bhardwaja et al., 2011).

What alert design features do users find useful in practice?

Key findings: *Users' alert design preferences vary. Participants called for 'attention-getting' features especially if the risk of harm to patients is significant.*

In the exploratory study, practicing pharmacy professionals described the type of alerts they find useful in practice (section 4.4.2), such as hazard-matched, contextual and concise alerts with clear levels of severity and clinical significance. They also favour alerts that offer management advice and links to referential information if required. Consideration for design principles that take into account human factors for alerting, such as the position of alerts, visual pointers used, suitable keywords to draw users' attention, specificity, content of alert information, sensitivity, workflow, and safe and efficient handling have been highlighted as important in designing effective alerts in health information systems. In addition, it has been suggested that alerts should be accurate, clinically significant and should denote urgency (Phansalkar et al., 2010; Horn et al., 2013).

What are the inhibitors of alert usefulness?

Key findings: *Findings indicate that there is no 'one-size fits all' alert. Various alert features were observed or mentioned by participants, which may inhibit alert usefulness.*

Participant interviews and observations were used to explore the inhibitors of alert usefulness (section 4.4.2, section 6.4.1 and appendix C.9). Participants highlighted that failure to present alerts in context, lack of clinical significance, lack of alert management guidance and long-windedness, make alerts ineffective and may lead to alerts being ignored. They also emphasised that lack of consistency of alert information, lack of severity levels and mixing administrative information together with clinically significant alerts make alerts less beneficial at the point of dispensing. Displaying alerts mostly in red colour or severe alerts in colours that are not normally

associated with danger, such as white text on green also encourage users to ignore or automatically behave towards alerts. Failure to wrap alerts onto multiple lines where necessary, scroll bars in alerts and lack of management advice were also reported as inhibitors of alert usefulness. These findings suggest the need for system vendors to make use of available evidence and recommendations in the literature in designing effective alerts that can facilitate user compliance in the interest of patient safety.

7.3 Priority focus areas for improvements

Some immediate improvement areas emerged from the issues highlighted in section 7.2 and these are discussed below.

False alerts

The systematic review reported in chapter 3 highlighted some of the problems associated with alerts such as false alerts and inconsistencies in alert management. False alerts have been implicated as a prime driver of alert bypass in many studies. They were observed in five of the six systems that were assessed in the simulated observational study presented in chapter 5. One system did not produce any spurious alert suggesting that it is possible to achieve a '*spurious-alert-free*' ePMR system and solve some if not all of the problems associated with alerts. Collaborative working by system vendors would help considerably in finding solutions to alert related problems such as false alerts, which often desensitise system users to the importance of alerts. Lessons learned and best practices in risk and alert management should be shared with pharmacy professionals regularly.

Alert management

Alert management varied considerably from users not paying attention to alerts at all to users who seemed to look at all alerts and many others at various points on the spectrum. There were instances during observations where pharmacists were not informed about alerts and alerts were not printed for them to review during the final prescription checks. Total disregard of alerts admitted by some participants coupled with the observation that pharmacy staff seemed not bothered about the situation is worrying. It suggests that those professionals are reliant on other means of ensuring medication safety such as their own knowledge or that they lack a culture of discipline

and safety. Pharmacists' training programme should include skills to help them create and maintain a safety climate in the practice environment.

Standards and minimum specifications

Findings from the exploratory study presented in chapter 3 indicate that the majority of participants were unaware of standards and regulations governing the operation of ePMR systems and alerts. A central repository for alerts, alert information, standards and regulations affecting pharmacy practice should be developed and access granted to pharmacy professionals to update themselves. This would also be useful as a reference resource for developers of next generation ePMR systems.

Standards and minimum specifications would have to be developed for ePMR systems and alerts to ensure reliability of ePMR system performance. This would also provide pharmacy owners with ePMR system suitability criteria on which to base system selection decisions. Where standardisation may not be appropriate, harmonisation may be the solution. For example, it may be difficult to standardise the levels of severity of alerts in current ePMR systems. However, these can be harmonised and taught to system operators to help them interpret the harmonised alert severity levels appropriately. An authoritative body should work out minimum alerts that should be presented to community pharmacy professionals to ensure they do not miss important alerts and to prevent over-alerting.

Defensive, evidence based alert design and software engineering

In designing ePMR systems and alerts, system vendors should make use of the vast amount of evidence that is already available in the literature including evidence about ergonomic, usability and other design principles to improve alert functionality. For example, the fact that an ePMR system brings up the pick list in a specific way does not mean that it is safe. There is evidence in the literature about how best to design pick lists to help users select the right product each time.

Design of ePMR systems should include appropriate defences against potential medication errors and clinical hazards. For example, high hazard alerts should be highlighted conspicuously and it should not be easy to override them. Lack of signal words, inappropriate combination of signal words, colours and icons should be

eliminated to ensure that pharmacy professionals do not make preventable mistakes. The design of ePMR systems, including the interface and alerts should be simple enough to allow pharmacy staff to do their work efficiently without confusion. Design that focuses the system operator's attention on the task, especially the clinical and safety aspect during the dispensing process is important.

Evaluation

It is important to evaluate ePMR systems regularly to help pharmacy organisations identify any weaknesses that ePMR systems may have with the aim of tackling them. This should include any workarounds that users might have created, which could result in unintended consequences for patient safety. It will also help in identifying cases where implementation of ePMR systems is inadequate or has the potential to cause new errors or harm. Another advantage of evaluation is that it can drive the discovery of aspects of ePMR systems' functionality that are efficient and work well. For example, some ePMR systems perform excellently when highlighting potential drug-drug interactions. Lessons can be learned about how system vendors have been able to achieve this.

7.4 Reflections

7.4.1 Reflection on methodology

7.4.1.1 Triangulation

Triangulation symbolises the use of different methods, multiple theories, observers and empirical materials to ensure consistency of data and to ensure a more accurate representation of the overall research objective (Silverman, 2011). According to Patton (2002), the following four types of triangulation can contribute to verification and validation of qualitative analysis. Triangulation of sources, also known as data triangulation can be used to check the consistency of different data sources within the same method, for example, sources such as the various participants (individual and groups) who participated in the exploratory study. Analyst triangulation involves using multiple analysts to review findings. Theory or perspective triangulation involves using multiple perspectives to interpret the data. Methods triangulation involves checking the consistency of findings generated by different data collection methods.

In this thesis, I used both data and methods triangulation. In the case of data triangulation, data obtained from the in-depth interviews conducted with participants in the exploratory study were analysed and compared to determine where participants agreed or disagreed. I also compared the findings obtained through different data collection methods - the qualitative interviews, observations and follow-up interviews to check their consistency.

7.4.1.2 Validity

The extent to which a study accurately represents the social phenomena to which it refers or the amount of value that can be placed on the study findings is referred to as '*validity*' (Silverman, 2011). It can be described as internal validity, which examines if an independent variable is truly responsible for any variation observed in the dependent variable or external validity, which concerns generalisability to a wider population. Using a combination of data types increases validity as the strengths of one approach can compensate for the weaknesses of another approach (Patton, 2002). In this research, schedules were designed for the qualitative interviews and observations to ensure internal validity. The findings were then linked with existing evidence where possible.

7.4.1.3 Reliability

If two researchers interviewed the same person or observed the same event at the same time or at different times using a non-structured schedule, it is unlikely that they would obtain exactly the same information or report the same data. However, their findings should be consistent for the data to be regarded as reliable. According to Hall et al. (1996), reliability involves '*using different research methods or sources of data to examine the same problem,*' to confirm interpretation through comparison of different data sources or to ensure that the understanding of an area is as complete as possible. For the sake of reliability, detailed description of the research strategy and data analysis methods were given in chapter 2 to ensure transparency of the research process. In addition, the theoretical influences and position from which the interpretation of findings took place ('*theoretical transparency*') were also highlighted as suggested by Silverman (2011).

7.4.1.4 Interviews and field observations

I learned new data gathering and analytical techniques that although satisfying, were extremely demanding and time consuming. The time allocated for the fieldwork and data collection and the timing of activities had to be right. This was because some pharmacies would not accommodate a researcher in-branch at busy times of the day or year, such as when the pharmacy is busy processing lots of walk-in prescriptions or one month before Christmas. For this study, the three to four (3-4) observational sessions each lasting about 30 minutes, were originally planned to be conducted over three (3) days as a single block or spread over a two-week period. However, the two-week period had to be extended to four weeks because some pharmacies were not able to accommodate me (the researcher) in-branch as originally planned. A change request was successfully made to the ethics committee for the extension.

7.4.1.5 Use of mixed-methods

The research employed a mixed-methods approach. The research questions determined the overall strategy for the research rather than any philosophical position. Consequently, a pragmatic approach was adopted and the data collection and analysis methods were matched to the relevant research questions and the purpose of the research (Mackenzie and Knipe, 2006). Both quantitative and qualitative data were collected and key information from each of these sources was integrated into the final discussion (Niglas, 1999).

Multiple methods including interviews and observations were combined successfully to expound complementary aspects of ePMR systems' functionality, including their safety performance. This helped to increase understanding of the topic under exploration especially where one single method would have been insufficient in providing answers to the research questions posed. For example, some members of the dispensing staff said during the interviews that they were told to inform the responsible pharmacist about '*red*' alerts. However, observations revealed that this does not always happen and that system operators often apply extra criteria when managing alerts.

7.4.2 Personal reflection on the research process

Participants received me warmly everywhere I went. They were happy to talk to me (the researcher) and share their perceptions and concerns about ePMR systems, safety features and alert practices in community pharmacy freely. This was perhaps because they felt that as a practicing community pharmacist, I understood some of the issues they face daily in practice. Some participants also expressed during the debriefing exercise that took place after the interviews that at last, the voice of pharmacy professionals was being heard and that issues of concern to them would now be addressed. I believe that participants also saw themselves as contributing to the overall goal of patient safety improvement and were therefore willing to share their experiences with me. For example, participants freely talked about issues that they felt were relevant to the studies even when not asked directly.

7.5 Future work

This thesis has evaluated electronic patient medication record systems functionality focusing on safety features and alerts. The study has stimulated some interesting ideas that are worth exploring. Potential areas for further investigation could include:

- Surveying a larger sample of practicing community pharmacists to establish the prevalence of the safety management issues identified in this study
- Exploring the possibility of eliminating alerts considered irrelevant or non-clinically significant
- Identifying and establishing alerts that should be presented to pharmacy professionals and appropriate design features that can facilitate compliance
- Exploring the best ways to present alerts to users, taking note of established best practices

7.6 Conclusions

This thesis sought to explore, describe, explain and understand electronic patient medication record (ePMR) systems' functionality focusing on safety features and alerts. To achieve this aim, four mixed-method studies were conducted. Systematic review evidence indicated that ePMR systems in conjunction with embedded safety features successfully picked up clinical hazards at the point of dispensing but there were problems of false alerts and inconsistencies in alert management. Participants in the exploratory study provided accounts suggesting that the low rate of alert acceptance and compliance was due to several factors such as lack of agreement about the levels of severity of alerts, lack of standardisation of alerts as well as absence of alert management guidance.

Although the ePMR systems that were tested do check for clinical hazards and provide warnings, however, the performance of the systems was variable and sub-optimal. Many of the inadequacies that were found limit the quality of support provided to community pharmacy practitioners. Furthermore, there are major concerns with the way ePMR systems are currently designed and used. It is important that system vendors make use of the vast amount of evidence in the literature in designing enhanced and effective ePMR systems, alerts and user interfaces. This would help to improve user access to all the required features and functions without introducing errors into the dispensing process.

Stakeholders also need to work out critical alerts that should be presented to users during order entry, alert severity levels and aspects of ePMR systems, which could benefit from standardisation and harmonisation. Minimum specifications, standardisation and harmonisation of ePMR systems and alerts are required to ensure consistency of performance.

The findings indicate that pharmacists need to be familiar with the systems they are using in practice, be conscientious and consistently demonstrate a culture of safety when using ePMR systems or managing alerts. Undergraduate, pre-registration and where required, post-graduate training in the use of health information and communications technologies should be introduced to improve safety. This should cover areas such as informatics, clinical decision-making, human factors; risk management, alert management and communication. The findings further highlight the need to incorporate patient context into alerts to increase their clinical significance. This research is part of a growing body of evidence indicating that ePMR systems, their safety features and alerts require improvements if they are to effectively support patient safety and consistently deliver improved patient outcomes.

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Appendices

Appendix A. Supporting documents for this research

A.1 EPS Release 2 – Status of dispensing system suppliers

Last updated: 18 October 2013

Pharmacy Systems / Status	Scope	Authority to Proceed (ATP)	Initial Design	Detailed Design	Module/System Test	Authority to Proceed (ATP)	Integration Test	Ready for Operation tests	Development Milestone Achieved Certificate (DevMAC)	Reference stage testing	Initial Implementation: Date entered /anticipated	Initial Implementation: Successful progress in prescribing/ dispensing 2500 items	Development Milestone Achieved Certificate (DevMAC)	Date (expected quarter) for Full Rollout Approval (FRA)
	Patient Safety Assessment		Clinical Safety Case				Clinical Safety Closure Report			Clinical Authority to Release (CATR)	Deployment Verification Period (DVP)			Clinical Authority to Release (CATR)
AAH ProScript LINK	Jan 08		Oct 08	Jan 09			Feb 10			Nov 09	Mar 10			Approved 31 March 2011
Cegedim Rx Ltd Pharmacy Manager 8.4	Jan 08		Jun 08	July 08			Sep 08			Jul 09	Jul 09			Approved 16 Aug 2010
Cegedim Rx Ltd Nexphase 8.2	Jan 08		April 08	Aug 08			Sep 08			Nov 09	Jan 11			Approved 27 Sept 2011
Helix Health QicScript	Oct 08		June 09	Nov 09			Feb 10			Jan 12	Mar 12			Approved 30 Nov 2012
Helix Health RxWeb 2.01F(formerly pharmaSys)	Aug 07		Nov 07	Jul 08			May 13			Aug 13	Aug 13			Approved 18 Oct 2013
Positive Solutions Ltd Analyst PMR/Integrated PMR and EPOS 1.11	Aug 07		March 08	Aug 08			Jul 10			Feb 11	Feb 11			Approved 23 Aug 2011
Rx Systems Proscript 2.59.1	Dec 07		Oct 08	Jan 09			April 09			Nov 09	Mar 10			Approved 31 March 2011
Lloyds CoMPaSS														Approved 12 July 2011

A.2 Ethics letter

Direct line/e-mail
+44 (0) 115 8231063
Louise.Sabir@nottingham.ac.uk



The University of Nottingham
Faculty of Medicine and Health Sciences

Medical School Research Ethics Committee
Division of Therapeutics & Molecular Medicine
D Floor, South Block
Queen's Medical Centre
Nottingham
NG7 2UH

Tel: +44 (0) 115 8231063
Fax: +44 (0) 115 8231059

17th January 2012

Oluwagbemileke Ojeleye
PhD Research Student
Division of Social Research in Medicines & Health
School of Pharmacy
University of Nottingham
East Drive, University Park
Nottingham
NG7 2RD

Dear Oluwagbemileke

Ethics Reference No: A8122011 CHS
Study Title: Evaluation of Community Pharmacy Patient Medication Record Systems
Chief Investigator: Dr Matthew Boyd, Lecturer in Pharmacy Practice and Academic Lead for Community Pharmacy and Primary Care Placements, Division of Social Research in Medicines and Health, School of Pharmacy, University of Nottingham, East Drive, University Park.
Co Investigators: Professor Anthony Avery, Professor of Primary Health Care/Joint Head of Division of Primary Health Care, School of Community Health Sciences
PhDStudent: Oluwagbemileke Ojeleye, Division of Social Research in Medicines and Health, School of Pharmacy
Duration of Study: 15/1/2012 -31/03/2013 (14 months)

Thank you for your letter dated 10th January 2012 responding to the issues raised by the committee and enclosing the following revised documents:

- Evaluation of PMR systems_ethics_response v2.2012.01.09
- Evaluation of PMR systems__LPF_letter 09/01/2012
- Evaluation of PMR systems_RPS_e-mail 10/01/2012
- Evaluation of PMR systems_MedEthics_dv1.3 10/01/2012
- Evaluation of PMR systems_Protocol_dv1.4 10/01/2012
- Insurance 15/11/2011
- SponsorLtr 15/11/2011
- Evaluation of_SSI_KBC_ver1.8 16/11/2011
- Evaluation of_SSI_LExperts_ver1.8 16/11/20111
- Evaluation of_SSI_PMakers_ver1.8 16/11/2011
- Evaluation of_SSI_PTeam_ver1.8 16/11/2011
- Evaluation of_SSI_Vendors_ver1.8 16/11/2011
- Evaluation of_ PMR_LTR_OBS_dv1.2 01/11/2011
- Evaluation of_ PMR_LTR_QUE_dv1.1 01/11/2011
- Evaluation of PMR SSI_dv1.2 01/11/2011
- Evaluation of PMR PIS_OBS_dv1.2 10/01/2112
- Evaluation of PMR PIS_QUE_dv1.2 10/01/2012
- Evaluation of PMR PIS_SSI_dv1.2 10/01/2012

These have been reviewed and are satisfactory and the study is approved.

Approval is given on the understanding that the Conditions of Approval set out below are followed.

Conditions of Approval

You must follow the protocol agreed and any changes to the protocol will require prior Ethics' Committee approval.

This study is approved for the period of active recruitment requested. The Committee also provides a further 5 year approval for any necessary work to be performed on the study which may arise in the process of publication and peer review.

You promptly inform the Chairman of the Research Ethics Committee of

(i) Deviations from or changes to the protocol which are made to eliminate immediate hazards to the research subjects.

(ii) Any changes that increase the risk to subjects and/or affect significantly the conduct of the research.

(iii) All adverse drug reactions that are both serious and unexpected.

(iv) New information that may affect adversely the safety of the subjects or the conduct of the study.

(v) The attached End of Project Progress Report is completed and returned when the study has finished.

Yours sincerely



Dr Clodagh Dugdale
Chair, Nottingham University Medical School Research Ethics Committee

A.3 NHS permission letter – NHS Nottinghamshire County

positive

Nottinghamshire Healthcare NHS
NHS Trust
Positive about mental health and learning disability

Research Management and Governance
Institute of Mental Health
2nd Floor, Duncan MacMillan House
Porchester Road
Nottingham

8th February 2012

Mr Oluwagbemileke Ojeleye
Division of Social Research in Medicines and Health
School of Pharmacy, University of Nottingham
University Park
Nottingham
NG7 2RD

Dear Mr Ojeleye

REC ref: N/A as it is a staff study
Title: Evaluation of Community Pharmacy Patient Medication Record (PMR) Systems
Brief study summary
This study aims to investigate the factors which influence pharmacy owners' decisions in regards to the PMR systems and/ or alert database. The researcher will evaluate the PMR systems in terms of their functionality and ability to detect and alert users about clinically hazardous interactions and errors at the point of dispensing and the impact on their work practices.

A poster will be displayed in all participating pharmacies to inform patients that their information may be seen by the researcher, they may then request that the system is not observed during their visit if they do not want their details to be seen

A confidentiality agreement will be signed by all participating pharmacies and the researcher, a copy will be sent to the R&D Department for information.

Implications on resources
Pharmacists will be invited to take part in either an interview and observation period or to complete a questionnaire.

The interview is expected to take no longer than 60 minutes whilst the observation phase of the study will consist of 3 or 4 30 minute sessions over a period of 3 days. The questionnaire is expected to take 10 – 15 minutes to complete.

There are no service support costs associated with this study.

Thank you for submitting the above project to the Nottinghamshire Healthcare NHS Trust's R&D Department. The project has now been given Organisational Approval by:

Dr Amanda Sullivan, R & D Lead, on behalf of NHS Nottinghamshire County

Although Organisational approval has been given for this study it does not guarantee that independent contractors such as GPs, dentists, optometrists and community pharmacists will be able to take part in your study.

Conditions of approval
Please note that approval for this study is dependent on full compliance with the following. To that end, please complete and return the form attached to this letter confirming your acceptance of these terms and conditions:

- You are required to ensure that all information regarding patients or staff remains secure and **strictly confidential** at all times. You must ensure that you understand and comply with the requirements of the

NHS Confidentiality Code of Practice (*http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf*) and the Data Protection Act (1998). Furthermore, you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

- You must not hold person identifiable data on portable media unless it is encrypted. Protecting data files with passwords does not constitute encryption
- To complete yearly/final reports as requested, and to feedback study findings to the Research and Development Department and participants (as appropriate)
- To endeavour to publish and/or disseminate research findings on completion of the project
- To inform the Research and Development Department of any changes that occur, e.g. amendments to approved documentation, project not started for any reason, change in personnel etc
- That you inform the Research and Development Department which GP Practices you have recruited to your study from NHS Nottinghamshire County (where applicable)
- That you inform the Research and Development Department of all serious adverse incidents in accordance with Trust Policy and/or Legal requirements (e.g. Sponsor, MHRA). This is in addition to the reporting of serious or unexpected adverse events and adverse drug reactions (which may affect the conduct and continuation of the study) to the approving research ethics committee
- That you are aware of and comply with the PCT Research and Development Policies and Best Practice Guidance
- That you agree to cooperate with a Research Governance Audit of the project if requested by the Research and Development Department
- That you have read and agree to abide by the Research Governance Framework (RGF) for Health and Social Care (second edition 2005)

The *Research Governance Framework for Health & Social Care* sets out the responsibilities of all those involved in research in order to enhance the ethical and scientific quality of health research and to safeguard patients and the public. The lead investigator and all involved in the research have a responsibility to comply with Research Governance.

Full details can be found in the RGF document available at www.dh.gov.uk or via the Research and Evaluation Department.

Yours sincerely,



Shirley Mitchell
Head of Research Management and Governance

Copy to:
Sponsor
Ethics

Project title:	
Ethics Reference Number:	

Organisational Approval: Acceptance of Terms and Conditions

Statement of compliance: I confirm acceptance of NHS Nottinghamshire County research approval terms and conditions as detailed in the Organisational Approval Letter (Version 7, May 2011)

Signed.....

Print Name.....

Date.....

A.4 NHS permission letter – NHS Nottinghamshire City PCT

positive

Nottinghamshire Healthcare NHS
NHS Trust
Positive about mental health and learning disability

Research Management and Governance
Institute of Mental Health
2nd Floor, Duncan MacMillan House
Porchester Road
Nottingham

Date: 02/02/2012

Mr Oluwagbemileke Ojeleye
Division of Social Research in Medicines and Health
School of Pharmacy, University of Nottingham
University Park
Nottingham
NG7 2RD

Dear Mr Ojeleye

REC ref: N/A as it is a staff study
Title: Evaluation of Community Pharmacy Patient Medication Record (PMR) Systems
Brief study summary
This study aims to investigate the factors which influence pharmacy owners' decisions in regards to the PMR systems and/ or alert database. The researcher will evaluate the PMR systems in terms of their functionality and ability to detect and alert users about clinically hazardous interactions and errors at the point of dispensing and the impact on their work practices.

A poster will be displayed in all participating pharmacies to inform patients that their information maybe seen by the researcher, they may then request that the system is not observed during their visit if they do not want their details to be seen.

A confidentiality agreement will be signed by all participating pharmacies and the researcher and a copy will be forwarded to the R&D department.

Implications on resources
Pharmacists will be invited to take part in either an interview and observation period or to complete a questionnaire.

The interview is expected to take no longer than 60 minutes whilst the observation phase of the study will consist of 3 or 4 30 minute sessions over a period of 3 days. The questionnaire is expected to take 10 – 15 minutes to complete.

There is no service support costs associated with this study.

Thank you for submitting the above project to the Nottinghamshire Healthcare NHS Trust's R&D Department. The project has now been given Organisational Approval by:

Dr Peter Cansfield, R & D Lead, on behalf of NHS Nottinghamshire City PCT

Although Organisational approval has been given for this study it does not guarantee that independent contractors such as GPs, dentists, optometrists and community pharmacists will be able to take part in your study.

Conditions of approval
Please note that approval for this study is dependent on full compliance with the following. To that end, please complete and return the form attached to this letter confirming your acceptance of these terms and conditions:

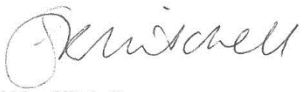
- You are required to ensure that all information regarding patients or staff remains secure and **strictly confidential** at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (*http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf*)

- You must not hold person identifiable data on portable media unless it is encrypted. Protecting data files with passwords does not constitute encryption
- To complete yearly/final reports as requested, and to feedback study findings to the Research and Development Department and participants (as appropriate)
- To endeavour to publish and/or disseminate research findings on completion of the project
- To inform the Research and Development Department of any changes that occur, e.g. amendments to approved documentation, project not started for any reason, change in personnel etc
- That you inform the Research and Development Department which GP Practices you have recruited to your study from NHS Nottingham City (where applicable)
- That you inform the Research and Development Department of all serious adverse incidents in accordance with Trust Policy and/or Legal requirements (e.g. Sponsor, MHRA). This is in addition to the reporting of serious or unexpected adverse events and adverse drug reactions (which may affect the conduct and continuation of the study) to the approving research ethics committee
- That you agree to cooperate with a Research Governance Audit of the project if requested by the Research and Development Department
- That you have read and agree to abide by the Research Governance Framework (RGF) for Health and Social Care (second edition 2005)

The *Research Governance Framework for Health & Social Care* sets out the responsibilities of all those involved in research in order to enhance the ethical and scientific quality of health research and to safeguard patients and the public. The lead investigator and all involved in the research have a responsibility to comply with Research Governance.

Full details can be found in the RGF document available at www.dh.gov.uk or via the Research and Evaluation Department.

Yours sincerely,



Shirley Mitchell
Head of Research Management and Governance

Copy to
R&D leads
Ethics

Appendix B. Supporting documents for the systematic review

B.1 Search protocols used for identifying studies in other databases

PsycINFO

1. (e adj2 prescrip$).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
2. (elec$ adj prescrip$).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
3. Drug Utili?ation Review.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
4. Pharmacy Information System$.mp.
5. Patient Medication Record$.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
6. (Pharmacy or Pharmacies or Pharmacist$).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
7. 1 or 2 or 3 or 4 or 5 or 6
8. (Safety adj2 (Alert$ or Feature$ or Alarm$ or Warning$ or Prompt$)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
9. (Over?rid$ adj25 Alert$).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
10. alert$.mp.
11. Decision Support$.mp.
12. 8 or 9 or 10 or 11
13. 7 and 12

Inspec

1. (e adj2 prescrip$).mp. [mp=title, abstract, subject heading words, key phrase identifiers]
2. (elec$ adj prescrip$).mp. [mp=title, abstract, subject heading words, key phrase identifiers]
3. Drug Utili?ation Review.mp. [mp=title, abstract, subject heading words, key phrase identifiers]
4. exp safety-critical software/
5. Pharmacy Information System$.mp.
6. Patient Medication Record$.mp. [mp=title, abstract, subject heading words, key phrase identifiers]
7. (Pharmacy or Pharmacies or Pharmacist$).mp. [mp=title, abstract, subject heading words, key phrase identifiers]
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. (Safety adj2 (Alert$ or Feature$ or Alarm$ or Warning$ or Prompt$)).mp. [mp=title, abstract, subject heading words, key phrase identifiers]
10. (Over?rid$ adj25 Alert$).mp. [mp=title, abstract, subject heading words, key phrase identifiers]
11. alert$.mp.
12. Decision Support$.mp.
13. 9 or 10 or 11 or 12
14. 8 and 13
15. (e adj2 prescrip$).mp. [mp=title, abstract, subject heading words, key phrase identifiers]
16. (elec$ adj prescrip$).mp. [mp=title, abstract, subject heading words, key phrase identifiers]
17. Drug Utili?ation Review.mp. [mp=title, abstract, subject heading words, key phrase identifiers]
18. exp safety-critical software/
19. Pharmacy Information System$.mp.
20. Patient Medication Record$.mp. [mp=title, abstract, s! ubject heading words, key phrase identifiers]
21. (Pharmacy or Pharmacies or Pharmacist$).mp. [mp=title, abstract, subject heading words, key phrase identifiers]

22. 15 or 16 or 17 or 18 or 19 or 20 or 21

23. (Safety adj2 (Alert$ or Feature$ or Alarm$ or Warning$ or Prompt$)).mp. [mp=title, abstract, subject heading words, key phrase identifiers]

24. (Over?rid$ adj25 Alert$).mp. [mp=title, abstract, subject heading words, key phrase identifiers]

25. alert$.mp.

26. Decision Support$.mp.

27. 23 or 24 or 25 or 26

28. 22 and 27

International Pharmaceutical Abstracts

1. (e adj2 prescrip$).mp. [mp=title, subject heading word, registry word, abstract, trade name/generic name]
2. (elec$ adj prescrip$).mp. [mp=title, subject heading word, registry word, abstract, trade name/generic name]
3. Drug Utili?ation Review.mp. [mp=title, subject heading word, registry word, abstract, trade name/generic name]
4. Pharmacy Information System$.mp.
5. Computer System$! .mp.
6. Patient Medication Record$.mp. [mp=title, subject heading word, registry word, abstract, trade name/generic name]
7. (Pharmacy or Pharmacies or Pharmacist$).mp. [mp=title, subject heading word, registry word, abstract, trade name/generic name]
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. (Safety adj2 (Alert$ or Feature$ or Alarm$ or Warning$ or Prompt$)).mp. [mp=title, subject heading word, registry word, abstract, trade name/generic name]
10. (Over?rid$ adj25 Alert$).mp. [mp=title, subject heading word, registry word, abstract, trade name/generic name]
11. alert$.mp.
12. Reminder System$.mp.
13. Decision Support$.mp.
14. Clinical Decision$.mp.
15. 9 or 10 or 11 or 13 or 14
16. 8 and 15

Embase

1. (e adj2 prescrip$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
2. (elec$ adj prescrip$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
3. exp Drug Labeling/
4. Drug Utili?ation Review.mp. [mp=title, abstract, subject headings, heading ! word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
5. Pharmacy Information System$.mp.
6. Patient Medication Record$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
7. (Pharmacy or Pharmacies or Pharmacist$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. (Safety adj2 (Alert$ or Feature$ or Alarm$ or Warnin! g$ or Prompt$)).mp. [mp=title, abstract, subject headings, heading wor d, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
10. (Over?rid$ adj25 Alert$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
11. Reminder System$/
12. alert$.mp.
13. Decision Support$.mp.
14. exp Decision Making, Computer-Assisted/
15. exp Drug Dosage Calculations/
16. 9 or 10 or 11 or 12 or 13 or 14 or 15
17. 8 and 16

B.2 Pre-designed data extraction template

Form version/date: *Version 1.0, 11 August 2011)*

Review Title:

Name of review author completing this form:

Date form completed:

Notes:
For example, references to be followed up, or unpublished data/personal communication included Contact with author (Yes (information obtained)/No).

Methods:

Details of Study:

Aim of intervention: *(As stated in the study report. What was the problem that this intervention was designed to address?)*

Aim of study: *(As stated in the study report. What was the study designed to assess?)*

Study design:

Methods of recruitment of participants *(How were potential participants approached and invited to participate?)*

Inclusion/exclusion criteria for participation in study:

Informed consent obtained? *(Yes/No/Unclear)*

Ethical approval *(Yes/No/Unclear)*

Funding *(including source, amount, if stated).*

Statistical methods and their appropriateness (if relevant):

Assessment of Risk of Bias for RCTs, quasi-RCTs and CBAs

Domain	Review authors' judgement	Support for judgement
Allocation (selection) bias/ Random sequence generation* Quasi-RCTs and Controlled Before and After (CBA) studies must be rated as 'High Risk' for random sequence generation as the methods were not, by definition, truly random.	***High risk*** ***Unclear*** ***Low risk***	**Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.**
Allocation sequence concealment CBA Studies should be rated 'High Risk. Quasi-RCTs are likely to be rated 'High Risk but there may be some exceptions.	***High risk*** ***Unclear*** ***Low risk***	**Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.**
Blinding of participants and staff *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	**Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.**
Blinding of outcome assessment *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	**Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective**. If the outcome is objective (e.g. length of hospital stay) the rating should be 'Low risk.
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	**Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.**
Selective reporting	***High risk*** ***Unclear*** ***Low risk***	**State how the possibility of selective outcome reporting was examined by the review authors, and what was found.**
Other sources of bias	***High risk*** ***Unclear*** ***Low risk***	**State any important concerns about bias not addressed in the other domains in the tool.**

Population:
Description: Patient medication record (PMR) or pharmacy order entry (POE) systems used in pharmacies.

Geographic location *(e.g. City/State/Country)*

Setting (*e.g. Primary or Secondary Care)*

Number*: (Eligible, excluded, refused to take part, randomised to intervention, randomised to control, excluded post randomisation, withdrawn, lost to follow-up, died, included in analysis, included for each outcome)*

Interventions:

Details of intervention, including theoretical basis (with key references), aim, content, format(s) (media), source, setting. *(Capture this information for each arm of the study, e.g. Intervention A, Intervention B…)*

Details of control/usual or usual care

Details of co-interventions in all groups *(co-interventions may be separate to the intervention of interest for this review, or they may be other similar elements in a suite of interventions having a common purpose. Record all relevant information).*

Delivery of intervention *(e.g. stages, timing, frequency, duration) (for each intervention included in the study, e.g. Intervention A; Intervention B…)*

Details of providers (W*ho delivers the intervention?; number of providers; training of providers in delivery of intervention*).

Intervention quality (if relevant): *(Record any information on the quality of the intervention - assessed by study authors, others or by you - such as the evidence base of the intervention, or the quality of staff training for intervention delivery)*

Fidelity/integrity *(Was the intervention delivered as intended? Record any assessment of this*).

Outcomes:
Principal and secondary outcome measures *(as identified by the study authors).*

Methods of assessing outcome measures *(e.g., phone survey, questionnaire, physical measurements (for each outcome))*

Validity and reliability of outcome measures

Timing of outcome assessment *(including frequency, length of follow-up (for each outcome))*

Adverse events (*e.g. complaints, levels of dissatisfaction, adverse incidents, side effects))*

Results

All data are numbers

Dichotomous outcomes

Outcome	Timing of outcome assessment	Intervention group		Usual care group		Notes
		Observed (n)	Total (N)	Observed (n)	Total (N)	

Continuous outcomes

Outcome	Timing of outcome assessment	Intervention group			Control group			Notes
		Mean / Mean change	Standard deviation	N	Mean / Mean change	Standard deviation	N	

Other relevant information

B.3 List of excluded articles

A	Rejected based on the population
1	Kuperman, G. J., Bates, D. W., Teich, J. M., Schneider, J. R. & Cheiman, D. 1994. A new knowledge structure for drug-drug interactions. Proceedings / Annual Symposium on Computer Application in Medical Care, 836-840.
2	Malone, D. C., Abarca, J., Hansten, P. D., Grizzle, A. J., Armstrong, E. P., Van Bergen, R. C., Duncan-Edgar, B. S., Solomon, S. L. & Lipton, R. B. 2005. Identification of serious drug-drug interactions: Results of the partnership to prevent drug-drug interactions. American Journal Geriatric Pharmacotherapy, **3**, 65-76.
3	Mannheimer, B., Ulfvarson, J., Eklof, S., Bergqvist, M. & Von Bahr, C. 2008. A clinical evaluation of the Janus Web Application, a software screening tool for drug-drug interactions. European Journal of Clinical Pharmacology, **64**, 1209-1214.
4	Miller, J. E., Reichley, R. M., McNamee, L. A., Steib, S. A. & Bailey, T. C. 1999. Notification of real-time clinical alerts generated by pharmacy expert systems. AMIA Annual Symposium Proceedings, 325-329.
5	Oliven, A., Michalake, I., Zalman, D., Dorman, E., Yeshurun, D. & Odeh, M. 2005. Prevention of prescription errors by computerized, on-line surveillance of drug order entry. International Journal of Medical Informatics, **74**, 377-386.
6	Peterson, J. F. & Bates, D. W. 2001. Preventable medication errors: identifying and eliminating serious drug interactions. Journal of the American Pharmaceutical Association, **41**, 159-60.
7	Senger, C., Kaltschmidt, J., Schmitt, S. P. W., Pruszydlo, M. G. & Haefeli, W. E. 2010. Misspellings in drug information system queries: Characteristics of drug name spelling errors and strategies for their prevention. International Journal of Medical Informatics, **79**, 832-839.
8	Tamblyn, R., Huang, A., Kawasumi, Y., Bartlett, G., Grad, R., Jacques, A., Dawes, M., Abrahamowicz, M., Perreault, R., Taylor, L., Winslade, N., Poissant, L. & Pinsonneault, A. 2006. The development and evaluation of an integrated electronic prescribing and drug management system for primary care. Journal of the American Medical Informatics Association, **13**, 148-159.
9	Williams, M., Peterson, G. M., Tenni, P. C., Bindoff, I. K., Curtain, C., Hughes, J., Bereznicki, L. R. E., Jackson, S. L., Kong, D. C. M. & Hughes, J. D. 2011. Drug-related problems detected in Australian community pharmacies: The PROMISe trial. Annals of Pharmacotherapy, **45**, 1067-1076.
10	Zillich, A., Saleem, J., McManus, M. & Russ, A. 2010. Qualitative study of medication alerts and computerized prescriber order entry: Opportunities for pharmacist consultation at the point of prescribing. Journal of the American Pharmacists Association, **50** (2), 284-285.

11	Zwart-Van Rijkom, J. E. F., Uijtendaal, E. V., Ten Berg, M. J., Van Solinge, W. W. & Egberts, A. C. G. 2009. Frequency and nature of drug-drug interactions in a Dutch university hospital. British Journal of Clinical Pharmacology, **68**, 187-193.
B	**Rejected based on the type of intervention**
1	Chui, M. A. & Rupp, M. T. 2000. Evaluation of online prospective DUR programs in community pharmacy practice. Journal of Managed Care Pharmacy, **6**, 27-32.
2	Reeve, J. F., Tenni, P. C. & Peterson, G. M. 2008. An electronic prompt in dispensing software to promote clinical interventions by community pharmacists: A randomized controlled trial. British Journal of Clinical Pharmacology, **65**, 377-385.
C	**Rejected based on the type of study design**
1	Abarca, J., Colon, L. R., Wang, V. S., Malone, D. C., Murphy, J. E. & Armstrong, E. P. 2006. Evaluation of the performance of drug-drug interaction screening software in community and hospital pharmacies. Journal of Managed Care Pharmacy, **12**, 383-389.
2	Armstrong, E. P. & Denemark, C. R. 1998. How pharmacists respond to online, real time DUR alerts. Journal of the American Pharmaceutical Association, **38**, 149-154.
3	Brien, J. A. E., Reeve, J., Sweidan, M., Jayasuriya, P. & Martin, J. 2009. Drug interaction alerts in dispensing and prescribing software. Journal of Pharmacy Practice and Research, **39**, 81-82.
4	Buurma, H., De Smet, P. A. & Egberts, A. C. 2006. Clinical risk management in Dutch community pharmacies - The case of drug-drug interactions. Drug Safety, **29**, 723-732.
5	Buurma, H., De Smet, P. & Egberts, A. 2007. Clinical risk management in community pharmacy. [Dutch]. Risicomanagement in de zorgpraktijk van de openbare apotheker. Huisarts en Wetenschap, **50**, 623-627.
6	Buurma, H., Schalekamp, T., Egberts, A. C. & De Smet, P. A. 2007. Compliance with national guidelines for the management of drug-drug interactions in dutch community pharmacies. Annals of Pharmacotherapy, **41**, 2024-2031.
7	Calabretto, J. P., Warren, J. & Bird, L. 2005. Pharmacy decision support: Where is it? A systematic literature review. International Journal of Pharmacy Practice, **13**, 157-163.
8	Chrischilles, E. A., Fulda, T. R., Byrns, P. J., Winckler, S. C., Rupp, M. T. & Chui, M. A. 2002. The role of pharmacy computer systems in preventing medication errors. Journal of the American Pharmaceutical Association, **42**, 439-448.
10	Cremades, J., Gonzalo, M. & Arrebola, I. 2009. Relationship between drug interactions and drug-related negative clinical outcomes. Pharmacy Practice, **7**, 34-39.

11	Gardner, R. M., Hulse, R. K. & Larsen, K. G. 1990. Assessing the effectiveness of a computerized pharmacy system. Fourteenth Annual Symposium on Computer Applications in Medical Care. Standards in Medical Informatics. A Conference of the American Medical Informatics Association, 668-672.
12	Goldberg, D. E., Baardsgaard, G., Johnson, M. T., Jolowsky, C. M., Shepherd, M. & Peterson, C. D. 1991. Computer-based program for identifying medication orders requiring dosage modification based on renal function. American Journal of Hospital Pharmacy, **48**, 1965-1969.
13	Grissinger, M. 2002. Optimizing the use of computer system clinical alerts. P & T, **27**, 593.
14	Hatton, R. C., Rosenberg, A. F., Morris, C. T., McKelvey, R. P. & Lewis, J. R. 2011. Evaluation of contraindicated drug-drug interaction alerts in a hospital setting. Annals of Pharmacotherapy, **45**, 297-308.
15	Hazlet, T. K., Lee, T. A., Hansten, P. D. & Horn, J. R. 2001. Performance of community pharmacy drug interaction software. Journal of the American Pharmaceutical Association, **41**, 200-204.
16	Heikkila, T., Lekander, T. & Raunio, H. 2006. Use of an online surveillance system for screening drug interactions in prescriptions in community pharmacies. European Journal of Clinical Pharmacology, **62**, 661-665.
17	Hines, L. E., Saverno, K. R., Warholak, T. L., Taylor, A., Grizzle, A. J., Murphy, J. E. & Malone, D. C. 2011. Pharmacists' awareness of clinical decision support in pharmacy information systems: An exploratory evaluation. Research in Social & Administrative Pharmacy, **7**, 359-368.
18	Indermitte, J., Beutler, M., Bruppacher, R., Meier, C. R. & Hersberger, K. E. 2007. Management of drug-interaction alerts in community pharmacies. Journal of Clinical Pharmacy & Therapeutics, **32**, 133-142.
19	Jankel, C. A. & Martin, B. C. 1992. Evaluation of six computerized drug interaction screening programs. American Journal of Hospital Pharmacy, **49**, 1430-1435.
20	Mackowiak, L. R. & Hayward, S. L. 1998. Issues of decision support in institutional pharmacy systems. Pharmacy practice management quarterly, **18**, 35-45.
21	Murphy, J. E., Forrey, R. A. & Desiraju, U. 2004. Community pharmacists' responses to drug-drug interaction alerts. American Journal of Health-System Pharmacy, **61**, 1484-1487.
22	Resetar, E., Reichley, R. M., Noirot, L. A., Doherty, J. A., Dunagan, W. C. & Bailey, T. C. 2005. Strategies for reducing nuisance alerts in a dose checking application. AMIA Annual Symposium Proceedings, 624-628.
23	Robertson, J., Walkom, E., Pearson, S. A., Hains, I., Williamson, M. & Newby, D. 2010. The impact of pharmacy computerised clinical decision support on prescribing, clinical and patient outcomes: A systematic review of the literature. International Journal of Pharmacy Practice, **18**, 69-87.

24	ROSENBERG, S. N., SULLIVAN, M., JUSTER, I. A. & JACQUES, J. 2009. Overrides of medication alerts in ambulatory care. Archives of Internal Medicine, **169**, 1337.
25	Saverno, K. R., Hines, L. E., Warholak, T. L., Grizzle, A. J., Babits, L., Clark, C., Taylor, A. M., & Malone, D. C. 2011. Ability of pharmacy clinical decision-support software to alert users about clinically important drug-drug interactions. Journal of the American Medical Informatics Association, **18**, 32-37.
26	Schiff, G. D., Klass, D., Peterson, J., Shah, G. & Bates, D. W. 2003. Linking laboratory and pharmacy: opportunities for reducing errors and improving care. Archives of Internal Medicine, **163**, 893-900.
27	Seymour, R. M. & Routledge, P. A. 1998. Important drug-drug interactions in the elderly. Drugs and Aging, **12**, 485-494.
28	Shah, V. S., Weber, R. J. & Nahata, M. C. 2011. Contradictions in contraindications for drug-drug interactions. Annals of Pharmacotherapy, **45**, 409-411.
29	Sweidan, M., Reeve, J. F., Brien, J. A., Jayasuriya, P., Martin, J. H. & Vernon, G. M. 2009. Quality of drug interaction alerts in prescribing and dispensing software. Medical Journal of Australia, **190**, 251-254.
29	Sweidan, M., Reeve, J. F. & Dartnell, J. G. A. 2009. Consider the content of drug-drug interaction alerts. Archives of Internal Medicine, **169**, 1338.
30	Trygstad, T. K., Christensen, D., Garmise, J., Sullivan, R. & Wegner, S. 2005. Pharmacist response to alerts generated from Medicaid pharmacy claims in a long-term care setting: results from the North Carolina polypharmacy initiative. Journal of managed care pharmacy, **11**, 575-583.
31	Van Der Sijs, H., Mulder, A., Van Gelder, T., Aarts, J., Berg, M. & Vulto, A. 2009. Drug safety alert generation and overriding in a large Dutch university medical centre. Pharmacoepidemiology and Drug Safety, **18**, 941-947.
32	Warholak, T. L., Hines, L. E., Saverno, K. R., Grizzle, A. J. & Malone, D. C. 2011. Assessment tool for pharmacy drug-drug interaction software. Journal of the American Pharmacists Association, **51**, 418-424.
33	Watanabe, M., Sugiura, M., Seino, T., Mitsunaga, Y., Nakamura, H., Yamada, Y., Tsuchiya, F., Ohe, K. & Iga, T. 2002. The construction and evaluation of the preventing method for the input mischoice in a prescription order entry system - Usefulness of a three-character input and a warning screen display system. [Japanese]. Yakugaku Zasshi, **122**, 841-847.
34	Young, D. 2001. Electronic system alerts pharmacists to potential adverse drug events. American Journal of Health-System Pharmacy, **58**, 2362, 2365.

D	**Abstract only**
1	Seidling, H. M., Eder, N., Czock, D., Schmitt, S. P. W., Kaltschmidt, J., Bertsche, T. & Haefeli, W. E. 2010. Detection of drug underdosage in electronic prescriptions. British Journal of Clinical Pharmacology, **70**, 28.

2	Taegtmeyer, A. B., Jetter, A., Widmer, N., Falk, V. & Kullak-Ublick, G. A. 2011. Performance of electronic druginteractions checking in the care of cardiovascular surgery patients. British Journal of Clinical Pharmacology, **72**, 38.
E	**Unable to locate**
1	Hardy, R. W., Nance, B. J. & Brown, E. T. 1970. 'Drug Alert': system devised to prevent drug interactions. Hospital topics, **48**, 83-88.

B.4 Risk of bias assessment

Bhardwaja et al. (2010)

Bias	Authors' judgement	Support for judgement
Allocation (selection bias)	Low risk	Quote: '…the entire membership of KPCO was randomly assigned to either the usual care group or the intervention group…by using the uniform distribution function in SAS…'
Allocation sequence concealment	Unclear risk	Comment: Not reported
Blinding of participants and personnel (performance bias)	Low risk	Quote: 'The study subjects, study investigators and study personnel were blinded to group assignments'
Blinding of outcome assessment (detection bias)	Low risk	Quote: '…a research pharmacist blinded to group assignments performed a medical record review of all target drug dispensing to patients in the intervention group…'
Incomplete outcome data (attrition bias)	Low risk	Comment: None were identified
Selective reporting (reporting bias)	Low risk	Comment: None were identified
Other bias	Unclear risk	Comment: Randomisation was unbalanced. (2) False positive alert types Quote: 'At the beginning of the study, the number of false-positive alerts (determined as the proportion of alerts that had Clcr > 51 ml/min on medical record review) was almost 32%. One year after changing the alert to the drug-specific Clcr cut-off, the false-positive rate was reduced to 0.5%.'

Humphries et al. (2007)

Bias	Authors' judgement	Support for judgement
Allocation (selection bias)	High risk	Comment: Not randomised
Allocation sequence concealment	High risk	Comment: Not reported
Blinding of participants and personnel (performance bias)	High risk	Comment: Blinding not described
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Blinding of outcome assessors was not described
Incomplete outcome data (attrition bias)	Low risk	Comment: None were identified
Selective reporting (reporting bias)	Low risk	Comment: None were identified
Other bias	Unclear risk	Comment: Bias related to before-after study design

Mansour et al. (2010)

Bias	Authors' judgement	Support for judgement
Allocation (selection bias)	High risk	Comment: Not randomised
Allocation sequence concealment	High risk	Comment: Not randomised
Blinding of participants and personnel (performance bias)	High risk	Comment: Before-after study, blinding not described
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Blinding of outcome assessors was not described
Incomplete outcome data (attrition bias)	Low risk	Comment: None were identified
Selective reporting (reporting bias)	Low risk	Comment: None were identified
Other bias	Unclear risk	Comment: Bias related to before-after study design

Raebel et al. (2007a)

Bias	Authors' judgement	Support for judgement
Allocation (selection bias)	Low risk	Quote: '…approximately 340,000 individuals were randomized (using the uniform distribution function in SAS…' Comment: Randomisation was unbalanced. It is unlikely to have had any negative impact on group assignment
Allocation sequence concealment	Unclear risk	Comment: Not reported
Blinding of participants and personnel (performance bias)	Low risk	Quote: 'Physicians, patients and pharmacists were blinded to study group assignment'
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Blinding of outcome assessors was not described
Incomplete outcome data (attrition bias)	Low risk	Comment: None were identified
Selective reporting (reporting bias)	Low risk	Comment: None were identified
Other bias	Unclear risk	Comment: (1) Randomisation was unbalanced. (2) Study was stopped early due to false-positive alert types but it is unclear if this could have introduced other biases into the study.

Raebel et al. (2007b)

Bias	Authors' judgement	Support for judgement
Allocation (selection bias)	Low risk	Quote: '…the entire membership of KPCO was randomized to an intervention or usual care group using the uniform distribution function in SAS'
Allocation sequence concealment	Unclear risk	Comment: Not reported
Blinding of participants and personnel (performance bias)	Low risk	Quote: 'Physicians, patients and pharmacists were blinded to study group assignment'
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Blinding of outcome assessors was not described
Incomplete outcome data (attrition bias)	Low risk	Comment: None were identified
Selective reporting (reporting bias)	Low risk	Comment: None were identified
Other bias	Unclear risk	Comment: False positive alerts Quote: 'In the context of this study, alerts for excluded indications could be considered false-positives, because the pharmacist reviewed the prescriptions to determine that the alerts were for excluded indications and documented that, but the pharmacist did not intervene'

Appendix C. Supporting documents for the exploratory study

C.1 List of participants

Interview no	Gender	Study Code	Professional Background	Interview time (minutes)
Pharmacy professionals				
01	F	P1	Pharmacist	34
02	F	P2	Pharmacist	27
03	M	P3	Pharmacist	22
04	F	P4	Pharmacist	22
05	M	S1I	Superintendent pharmacist	38
06	M	S2I	Superintendent pharmacist	47
07	M	S3SM	Superintendent pharmacist	47
08	M	S4LM	Superintendent pharmacist	33
09	F	S5LM	Professional standards manager	31
10	M	S6I	Superintendent pharmacist	46
11	M	D1	Dispenser	17
12	F	D2	Dispenser	22
13	F	D3	Dispenser	22
Health care policy makers				
14	F	PM1	Health care policy maker	18
15	M	PM2[1]	Health care policy maker	82
16	F	PM3[1]	Health care policy maker	82
17	M	PM4	Health care policy maker	42
18	M	PM5**	Health care policy maker	20
Legal experts				
19	M	LE1	Legal Expert	56
20	M	LE2	Legal Expert	51
21	F	LE3**	Legal Expert	58
Drug database vendors				
22	F	KB1	Drug database vendor	38
23	M	KB2	Drug database vendor	25
24	M	KB3[2]	Drug database vendor	74
25	F	KB4[2]	Drug database vendor	74
System vendors				
26	F	V1	System vendor	29
27	M	V2*	System vendor	38
28	M	V3*	System vendor	51
29	M	V4*	System vendor	23
30	M	V5	System vendor	41

[1,2] Joint Interviews *Telephone Interview

C.2 Letter of introduction

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

School of Pharmacy
Division of Social Research in Medicines and Health
University Park
Nottingham
NG7 2RD
Tel +44(0)115 823 2277

Dear ***(insert person's name or title):***

This letter is an invitation to participate in a research study investigating community pharmacy Patient Medication Record (PMR) systems' functionality in relation to highlighting clinically important medication and patient safety concerns during the dispensing process.

Patient Medication Record (PMR) systems are used in the UK for recording details of prescriptions dispensed; checking medications for potential hazards and errors; and producing labels for dispensed items. The aim of this study is to explore your knowledge, views and experiences regarding PMR systems and their functionality focusing on safety features and alerts.

Participation is entirely voluntary. If you agree to participate, I will follow up with you to arrange a face-to-face interview at a time that is convenient for you. The interview will last approximately 30 minutes. To facilitate collection of information and prevent disruptions from note taking, the interview will be audio recorded.

All information you provide will be confidential. Your name and the name of your organisation will not appear in any report or publications resulting from this study. As with all University of Nottingham projects involving human participants, this study was reviewed and given favourable ethical opinion by the University of Nottingham Medical School Research Ethics Committee.

If you have any questions, comments or concerns regarding this study, or would like additional information about participation, please contact me using the details at the end of this letter. You can also contact either of my supervisors, Dr Matthew Boyd (matthew.boyd@nottingham.ac.uk) or Prof Anthony Avery (anthony.avery@nottingham.ac.uk). A copy of the information sheet is included with this letter.

Thank you for your interest and assistance with this research.

Yours sincerely,

Oluwagbemileke Ojeleye
Research Student
paxoo1@nottingham.ac.uk

C.3 Participant information sheet



Participant Information Sheet

(Draft Version 1.3 / Final version 1.0: 10 January 2012)

Title of Study: Evaluation of Community Pharmacy Patient Medication Record Systems

Name of Researcher(s):

- Oluwagbemileke Ojeleye (Researcher)
- Dr Matthew Boyd (Project Supervisor)
- Prof Anthony Avery (Project Supervisor)

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. A member of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?
Patient Medication Record (PMR) systems are used in the UK for recording details of prescriptions dispensed; checking medications for potential hazards and errors; and producing labels for dispensed items. The aim of this study is to explore the views, opinions and experiences of community pharmacists and pharmacy support staff; PMR systems' software vendors; PMR systems' software knowledgebase creators; policy makers, patient safety and legal experts concerning PMR systems and their functionality focusing on safety features and alerts.

Why have I been invited?
You are being invited to take part because of your knowledge about and/or experience of using PMR systems. We are inviting approximately 30 participants to take part.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?
The study will explore the views, opinions and experiences of a range of stakeholders about PMR systems and their functionality focusing on safety features and alerts, in an interview lasting approximately 30-60 minutes. The meeting will take place at a time and date that is convenient for you. Questions will focus on how PMR systems affect work flow and processes; facilitators of and barriers to safety alert use, control of alerts, responses to alerts; suggestions for improvement and; current and future training needs. The interview will be audio-recorded and transcribed verbatim. The recordings and transcripts will be anonymised and kept in a safe location for 7 years after the last publication and then destroyed.

Expenses and payments
Participants will not be paid to participate in the study, and it is unlikely that any out of pocket expenses would be incurred by any participant.

What are the possible disadvantages and risks of taking part?
There are no risks or disadvantages involved if you decide to take part in this study.

What are the possible benefits of taking part?
The information gained from this study will potentially advance further development, refinement and research efforts surrounding the safety features and alerts in PMR systems. It may provide pharmacists and their support staff with a chance to reflect on their professional practice and help them to review how they use safety features and respond to alerts in PMR systems; to use safety features competently and with confidence. Ultimately, it may lead to better management of alerts, prevention of potentially hazardous interactions, reduction in medication errors and an improvement in patient safety.

What if there is a problem?
If you have a concern about any aspect of this study, you can initially approach the researchers using the contact details at the end of this information sheet. We will do our best to answer your questions. If this does not address your concern, then please contact Prof Clare Anderson, Head of the Division of Social Research in Medicines and Health, School of Pharmacy, University of Nottingham, University Park, Nottingham NG7 2RD. If this achieves no satisfactory outcome, you should then contact the Ethics Committee Secretary, Mrs Louise Sabir, Division of Therapeutics and Molecular Medicine, D Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH. E-mail louise.sabir@nottingham.ac.uk

Will my taking part in the study be kept confidential?
We will follow ethical and legal practice and all information about you will be handled in confidence. If you join the study, the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential** according to the Data Protection Act, 1998. All data will be stored in a secure and locked office, and on a password protected database. Any information about you which has your name and address will be anonymised and a unique code will be used so that you cannot be recognised from it.

All research data will be kept securely for 7 years after the last publication. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

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. This information may still be used in the project analysis.

What will happen to the results of the research study?

A summary of the results of the study will be sent to participants if requested. The results of the study will be written up and published in academic papers, conference abstracts and the PhD thesis of Oluwagbemileke Ojeleye. Participants will not be identified in any report/publication.

Who is organising and funding the research?

This research is being organised and funded by the University of Nottingham.

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 the University of Nottingham Medical School Research Ethics Committee.

Further information and contact details

If you require further information, please contact:

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School of Pharmacy
University of Nottingham
Tel.: 0115 82 32277
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Dr Matthew Boyd	matthew.boyd@nottingham.ac.uk	0115 95 15061
Prof Anthony Avery	anthony.avery@nottingham.ac.uk	0115 82 30207

Thank you for taking time to read this information sheet.

C.4 Consent form

(Draft Version 1.2 / Final version 1.0: 26 October 2011)

Title of Study: Evaluation of Community Pharmacy Patient Medication Record (PMR) Systems

REC ref: ***(to be added after approval given)***

Name of Researcher: Oluwagbemileke Ojeleye

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number _____ dated _____ for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my employment and legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I give permission for the future use of the information obtained from my participation in this study. ☐

5. I understand that the interview will be audio recorded and that anonymous quotes from the interview may be used in the study reports. ☐

6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

C.5 Interview guide

Introduction
This interview is being conducted as part of a study evaluating electronic Patient Medication Record (PMR) systems in England. We are exploring the knowledge, viewpoints and experiences of community pharmacy professionals (CPPs) including superintendent pharmacists (SPs), pharmacists (Ps), and dispensers (Ds), system vendors (SVs), drug database vendors (DDVs), health care policy makers (HCPMs) and legal experts (LEs), about the functionality of PMR systems, focusing on safety features and alerts.

We would really appreciate your help by spending 30 minutes talking to the interviewer and answering the following questions.

Opening question

- Could you please tell me a little bit about your involvement with pharmacy and PMR systems in your current role?

Thank you. I will now swiftly move on to some specific questions about PMR systems and alerts.

Questions regarding patient medication record systems

- [HCPMs and LEs] Could you please tell me what you understand by a PMR system?
- How familiar are you with the different PMR systems used in community pharmacies in England?
- How would you describe an ideal PMR system?
    - [SVs] Please describe your experience in delivering such a system
    - What safety features would you expect such a system to have?
    - Which of those features do you consider most important?
- [LEs] From a legal and a safety standpoint, how would you describe an ideal clinical computer system?
- [CPPs] Which PMR system is used in your pharmacy/pharmacies?
    - Which other PMR system(s) can you use?
    - How do they compare with the '*ideal*' PMR system you described above?
- [SPs] Why did [insert company name] choose a [name of ePMR system]?
- What are your perceptions of the safety features in PMR systems?
- [DDVs and SVs] What did you set out to achieve with [this] knowledgebase (KB)/PMR system?
- [DDVs and SVs] Could you please tell me how new developments/enhancements occur?
    - What does the KB/alert database/system update involve?
    - Please tell me a little bit about the development team
- [DDVs and SVs] How do you support your clients/users?
- Are there any other safety features, which you would like to suggest?
- [CPPs, DDVs and SVs] What safety features are present in [name] PMR systems?
- [SVs] What are the knowledgebase(s) employed in this PMR system?
- [LEs] PMR system vendors often have to customise the knowledgebase for their customers. What are the legal implications of this?
    - What about a situation where system users are able to turn some/all alerts on/off?
- [LEs] Pharmacists do not often have access to all the information they require in making informed decisions about a patient's treatment when dispensing medications, for example, date of birth or allergy information may be missing. What are the legal implications of this?
- [LEs] Can you recall a situation where the PMR system or its safety feature supported a trial?

Questions regarding safety alerts

- How would you describe an ideal medication alert?
    - What characteristics would you expect such an alert to have?
- [CPPs, DDVs and SVs] Could you please tell me about the alerts on your PMR system in general
- What is your opinion about the current alert display?
- What are your perceptions of the current state of the alerts in PMR systems?
- [PPs] How do you handle medication safety alerts?
- Could you tell me what you think about current alert displays
- [CPPs] How would you react if there is a conflict between the alert information presented onscreen and what you know is clinically correct?
- [CPPs] Could you give me an example of a situation when an alert:
    - Helped you?
    - Would have helped you?
    - Was a hindrance to your work?
- [CPPs] Are you aware of whether it is possible to configure alerts on your PMR system?
    - Do you do this?
    - Would you like to be able to?
- [CPPs, DDVs and SVs] Automaticity and alert fatigue are problems often associated with alerts. How do you think these can be reduced?
- [SVs] How do you ensure consistency of alert information and display?
    - What challenges have you encountered in the process?
- [SVs] What modifications are customers and end-users allowed to make to the alert database/alerts?
- [CPPs and SVs] Could you please describe how alerts are displayed?
- [SVs & DDVs] In your opinion what key differences would you say exist between alert databases?
- [SVs] How does this PMR system process the alert information?
- [SVs] How do you ensure consistency of alert information and display?
    - What challenges have you encountered in the process?
- [SVs] What practical challenges are you currently facing in order to improve the quality and effectiveness of safety features and alerts?
- [CPPs] Studies have shown that health care professionals regularly override safety alerts. Does this ever happen to you?
    - Why do you feel this way?

Questions regarding training

- [CPPs] Could you describe how you learnt to use the PMR system?
    - What about the alert system?
- [CPPs] How do you currently learn about new functions and medication alerts?
- [CPPs] How would you like to learn about new developments and alerts?
- [CPPs] In what ways do you ensure safety of medications in your role?
- [DDVs] How do users currently learn about this knowledgebase?
    - How do they learn about new alerts?
- [SPs] Perhaps you could help me a bit with how you support users?
- [SPs] How do users currently learn to use this PMR system?
    - How do you inform users about new functions and alerts?
- [SPs] What opportunities are available for raising incidents about PMR systems?
    - How are they dealt with?
- [SPs] How do you evaluate or ensure that that PMR system is meeting the needs of users?
- [DDVs] Research has shown that many safety alerts are cancelled during medication prescribing and dispensing. What are the legal implications of this?
- What is your opinion about mandatory training of pharmacy staff in medication safety and ePMR system use?

- [SPs] How do locum pharmacists learn to use the PMR system?
    - Do you have any criteria for checking that they are able to use the system, their safety features and alerts competently?
- [SPs] What opportunities are available for users to express concerns or raise issues about PMR systems?
    - How are these dealt with?
- [SPs] If a user signifies an individual need for training in using the system or any module in the software, how is this organised?
- [SPs] How do you evaluate or ensure that that PMR system is meeting the needs of your users, delivering on set targets rather than just providing information technology (IT)?

Questions regarding standards, regulation and oversight of patient medication record systems

- What are the regulations governing clinical systems in community pharmacies?
- What are the current standards for PMR systems and alerts?
    - What about alerts?
- Could you tell me a little bit about your perception of current regulations, standards and guidelines as touching PMR systems and alerts?
- Which regulations govern community pharmacy PMR systems?
- What are the current standards for PMR systems?
    - What about alerts?
- What are your thoughts about having a common safety alert module/database for all PMR systems?
    - Who should champion this initiative?
- [HCPMs] How does your organisation support pharmacies and pharmacists in meeting medication/patient safety goals?
    - Please describe your involvement in this area?
- [LEs] How important is it to regulate these clinical computer systems?
    - Why?
- In your opinion, how could regulations and standards help ensure that (important) alerts are not ignored?

Closing question

- All things considered, if you could tell me one thing that should be remembered during future developments and implementation of PMR systems, safety features and alerts, what would that be?

Thank & close.

C.6 Facilitators of ePMR systems' usefulness

Category	Characteristics	Illustrative quotes
Structural	• Fast and efficient checks • Recalls information quickly, legibly and in a way that is understandable by the user • Uses mouse function moderately • Intuitive, user-friendly, with uncluttered interface • Tailor-able to a user's level of expertise • Uses unified dose codes • Modular and Lightweight in nature • Interoperable • Complies with industry standards • References and provides evidence-based information • Uses colours, icons and text moderately and appropriately • Integrates well with other clinical systems • Equipped with tools to enable the system to learn • Regularly updated	• '…preferably, one where I don't have to use the mouse, one where I can just use the functions on the keyboard' [Pharmacist (interview 1)] • *'I suppose it's how intuitive it is isn't it. If it's intuitive, you're more likely to get the most out of it, and for me that's what a good PMR system would be'* [Superintendent pharmacist (interview 8)] • *'…an ideal PMR system would be where pharmacy is fully integrated into the rest of the primary care IT structure, which predominantly would be the sharing of care records…a system that therefore knows the full entire record of the patient…'* [System vendor (interview 27)]
Functional	• Has built-in safety features • Generates automatic and on-demand reports • Contextualises alerts • Minimises the risk of selecting wrong products (Intelligent and short pick lists) • Good stock management • Records and manages clinical practice (encounter and intervention) • Captures the right record and amount of information	• *'Well something which would have built-in safety features. That we could minimise the risk of selecting the incorrect product. It would be supporting, full of knowledge base for the end user. So would have lots of subtle…breaks in the system, which would identify possible errors. So it would be aware of common errors and would already be anticipating that pharmacists could make an error and then should be…and if somebody was to select that kind of product or use the system that way, I think I would expect it to highlight that and say, 'Do you really want to do this?'* [Health care policy maker (interview 18)]

C.7 Inhibitors of ePMR systems' usefulness and development

Specific characteristics explored	Key findings	Illustrative quotes
• Community pharmacy practice	• Pharmacy is not regarded as a key member of primary care • Focus of NHS IT development has been on general practice computer systems	• *'…pharmacy is still not regarded in my personal view as a you know, key member of primary care and therefore they are not included and are directly excluded from some of the IT initiatives that government and the Department of Health get involved in.'* [System vendor (interview 27)] • *'…The focus of IT development within health care is predominantly for GP systems'* [System vendor (interview 27)]
• ePMR system architecture	• It is difficult to achieve the level of sophistication demanded by decision support systems on legacy computing platforms • Adoption of newer computing architecture and standards for clinical terms such as SNOMED presents issues with historical records	• *'…what it is as well is the system displays the first forty or fifty, maybe sixty, characters of the interaction message and if you double-click on it you can see the full message.'* [System vendor (interview 28)] • *'…it leaves people with added…other competing costs not only for redevelopment but also for redeployment. Any change in terminology is quite a major headache for any system provider'* [Drug database vendor (interview 25)]
• Stakeholder contributions to system development	• System vendors not proactive enough in taking the development of ePMR systems forward • ePMR systems have two main purposes in community pharmacy but only one is regarded as relevant to health care by the NHS	• *'What we're not getting from the PMR guys or the demands from the customer base is so what next? So whatever the next problem area is, we're waiting for the NPSA to tell us rather than thinking actually how could we build in enhancements to improve patient safety that we pharmacists decide we want to build in whatever they would be.'* [Health care policy maker(interview 15)] • *'…they serve two purposes. They are a business tool and they are a dispensing prescription tool, if you like, and the NHS would only pay for the second one'* [Legal expert (interview 21)]
• Resource availability	• Limited budget for ePMR system development	• *'…it reflects the business model you see because although GPs are technically contractors, many of their costs are actually met by the NHS, including their computer systems. So, if the NHS is paying for their computer systems, which it is, either all or in part, I'm not quite sure, but they certainly do make a contribution, then they will have a say in what that system should do…It has to come out of their profits, so it becomes very much more of a commercial decision'* [Legal Expert (interview 21)]

Specific characteristics explored	Key findings	Illustrative quotes
• Operational efficiency	• Electronic Prescription Service (EPS) is sometimes slow, re-input of prescription information and alert bypass is common. Doses on electronic prescriptions sometimes do not translate properly in the system	• *'…ETP2 is slowing us down. So if there's anything that's a concern for the future, it's the speed of ETP and…here's a good point actually is the non-conversion or non-understanding of the doctor's instructions on ETP2 and the simple fact that that then doesn't translate into the dose coding that the PMR understands….So you're basically, even with ETP2, having to start again and re-input it fresh for the PMR to understand it as opposed to it just reading nicely'* [Superintendent pharmacist (interview 6)]
• Data capture and data quality	• Lack of tools for meaningful recording of clinical encounters with patients	• *'…we don't necessarily have elegant tools in the PMRs to allow us to say, "I made this intervention. We did this, the patient said that," and for it to be there and highly visible to the pharmacists or the dispenser next time around if it's a different person'* [Health care policy maker (interview 15)]
• Audit trail in ePMR systems	• Audit trail is sub-optimal	• '…the prescription won't always be available…the audit trail issue…is an important one in pharmacy' [Legal expert (interview 19)]
• Safety climate	• Non-adoption of calendar pack dispensing is hindering the adoption of barcode scanning (safety feature), even though barcode scanners are now available in community pharmacies • Persistence of blame culture • Vendors use terms and conditions to absolve themselves of liabilities in case of ePMR software malfunction and inadequacy • Misconception that repeat prescriptions are safe	• *'…you reduce waste by giving people 14s instead of 28s, but there must be a system and a process… I'm talking about a broader system which would link bar coding and checking that was the right medication against the prescription…that would be a massive, massive safety feature I think.'* [Legal expert (interview 20)] • *'…the same organisation will sack somebody when they want to get rid of somebody because they decide that they haven't followed the SOP'* [Legal expert (interview 20)] • *'…I imagine that every IT supplier will build into their contracts, an indemnity against that. In other words, they'll say don't blame us…it's up to you to check everything'* [Legal expert (interview 21)] • '… there's a myth that, you know, repeat medication is safe, so you may as well just put that into a process which churns them…out…*that is all the holes in the cheese fitting together really, you know, where it starts to go wrong'* [Legal expert (interview 20)]
• Safety culture	• Users may not follow the SOP	• *'I'd like to see any SOP in any organisation that says take a batch of prescriptions from your doctors, label them all, leave them to one side and let somebody else dispense them when they come in. But everybody does it'* [Legal Expert (interview 20)]

Specific characteristics explored	Key findings	Illustrative quotes
• Feedback	• Lack of feedback to vendors about what the profession expects from an ideal ePMR system	• *'We've never actually told them the system suppliers what we really want. They've had feedback from individual customers, but often the feedback is probably… Well, the feedback is that they don't like the system, they go somewhere else. Their only feedback is good-bye, we're severing the contract, which is not constructive feedback for them*' [Health care policy maker (interview 15)]

C.8 Desirable features and improvements in electronic patient medication record systems

Category	Suggested feature or improvement	Illustrative quotes
Safety features and alerts	• Alert about large dose increases • Dose checking • Flagging of corresponding indication for a dose entered into the ePMR system. Highlight if there is no corresponding indication. • Alert for loading doses • Flagging of unlicensed doses • Paediatric dose alert • Presenting only the relevant information in alerts with the important information at the top and direct access to evidence-based resources for more information • Appropriate use of colours in alerts • Alert about similar records on the system • Alert about drug-disease interactions and high risk drugs • Barcode checking • Audible warning when dispensing medications that could cause serious harm to patients	• *'I think there is a lot of scope for flagging up large jumps in dosage…for example, a patient who is supplied with medication that hasn't previously been prescribed but would have serious…serious consequences if the patient hasn't previously been treated…'* [Legal expert (interview 19)] • *'…I'd like to see more active dose checking…'* [Health care policy maker (interview 15)] • *'Acyclovir has got a multitude of different indications and doses corresponding to it. If it was to give you that onscreen, that would be quite useful…'* [Superintendent pharmacist (interview 6)] • *'Well, you would want to be alerted that, that dose is a loading dose and you would want to take action on that'* [Health care policy maker (interview 17)] • *'…If when you label a drug, the dose doesn't correspond to any known BNF categories, that would be a nice thing to flash up…'* [Superintendent Pharmacist, S2I, M] • 'It would be nice if I put in a child, that the alert system is for children…that comes up…' [Pharmacist (interview 1)] • *'…in the real world, find a way of presenting the relevant information with the importance stuff at the top, the ability to drill down if you're looking into something…'* [Superintendent pharmacist(interview 10)] • *'…something that the colour coordination is chosen well…'* [Pharmacist (interview 3)] • *'…some sort of tick I don't know…to say oh hang on a minute, you know, that you've got someone and that address with that date of birth, you know something that can bring it up and say…are you sure it's not this person? I think it would save time, it would save errors…'* [Dispenser (interview 12)] • '*…maybe more absolutes, you know, this you know if you switch this off at your peril, do it. You know, so the, for example, opioids is one, anything in relation to the "Never Events…the Department of Health Never Events" there, that's another set. Things that require specific monitoring and by that I also include, such as the anti-epileptic drugs, Amiodarone, obviously Warfarin, anticoagulant, those things* [Health care policy maker' (interview 17)] • *'…the biggest number of errors that I perceive happen in pharmacy are people picking the wrong drugs and the bar code scanner stops you doing it'* [Superintendent Pharmacist (interview 5)] • *'…if you are dispensing a controlled drug or you've got a major interaction coming up, if there was some kind of alarm system that will, not disturb if you want but will be quite distinct for you to take note of that particular interaction'* [Pharmacist (interview 2)]
System development	• Improved user engagement • Standardised dosage syntax	• *'What they need is a user group of people who work on the frontline, who use the systems and who could sit around a table once a month or once a quarter and say, "…this is really annoying. If you can do that that would really make my life simpler," and they don't do that and that annoys me a lot…'* [Superintendent pharmacist(interview 7)]

Category	Suggested feature or improvement	Illustrative quotes
	• Correct identification of patients with important details displayed throughout the dispensing process • Improved management of clinical notes and data structure • Differentiation of repeat prescriptions in prescription queue • Display of medication record onscreen when dispensing	• *'…without a standardised dosage instruction, we are a little bit stuffed, because in terms of period of treatment, okay, I've got a prescription here for 56, but without knowing if that's one a day, twice a day, once every week, I can't tell you how that patient's going to do…'* [Superintendent pharmacist (interview 10)] • *'…I want a PMR that when I am typing the surname, Smith John, I can see all the John Smith so that I don't pick up the wrong person. So a PMR system that allows me to identify a person correctly but one preferably on my filter screen, where I can actually see the date of birth as well…'* [Pharmacist (interview 1)] • *'I'd like better management of notes and records, and I'd like them to use Read, SNOMED coding, so that we've got structured data that could be interrogated…'* [Health care policy maker (interview 15)] • *'…I would want to know whether…that for this prescription, the patient has had it before, nothing has changed, this needs a quick check…'* [Superintendent pharmacist (interview 10)] • *'…a complete medication record appearing on your screen so that you can sort of make a judgement…'* [Pharmacist (interview 2)]
Data security and user access	• Improved security of ePMR systems and data • Unique and universal login for pharmacists	• *'I would imagine if someone wanted to get into our system they would be able to, to some level, which concerns me because obviously there's a flow of information into and out of our PMR systems and how well guarded that is I have no idea and I don't know whether the…if it's incumbent upon the PMR companies to provide super-protection, but to my…I mean we've got Norton Anti-Virus on our systems [laughs]. I mean that's rubbish. I wouldn't put on my home computer and they're relying on that to keep out malware and that it just seems a little bit lax to me'* [Superintendent pharmacist (interview 6)] • *'I don't know if it would be better for pharmacists to have unique login so it doesn't matter where I go in the country, I am number 79 throughout the whole of the UK'* [Pharmacist (interview 1)]
Adherence monitoring	• Printing of compliance charts or short medication administration record charts for patients	• *'I'd love for us to be able to easily within a PMR system print out a compliance chart or easily produce MAR charts so normal patients…People who just get a bit confused and would benefit maybe at the end of an MUR, but maybe just when you're having a chat with them, at the press of a button and being able to produce a list of their medicines and when to take them in a succinct but good summary that they can stick on their fridge and act as a reminder.'* [Health care policy maker (interview 15)]
Integrated systems	• Feature for getting product recall information into ePMR systems in real-time. • Linking ePMR systems with the Medicines and Healthcare Products Regulatory Agency (MHRA) alert system • Central repository for alerts, alert databases and medicine optimisation information	• *'…if we had a product recall, how we could get that quickly into systems so that every time you went to dispense a product that may have been subject to the recall…'* [Health care policy maker (interview 14)] • *'…the packs, they looked identical apart from the writing. So there was a lot of mistakes being made when I believe the stock was being put away. So they were getting mixed up and it would have been very useful…so that an alert comes up to say, 'Make sure you're giving the right drug here. There's been an alert from MHRA'…so if our system was linked into the MHRA warning system, that would have been very helpful indeed'* [Superintendent pharmacist (interview 7)]

Category	Suggested feature or improvement	Illustrative quotes
		• *'What they could do is have almost like a, a bulletin board that the manufacturers, MHRA, PPD, anybody that wants to inform say we would like to inform everyone of this, then we would choose anything relevant to display on our system'* [Vendor (interview 30)]
Electronic feedback	• Electronic feedback to the general practice surgery about high risk alerts seen in the pharmacy	• *'…I don't know how if it's possible, but if something was sort of a major interaction, there should be a trigger from your pharmacy to the doctor's as well so that both come to judgement…I mean something that is significant 'cause every now and again, you have to ring them'* [Pharmacist (interview 2)]
Recording and reporting errors and adverse drug reactions	• Recording of patient specific errors and adverse drug reactions (ADRs) in patients' medication record, alerting about implicated products during subsequent dispensing and facility for submitting ADR reports electronically	• *'I think it would be really useful if you've got the recording of errors, actually, on that patient record. It may be completely relevant to that patient, but with a little button, you can just send it off, email it off or if you've used the yellow card reporting system, you click a button to send it off… It's actually there on a permanent basis, so that if there is a…like a prescription, maybe not exactly for that but for the same family, you might actually then have it flagged up, and you may want to discuss it with the prescriber'* [Health care policy maker (interview 16)]

C.9 Inhibitors of alert usefulness

Specific characteristics explored	Key findings	Illustrative quotes
• **Alert design and implementation**	• Challenges with workflow often result in software vendors displaying all alerts to users • Difficulty in establishing what the right information is from a community pharmacy perspective • Inability to read all alert information at once • Lack of cut-off date for medications that should feature in alerts • Alerts may be obscure and alert messages may not be prominent enough • Multiple alert screens and scroll bars in alert window encourage users to click through alerts • Difficulty in determining the net effect of interaction between multiple ingredient products • Difficulty in balancing professional knowledge and experience within alerts to ensure that the user is not over-alerted • Duplication of alerts and alert information	• *'Work flow is one the biggest issues so it's about getting right information to the right person at the right time. Understanding who is the right person, is difficult because we don't actually know the person in that role. We don't know their level of ability, their level of knowledge, their level of familiarity with the patient, the level of familiarity with the drug that they're prescribing or dispensing. Taking all of those unknowns means that you have to err on the side of caution and do you then say well that's down to the user to filter out what they know and don't know…'* [Drug Database Vendor, KB4, M] • *'…it's about how you promote the right information to the right people. What is the right information from a community pharmacy perspective?'* [Drug Database Vendor, KB4, M] • *'…with [System S5], you can't even read it, you have to click it and all that kind of thing…'* [Pharmacist, P1, F] • *'There is no date cut-off, so if it's something they've had six years ago, if it's still in the PMR, it will have that interaction.'* [Health care Policy Maker, PM3, F] • *'I don't think it's clear enough. I don't think it stands out well enough for you to… want to stop and then call the pharmacist 'cause it's quite easily…you could easily miss it. It's just on the side…'* [Dispenser, D1, M] • *'…they don't put all the information on the same screen. So they've got scroll-down bars which aren't helpful because you don't generally scroll-down.'* [Health care Policy Maker, PM5, M] • *'…for example a new product comes out that has got, you know, four or five ingredients in. Maybe let's say four ingredients in. We aren't able to determine what the net effect of that interaction is with another multiple ingredient products. So the tendency is now just to have ingredient level interactions rather than product level interactions. So that you'll get as many interactions as there are between each ingredient.'* [System Vendor, V3, M] • *'…you need to balance the professional knowledge and experience within alerting as some that might actually be really dangerous so that you don't dilute the really dangerous down.'* [Drug Database Vendor, KB2, F] • *'…in a lot of cases you've got double the amount of information, which is repeated. It's just duplicated. And when you're trying to look through all of them, that isn't particularly useful, but I don't know because of the way it's set up whether there is any way of actually reducing the bumf that comes out.'* [Health care Policy Maker, PM3, F]

Specific characteristics explored	Key findings	Illustrative quotes
• **Alert management**	• Other users of ePMR systems may not inform pharmacists about alerts • Wrong users may pick up decision making information within the workflow • Process of authorising alerts when the person using the system is not the pharmacist is unwieldy • Insignificant alerts encourage alert bypass • Alerts may be printed on prescription labels and placed in patients' prescription bags with no indication that they have been reviewed by a pharmacist • If the pharmacist is not the one using the ePMR system, without repeating the dispensing scenario, it is impossible to see alerts in context once overridden	• *'…if it isn't the pharmacist that's seeing the notification, there needs to be some way of that being communicated to the person doing the pharmaceutical check.'* [Superintendent Pharmacist, S6I, M] • *'The problem comes then, is these notes may only been seen by the person who's operating the PMR, and in which case that may well be a technician. So sometimes it might just be the wrong people getting to the right information to be able to make decisions.'* [Legal expert, LE2, M] • *'… it is annoying when you have to be called to confirm them…'* [Pharmacist, P1, F] • *'…many interactions even with food or with other things are theoretically possible but not necessarily clinically significant, even if they happen.'* [Legal Expert, LE3, F] • *'…my wife…brings home my prescription and there's a length of alerts the length of my arm…what happens is that the really serious alerts get lost in this morass of potential possibilities and really I think what we ought to have…that's for the you know, key people to work out, is what are the real, real problem alerts'* [Legal Expert, LE2, M] • 'if you are the pharmacist and you are in a busy pharmacy and you are mainly just checking, checking, checking, there's no way…unless you go back to the system every single time to check if there's an interaction with the medicines you are dispensing…' [Pharmacist, P2, F]
• **Alert display**	• Constant pop-up alerts are not helpful • Mixing non-clinical alerts with clinical alerts add to the alert load and prevents effective management of alerts	• *'…pop-up alerts, they're great but how many pop-up alerts will it take before you stop reading them? You get pop-up alerts in software for everything.'* [System Vendor, V3, M] • *'The thing is that those…alerts aren't the only alerts that appear on PMR systems because there's alerts that the orders are going to be sent and there's lots of other alerts that happen on PMR systems to do with the day-to-day running of the pharmacy as opposed to just clinical risks.'* [Vendor, V1, F]
• **Alert timing**	• Deferring all alerts until the end of the dispensing process could result in serious alerts being missed • Some alerts are only relevant to specific stages of the medication use process	• *'…it doesn't prompt you or anything. It just comes up as is part of the routine.'* [Dispenser, D1, M] • *'So one and two stars may not be that appropriate at the prescribe time but in administration time they're actually very relevant…'* [Drug Database Vendor, KB4, M]

Specific characteristics explored	Key findings	Illustrative quotes
• **Alert context**	• Electronic PMR systems not linked with other clinical systems for other patient data to enable contextual alerts • Pharmacists often do not have access to records of medications dispensed from other pharmacies and clinical settings for effective patient management • It is difficult to link prescribed drugs to actual patient conditions • Lack of user scenario and patient context often lead to subjective classification of alerts	• *'…there should be a basic level of information transmission on top of the prescription that's coming through…now. That would make a massive difference and it would also save a lot of silly phone calls to surgeries and also allow the pharmacist to make a much more informed clinical decision.'* [Superintendent Pharmacist, S2I, M] • *'…patients are getting medication prescribed that we don't know about and then we're expected to manage those patients effectively.'* [Superintendent Pharmacist, S1I, M] • *'…ways of linking the prescribing of a drug to the actual condition given…more difficult in pharmacy systems…the pharmacist has to put the patient's condition in to make sure but you can't always tell because we're not the prescribing system we're the dispensing system when taking orders from the prescriber but we can pick up if the patient is a smoke, pregnant, diabetic.'* [Vendor, V5, M] • *'…you think well actually maybe I'd better put it in three because it's going to be seen and it's always subjective, it has to be subjective. There is no…the reason it has to be subjective is because they haven't got the user scenario in mind, they haven't got full patient context.'* [Drug Database Vendor, KB3, F]
• **Alert presentation**	• Recognition of an alert or signal words in a list of multiple alerts could stop the user from reading the rest of the alert information	• *'…but then if represented with a…a list of alerts and they know the first couple that's it then the whole list is in their eyes negated, even though there might be one fundamental important piece of information further down that actually they didn't know, that…'* [Drug Database Vendor, KB4, M]
• **Alert granularity**	• Lack of agreement about alert severity levels and difficulty in determining the same	• *'Well the problem I guess is again how do you differentiate between the more serious alerts and the less serious alerts? It's a difficult one.' [Legal Expert, LE2, M]*
• **Alert databases**	• ePMR system vendors are reluctant to change data structure • Improved databases are not being deployed into ePMR systems promptly • Using outdated alert databases in ePMR systems encourages over-alerting	• *'…once you've set it up in a structure…that you are delivering to the individual companies, they're really reluctant to have you change that because it means that they have to change their programming and their systems… we're kind of restricted at the moment until we can get the system suppliers to agree the change to the data structure.'* [Drug Database Vendor, KB2, F] • *'…we're running one step ahead of the vendors, we're running one step ahead of what they've actually deployed to market in terms of development…'* [Drug Database Vendor, KB4, M] • *'…if we've got a later version available then they may well get benefits for the users by using the most up-to-date version.'* [Drug Database Vendor, KB3, F]

Specific characteristics explored	Key findings	Illustrative quotes
• **Clinical knowledge versus practice**	• What a user experiences in practice might be different from the knowledge the user holds	• *'But I think there are some things where because of the…the number of the alerts that come to us it has softened our approach to those things that really should be black and white. Everybody gets to, you know, don't take aspirin with the coumarin. Don't do it. Then you get into practice and you find out…it's fine.'* [Superintendent Pharmacist, S6I, M]
• **Workload**	• It is difficult to manage alerts effectively without slowing other operational processes down • Increasing workload in pharmacies is preventing pharmacists from managing alerts effectively	• *'…there's a constant battle between, especially within community pharmacy, between safety, clinical safety, and operational efficiency.'* [Requirements Analyst, V1, F] • *'…the amount of services that are expected of our pharmacists are increasing massively…But add into that the economic climate and every business is having to look at its spend, and although I'm comfortable that the branches are operating safely, there is no more that we could strip away. So they're trying to find ways to do things as quickly as possible and that's why we find people doing things potentially not as they should be because they are trying to find time.'* [Superintendent Pharmacist, S5LM, F]
• **Content development**	• The clinical information that is used for creating drug databases is usually implicit in nature	• *'…a lot of the information we were working with, is actually implicit, it's not explicit…some of the dosage information is a bit fuzzy, and it's fuzzy on purpose because it's giving the human clinician the option of molding the information to their individual clinical context…* *Move now to the digital domain, to the computer system where everything is just black or white, it's either right or it's wrong, it's yes or it's no…taking out that fuzziness and the ambiguity has been quite a challenge'* [Drug Database Vendor, KB1, M]
• **User control**	• Users want some degree of alert control but user differences and expertise presents ePMR system vendors with implementation challenges	• *'I think they face a challenge in that, every pharmacist is different…I've had the time and experience to tailor it to what I need. My colleague that works alongside me might have a completely different set…'* [Superintendent Pharmacist, S6I, M]

Appendix D. Supporting documents for the observational study

D.1 Letter of invitation

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

School of Pharmacy
Division of Social Research in Medicines and Health
University Park
Nottingham
NG7 2RD
Tel +44(0)115 823 2277

Dear ***(insert person's name):***

This letter is an invitation to participate in a research study investigating community pharmacy Patient Medication Record (PMR) systems' functionality in relation to highlighting clinically important medication and patient safety concerns during the dispensing process.

Patient Medication Record (PMR) systems are used in the UK for recording details of prescriptions dispensed; checking medications for potential hazards and errors; and producing labels for dispensed items. The aim of this study is to investigate alert-response practices in community pharmacies. It is an opportunity to understand how you and other members of the pharmacy team utilise PMR systems and their inherent safety features.

Observation will provide insight on what matters to you when using a PMR system. If you agree to participate, I will follow up with you to arrange the observation at a time that is convenient to your schedule. With your permission, you will be observed while using a PMR system in the course of your daily work routines. About three to four observations are required, each lasting about 30 minutes over 3 days. These 3 days can be spread over a 2-week period or as a single block. You will also be asked questions about how you would deal with a specific situation presented in the course of your daily routine.

Participation is entirely voluntary. All information you provide will be confidential. Your name and the name of your organisation will not appear in any report or publications resulting from this study. As with all University of Nottingham projects involving human participants, this study has been reviewed and given favourable ethical opinion by the University of Nottingham Medical School Research Ethics Committee.

If you are interested in participating, have any questions, comments or concerns regarding this study, or would like additional information about participation, please contact me using the details at the end of this letter. You can also contact either of my supervisors, Dr Matthew Boyd (matthew.boyd@nottingham.ac.uk) or Prof Anthony Avery (anthony.avery@nottingham.ac.uk). A copy of the information sheet is included with this letter.

Thank you for your interest and assistance with this research.

Yours sincerely,

Oluwagbemileke Ojeleye
Research Student
paxoo1@nottingham.ac.uk

D.2 Participant information sheet

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Participant Information Sheet

(Draft Version 1.3 / Final version 1.0: 10 January 2012)

Title of Study: Evaluation of Community Pharmacy Patient Medication Record Systems

Name of Researcher(s):

- Oluwagbemileke Ojeleye (Researcher)
- Dr Matthew Boyd (Project Supervisor)
- Prof Anthony Avery (Project Supervisor)

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. A member of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?
Patient Medication Record (PMR) systems are used in the UK for recording details of prescriptions dispensed; checking medications for potential hazards and errors; and producing labels for dispensed items. The aim of this study is to observe and explore how pharmacists and pharmacy staff use PMR systems and deal with alerts during the dispensing process; ergonomic factors that may facilitate or impede the usability of PMR systems' safety features and alerts such as alert display and placement onscreen and the frequency with which alerts flag up will be examined.

Why have I been invited?
You are being asked to take part because of your knowledge and experience of using PMR systems. We are inviting between 8-12 community pharmacies to take part.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?
The study will involve observing community pharmacists and pharmacy support staff to explore how they use PMR systems and their safety features; and how they respond to alerts. The observation will take place in the pharmacy at a time and date that is convenient for you. Three to four 30 minute sessions will be conducted over 3 days. The 3 days can be spread over a 2-week period or as a single block.
In addition to these observations, you will be asked to process some simulated prescriptions to understand how your system responds in hypothetical examples and what you would do in these situations. You do not need to answer any questions you are not comfortable with. Likewise if you feel unable to make a comment in front of your colleagues you can do so after the session by contacting us using the details provided at the end of this information sheet.

Expenses and payments
Participants will not be paid to participate in the study, and it is unlikely that any out of pocket expenses would be incurred by any participant.

What are the possible disadvantages and risks of taking part?
There are no risks or disadvantages involved if you decide to take part in this study.

What are the possible benefits of taking part?
The information gained from this study will potentially advance further development, refinement and research efforts surrounding the safety features and alerts in PMR systems. It may provide you with a chance to reflect on your professional practice and help you to review how you use safety features and respond to alerts in PMR systems; to use safety features competently and with confidence. Ultimately, it may lead to better management of alerts, prevention of potentially hazardous interactions, reduction in medication errors and an improvement in patient safety.

What if there is a problem?
If you have a concern about any aspect of this study, you can initially approach the researchers using the contact details at the end of this information sheet. We will do our best to answer your questions. If this does not address your concern, then please contact Prof Clare Anderson, Head of the Division of Social Research in Medicines and Health, School of Pharmacy, University of Nottingham, University Park, Nottingham NG7 2RD. If this achieves no satisfactory outcome, you should then contact the Ethics Committee Secretary, Mrs Louise Sabir, Division of Therapeutics and Molecular Medicine, D Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH. E-mail louise.sabir@nottingham.ac.uk

Will my taking part in the study be kept confidential?
We will follow ethical and legal practice and all information about you will be handled in confidence. If you join the study, the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential** according to the Data Protection Act, 1998. All data will be stored in a secure and locked office, and on a password protected database. Any information about you which has your name and address will be anonymised and a unique code will be used so that you cannot be recognised from it.

All research data will be kept securely for 7 years after the last publication. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

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. This information may still be used in the project analysis.

What will happen to the results of the research study?
A summary of the results of the study will be sent to participants if requested. The results of the study will be written up and published in academic papers, conference abstracts and the PhD thesis of Oluwagbemileke Ojeleye. Participants will not be identified in any report/publication.

Who is organising and funding the research?
This research is being organised and funded by the University of Nottingham.

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 the University of Nottingham Medical School Research Ethics Committee.

Further information and contact details
If you require further information, please contact:

Oluwagbemileke Ojeleye (Leke)
School of Pharmacy
University of Nottingham
Tel.: 0115 82 32277
paxoo1@nottingham.ac.uk

Dr Matthew Boyd	matthew.boyd@nottingham.ac.uk	0115 95 15061
Prof Anthony Avery	anthony.avery@nottingham.ac.uk	0115 82 30207

Thank you for taking time to read this information sheet.

D.3 Consent form

(Draft Version 1.2 / Final version 1.0: 26 October 2011)

Title of Study: Evaluation of Community Pharmacy Patient Medication Record (PMR) Systems

REC ref: ***(to be added after approval given)***

Name of Researcher: Oluwagbemileke Ojeleye

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number ___ dated _____ for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my employment and legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I give permission for the future use of the information obtained from my participation in this study. ☐

5. I give my consent for the researcher to carry out research observations as described in the information sheet. ☐

6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

D.4 Observation schedule and guidance notes

General

- Record as fully as possible, all talk and actions by pharmacists and dispensing staff in relation to PMR systems' safety features (SFs) and alerts below.
- Number pages at the top
- Please record any key time points within the session.
- Leave a lot of space so that annotations and corrections are easy to make
- Keep a key to any abbreviations used at the bottom of the page

Patient Medication Record system and alerts

Note down any problems encountered while using the system: safety features and/or alerts (user unable to carry out an action, software problem, computer crash).

- How do pharmacists and staff handle alerts?
    - Is there a SOP for handling alerts? [Do staff members follow it? If not, at which point(s) do they deviate from it and why?]
    - Are alerts presented in a way that facilitates adherence (if possible, include anonymised screen dumps)
    - Do they comment at all about the SFs/alerts? (e.g. user expresses opinion about learning something new while handling alerts)
- Please note the appearance of alerts (colour, font size onscreen relative to the size of the monitor).
- When dispensing a prescription, can you see all the patient details from start to finish e.g. Name, Add, DOB, M/F, NHS or PMR Number?

Communication

Please note verbal and non-verbal communication between the pharmacist and the other members of the team (including who those members are). If the communication is about the job being done ('*task oriented*'), document as precisely as possible what is said (or done if it is non-verbal). Also, note non-task communication, such as talking to the patient, general conversation with colleagues and non-verbal communication.

Things to consider include:

- Any discussion regarding the handling of safety alerts (for example, on receipt of a prescription, before any medication is dispensed or at the beginning of the shift. Try to document precisely how it is discussed.
- Try to record, word for word, the criticisms and praises of staff of the systems as accurately as possible.
- Do dispensing staff call the pharmacist's attention to alerts?
- Do team members acknowledge the pharmacist's instructions?
- Does the person receiving instructions/ information seek clarification?

Environment

- Briefly describe the dispensary (lighting, space, et cetera)
- Document any activity that might affect the dispensing operation (deliver driver waiting, et cetera)
- Are there any logistical problems with alert handling (for example, staff queuing to use the system)

Reflections

Refer to the observation notes for supporting evidence for these reflections. Try to differentiate these from the factual observations. An example could be the team dynamics and the communication between the staff that might have had an impact on the handling alerts.

- Did the team work well together; was communication effective within the team?
- What contributed to the success of the alert handling – e.g. clinical knowledge of the user?
- What made it unsuccessful — shortage of staff, user's perception, and/or dynamics within the team?

D.5 Report and data collection form

Setting

Pharmacy / PMR study number	/
Name of observer	
Date	
Pharmacy type (independent, small multiple or large multiple)	
Average number of prescription items dispensed per day	
Total number of prescription items (average per month)	
PMR software and/or database version	

Team members (Role)	**Number**	**Grade/Education**
Pharmacists		
Accredited Checking Technician		
Pharmacy Technician		
Dispensers		
Dispensary Assistant		
Other (please state)		
References sources used in this pharmacy		

Follow-up questions

Evaluation of current PMR system's capabilities

- Some categories/levels of interactions are suppressed or turned off [Yes/No]
- Alerts which have little or no clinical significance routinely appear on the screen [Yes/No]
- Alerts can be cancelled easily [Yes/No]
- The system allows the user to build alerts for serious error-prone situations (e.g., look-alike names, special precautions) [Yes/No]
- The system uses tall-man letters to differentiate between look-alike drug name pairs (hydrOXYzine, hydrALAzine) [Yes/No]
- The system allows the user to change font and colour to highlight look-alike drug name pairs to prevent confusion [Yes/No]
- The system is capable of providing reports of drug alert overrides by users [Yes/No]
- Have you encountered a situation where there was a conflict between the alert information presented onscreen and known clinical information [Yes/No]
- What did you do?

Training

- Find out about the training process for new members of staff

Pharmacy study no. & Date:
Session No.:
Observations

Reflections

D.6 Schedule of pharmacy observations and interviews

		Pharmacy visit 1		Pharmacy visit 2		Pharmacy visit 3		Number of 30-minute observation(s) per visit	Time spent in the pharmacy (hours)
Pharmacy code	**ePMR system code**	**Date**	**Time**	**Date**	**Time**	**Date**	**Time**		
P1	S1	03.09.12	15:00-17:00	17.09.12	15:30-16:30	22.09.12	15:30-17:30	1	5.00
P2	S2	20.09.12	14.45-17.45	27.09.12	14:45-16:00	17.10.12	15:15-16:45	1	5.75
P3	S3	25.09.12	14:30-17:00	09.10.12	14:30-16:00	23.10.12	15:30-16:30	1	5.00
P4	S2	08.10.12	10:00-12:30	10.10.12	10:30-12:00	12.10.12	10:30-12:30	1	6.00
P5	S4	18.10.12	14:30-17:00	25.10.12	15:00-16:45	07.11.12	16:00-17:30	1	5.75
P6	S2	22.10.12	15:30-17:00	01.11.12	15:30-17:30	07.11.12	10:00-12:00	1	5.50
P7	S5	24.10.12	16:20-18:50	31.10.12	18:30-20:30	23.11.12	13:00-15:00	1	5.50
P8	S2	12.11.12	14:00-16:30	22.11.12	10:30-12:30	27.11.12	16:30-18:00	1	6.00
Total									**44.50**

Note: The time spent in each pharmacy included the time for the simulated assessment of ePMR systems, a short interview with the responsible pharmacist and follow-up interviews with users of ePMR systems where required

D.7 Confidentiality agreement between researcher and pharmacy

Confidentiality agreement between researcher and Pharmacy

Pharmacies may wish to use a confidentiality agreement in addition to the clauses relating to confidentiality in any letter or honorary research contract issued by a Primary Care Organisation (PCT/LHB/Health Board).

Name of Researcher:
Name of Pharmacy:
Project Title:

I, the undersigned, acknowledge, understand and agree to adhere to the following conditions of access.

Insert details of dataset fields and other information to be accessed in course of research

- I will maintain the privacy and confidentiality of all accessible project data and understand that unauthorised disclosure of personal/confidential data is an invasion of privacy and may result in disciplinary, civil and/or criminal actions against me.
- I will not disclose data or information to anyone other than those to whom I am authorised to do so.
- I will access data only for the purposes for which I am authorised explicitly. On no occasion will I use project data, including personal or confidential information, for my personal interest or advantage, or for any other business purposes.
- I will comply at all times with the practice's data security policies and confidentiality code of conduct.
- I am informed that the references to personal, confidential and sensitive information in these documents are for my information, and are not intended to replace my obligations under the Data Protection Act 1998.
- I understand that where I have been given access to confidential information I am under a duty of confidence and would be liable under common law for any inappropriate breach of confidence in terms of disclosure to third parties and also for invasion of privacy if I were to access more information than that for which I have been given approval or for which consent is in place.
- Should my employment be terminated or my work in relation to the project discontinues for any reason, I understand that I will continue to be bound by this signed Confidentiality Agreement.

Researcher Signature:
Date:

Pharmacy Manager's Name:
Pharmacy Manager's Signature:
Date:

D.8 Poster displayed in the pharmacy during observational sessions

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Evaluation of Community Pharmacy Patient Medication Record Systems

A research study organised by the University of Nottingham is currently being undertaken in this pharmacy to explore how electronic patient medication record (PMR) systems are used in practice.

If you do not want the researcher to see your details, please let the pharmacist know.

For more information please contact:

Oluwagbemileke Ojeleye (Leke)

Telephone: 01158 232 277

paxoo1@nottingham.ac.uk