Patient Safety in Primary Healthcare: a review of the literature June 2009

AUSTRALIANCOMMISSION ON SAFETY AND QUALITY IN HEALTHCARE



Prepared for the Australian Commission on Safety and Quality in Health Care by:

Professor Alan Pearson and Eduardo Aromataris, The Joanna Briggs Institute, Adelaide.

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Report Design: Anthea Court

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Executive Summary

The Australian Commission on Safety and Quality in Health Care commissioned a review of the Australian and international literature regarding patient safety in primary care.

The review set out to address three questions: what are the main patient safety risks relevant to primary care; what research has been conducted regarding solutions to these risks; and what are the gaps in the evidence base about patient safety in primary care?

The review was undertaken during March-April 2009. It considered all forms of published evidence related to the topic, including quantitative and qualitative peer reviewed publications and other peer reviewed and non-peer reviewed publications, reports and guidelines published over the previous ten-year period (1999-2009). Literature unavailable in English was not considered for review.

- 1. Review Findings: What is the best available evidence on hazards, risks, errors and harms associated with patients/clients receiving primary care?
 - 1.1. The evidence suggests that the development and empirical testing of taxonomies of error may increase understandings of risks to patient safety. (Level III-3)
 - 1.2. Key safety issues that contribute to patient risk can be classified as process errors in domains such as diagnosis, prescribing, communication, policy and administration (Level I)
 - 1.3. There is evidence to suggest that the therapeutic intent of an activity, language barriers, errors of judgment, communication from another office, mistimed procedures, and medication errors are associated with harm. (Level IV-2)
 - 1.4. There is evidence to suggest that a failure to capture and maintain accurate and comprehensive clinical information may represent a risk in primary care in US settings. (Level IV-1)
 - 1.5. There is evidence to suggest that failure to maintain ultrasound equipment in chiropractic clinics is a potential risk to patient safety. (Level IV-1)
 - The evidence suggests that contaminated ultrasound equipment in physiotherapy clinics could increase the risk of nosocomial infection in Australian primary care. (Level IV-1)
 - 1.7. There is evidence to suggest that a failure to sterilize instruments and equipment in GP clinics may represent a risk to patient safety (Level IV-2).
 - 1.8. There is evidence to suggest that a failure to review and manage poly-pharmacy in older people represents a risk to patient safety in primary care. (Level IV-1)
 - 1.9. There is evidence to suggest that prescribing errors developed during the dispensing process and transcription stage contribute to patient risk. (Level IV-1)
 - 1.10. There is evidence to suggest that high prescription volumes, pharmacist fatigue, pharmacist overwork, interruptions to dispensing, and similar or confusing drug

names, lack of systematic dispensing workflow and lack of regulatory guideline dispensing errors may result in errors and compromise patient safety. (Level IV-2)

- 1.11. There is evidence to suggest that patient's misunderstanding of label instructions is a potential risk to patient safety, particularly for patients with low literacy and those who are prescribed multiple medications. (Level IV-1)
- 1.12. There is evidence to suggest that formatting and readability of consumer medication information that does not facilitate patient understanding is a potential risk to patient safety (Level IV-2).
- 1.13. The evidence suggests that gaps in US patient medication knowledge may represent a risk to patient safety. (Level IV-2)
- 1.14. There is evidence to suggest that GPs may benefit from training in cardiopulmonary resuscitation techniques in order to decrease risk to patients in emergency situations in Australia. (Level IV-2)
- 1.15. There is evidence to suggest that diagnostic errors are a particular risk to patient safety (Level IV-1)
- 1.16. The vast majority of literature directly related to patient safety in primary care is derived from general practice.
- 2. Review Findings: What interventions (processes and activities) are effective in identifying hazards and minimising risks, errors and harms associated with patients/clients receiving primary care?
 - 2.1. The evidence suggests that, in UK general practice, significant event analysis is feasible. (Level III-3)
 - 2.2. The evidence suggests that there is some small benefit of pharmacist led medication review to reduce hospital admissions (Level I-II).
 - 2.3. The evidence suggests accuracy in electronic prescribing is improving, but still has room to improve further (Level III)
 - 2.4. The evidence suggests that IT systems that utilize alerts, impact prescribing practice and may reduce risks associated with prescribing (Level III-1).
 - 2.5. Computerised systems that link prescribing to laboratory results and highlight drug-drug interactions may also reduce risk but there is evidence to suggest that they may also represent risk in terms of error or over-ride of system rules by clinicians (Level IV-2).
 - 2.6. There is evidence to suggest that educational interventions increase awareness of patient safety risk in both medical students and medical practitioners, however there is no evidence to suggest that this increased awareness can be observed as a increase in patient safety (Level III-3)
 - 2.7. There is some evidence to suggest that communication between patient and the healthcare professional via a telephone helpline can reduce the need for GP consultation without associated risk to patient safety. (Level III-3)

- 2.8. There is some evidence to suggest that that the use of technology to access radiological experts may have the potential to decrease errors made in diagnosis based on radiographs by GPs in primary care. (Level III-3)
- 2.9. The literature suggests that there are no simple solutions to the risks to patient safety in primary care.
- 2.10. The main challenges that warrant solutions in primary care appear to be related to organisational change, prescribing, communication and diagnosis.
- 2.11. Informatics and advances in computer technology may have the ability to mitigate error and harm in the health care sector particularly in relation to alleviating medication errors. However, the evidence on its effectiveness is equivocal, with some studies showing minimal improvement and others no improvement following the implementation of computerised systems.
- 2.12. It is apparent from the literature that any approach taken to solve risks to safety may require consideration of a number of factors such as:
 - 2.12.1. Adequate systems for reporting errors organised on a national scale.
 - 2.12.2. The use of implementation methods that are 'ground up' when designing solutions to minimise risks identified through mandatory and large scale reporting of error and harm.
 - 2.12.3. Education about safety as a core component of curricula for health professionals.
 - 2.12.4. Systems to aid efficiency, such as computers and the like will naturally find their niche to aid safety if they are designed and utilised with these processes in mind.
 - 2.12.5. Blame and litigation is detrimental to advances in patient safety.
 - 2.12.6. Communication is an important factor in health care and particularly so in primary care. Informed patients may make up for some of the deficit in communication that exists in the many disparate practices and professions that constitute primary care.
 - 2.12.7. More interaction and cooperation between service providers, such as doctors and pharmacists for example, is also an avenue by which error and harm can be reduced.
- 3. Review Findings: What are the gaps in the evidence base about patient safety in primary care?
 - 3.1. There is a paucity of high quality evidence related to the topic of risk to patient safety in primary care. Most of the research literature is based on surveys and questionnaires, particularly of clinicians, to quantify aspects such as the incidence of error and the effectiveness of interventions to reduce error, there is a specific lack of randomised controlled trials evaluating interventions to reduce patient safety risk.

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- 3.2. Drawing on the evidence and the literature, there are significant gaps in existing knowledge related to:
 - 3.2.1. The relationship between hazard, risk and error within Australian primary care;
 - 3.2.2. The relationship between errors and hazards;
 - 3.2.3. The nature of "risk" in relation to patient safety in primary care;
 - 3.2.4. The burden of harm, including financial and human costs, associated with errors, hazards and incidents in primary care;
 - 3.2.5. The capture and analysis of national data on the main hazards and level of risk inherent in contemporary primary care in Australia;
 - 3.2.6. The structures, processes and practices of health professionals delivering primary care (although there is some data related to general practice, pharmacy and to a much lesser extent nursing) that may be associated with errors, hazards and incidents;
 - 3.2.7. The role of existing taxonomies of error in increasing understandings of risk and the nature and prevalence of error in Australian primary health care;
 - 3.2.8. There are few patient safety solutions that have been robustly examined in primary care although a wide range have been proposed and discussed and there are numerous possible patient safety solutions that have not yet been examined including the feasibility and effects of:
 - 3.2.8.1. integrating and actioning patient safety strategies/interventions across all care settings including general practice, community care, private specialists rooms, public hospitals, and private hospitals;
 - 3.2.8.2. collecting and using data the identify the extent of errors, hazards and incidents in primary care as a baseline measure and impetus to promote improvement;
 - 3.2.8.3. identifying the economic costs of patient safety risk and the gains that could be made by increasing a focus on preventative strategies and involving consumers in their health care (reducing demand on the health system) and changing the way health care services are delivered (changing supply and the supply chain mechanisms);
 - 3.2.8.4. patient safety-related funding incentives and sanctions;
 - 3.2.8.5. the development and implementation of regulation for to improve patient safety; and
 - 3.2.8.6. involving patients/clients in driving a safety agenda.

1. Introduction

The Australian Commission for Safety and Quality in Health Care commissioned a team from the Joanna Briggs Institute in March 2009 to conduct a review of the Australian and international literature regarding patient safety in primary care. The purpose of the review was to "... summarise what is known about patient safety in primary care into a report that can be made public, and also inform future safety and quality work in primary care by the Commission."

Substantial progress has been made toward improving safety and quality in the Australian acute care sector. That up to 90% of the Australian population visit a GP at least once a year¹ is not reflected in the research evidence for safety and quality improvement. The Commission is therefore seeking to identify what is known about patient safety in primary care to inform its future safety and quality work in primary care. The literature review reported in this document set out to address three questions identified by the Commission:

- 1. What are the main patient safety risks relevant to primary care?
- 2. What research has been conducted regarding solutions to these risks?
- 3. What are the gaps in the evidence base about patient safety in primary care?

Over a period of 8 weeks, a structured, broad-ranging search of the literature was conducted. The scope of the search and subsequent review demanded the application of both the processes fundamental to the systematic review of evidence *and* a discursive, narrative review approach to the research and non-research literature as the project brief required that the review "...should include other published material on this topic, including material in non-peer-reviewed journals, other published media, and websites".

All *research-derived* publications that met the inclusion criteria developed for the review were critically appraised for relevance, applicability and quality. The search phase identified a range of cohort studies, case series studies, cross sectional studies, descriptive studies and evaluation reports, however few experimental studies on the effects of interventions to improve safety and quality were identified. The search also identified an extensive literature on patient safety based on opinion, professional debate and policy analysis.

This report summarises the evidence on the main safety risks relevant to primary care followed by the evidence on the existing research relating to solutions to these risks. Perceived current gaps in knowledge about patient safety in primary care are identified and discussed drawing on the evidence reviews related to risks and solutions, and on narrative summaries of the non-research derived literature. Although the summary of the research and non-research literature on patient safety and quality in primary care presented in the report identifies numerous gaps in the evidence, it also identifies potential patient safety hazards and risks relevant to primary care according to the contemporary literature.

2. Background

The *Quality in Australian Health Care Study* published in 1995 was amongst the first of a series of national reports highlighting the extent of iatrogenic patient injury in the hospital setting. The subsequent release of the Institute of Medicine's (USA) seminal document *To Err is Human* in 1999 and the National Health Service (NHS, UK) publication, *An Organisation with Memory* which was released in 2000, brought the issue of patient safety significant attention from the health professions, and to some extent, the general public.

Patient safety is an emergent discipline with a growing trans-disciplinary body of theoretical and research literature. Definitions and terms associated with patient safety are increasingly complex. Whilst patient safety generally emphasizes the reporting, analysis, and prevention of errors that may result in adverse events or outcomes, it is underpinned by the concepts of hazard, risk and harm and associated with error, events and incidents.²

Because of the need for greater precision in the use of language and terminology, patient safety researchers have attempted to develop a "common language" for patient safety. Runciman³, reporting on an international classification initiative associated with the WHO World Alliance for Patient Safety, defines safety as "freedom from hazard". A hazard is a "...circumstance or agent that can lead to harm, damage or loss". Patient safety is seen to be concerned with minimizing "hazards" in health care and is associated with:

- identifying risk ("...the chance of something happening that will have a negative impact ... measured in terms of consequences and likelihood");
- minimising harm ("...disease, injury, suffering, disability and death");
- identifying, monitoring and minimizing error ("...unintentionally being wrong in conduct or judgement... doing the wrong thing [commission)] or by failing to do the right thing [omission)]); and
- monitoring, analysing and minimizing incidents (an "... event or circumstance which could have resulted, or did result, in unintended or unnecessary harm to a person).

Any analysis of patient safety therefore requires a consideration of the potential hazards in a given health care setting and of the risk of these hazards occurring and their consequences. In the healthcare sector patient safety is associated with error and incidents that may lead to harm to a patient. Moreover, without proper consideration of a hazard and its root causes, solutions to minimising the risk of it occurring or of it causing harm will be peripheral and meaningless.

The focus of thought, research and discussion concerning patient safety has traditionally been on the acute, inpatient setting. More recently, the natural progression of this attention on patient safety has resulted in an inclusion of the primary or ambulatory care environment. ⁴ Although the definition of primary care is diffuse, it can simply be considered as the first point of contact of patients with health-care services. Internationally and in Australia, general practice constitutes the largest part of primary care.^{4,5}

Primary care has the potential to present a unique scope of hazards, risks and harms because of the specific nature of care provided, which is often quite distinct from that of

other parts of the health system. Diversity of hazard and risk in ambulatory care can be attributed to the unique, and often dispersed, physical organisation of the primary care sector and the particular relationship developed between patient and provider, which is often quite different to the inpatient setting. The organisation of primary care may introduce multiple opportunities for error. Although an individual episode of primary care may often only involve a patient with a single practitioner, the processes involved require communication and coordination between an increasing number of healthcare professionals, testing/diagnostic laboratories services, the patient and family members; who may be located in different physical sites often involving multiple handovers and transitions over an extended period of time.^{6,7}

3. Review Questions

The review focused on the three broad questions set out by the Australian Commission on Safety and Quality in Health Care:

- 1. What are the main patient safety risks relevant to primary care?
- 2. What research has been conducted regarding solutions to these risks?
- 3. What are the gaps in the evidence base about patient safety in primary care?

Focused questions were developed for the conduct of two systematic reviews undertaken to address the first two broad questions:

• What is the best available evidence on the hazards, risks, errors and harms associated with patients/clients receiving primary healthcare?

And

• What interventions (processes and activities) are effective in minimising hazards, risk, errors and harms associated with patients/clients receiving primary healthcare?

4. Review Methods

This large, scoping review was undertaken during March-April 2009. As the project brief required the reviewers to consider all forms of published material related to the topic (including quantitative and qualitative peer reviewed publications and other peer reviewed and non-peer reviewed publications, reviews, opinions, reports and guidelines published over the previous ten-year period [1999-2009]), two separate review protocols were developed and pursued focusing on the first two review questions. Literature unavailable in English was not considered for review and only those papers able to be retrieved during the short time scale were considered.

4.1 Review methods

The project team developed a-priori protocols that described rigorous and reliable methods to identify, retrieve, appraise, extract and synthesise findings reported in the national and international literature related to two systematic review questions (one review on patient safety risks in primary care and one on interventions to minimise risks to patient safety in primary care). The methods of systematically reviewing quantitative evidence developed by the Joanna Briggs Institute (JBI) were employed and these methods are congruent with both the Cochrane approach to systematic reviews, and the NHMRC guidance and levels of evidence. The detailed review protocols are appended to this report. (Refer Appendix 1).

Both of these systematic reviews followed the same structure and process and considered existing systematic reviews, randomised controlled trials, individual experimental studies of other designs, cohort studies and case control studies. Other peer reviewed and non-peer reviewed publications, reviews, opinions, reports and guidelines published over the previous ten-year period (1999-2009) relevant to the review were also considered for inclusion in narrative form.

4.1.1 Search Strategy

Databases searched included MEDLINE, EMBASE, CINAHL and specialist databases. For example, published and unpublished Randomised Controlled Trials (RCTs) and controlled trials were searched for in specialist collections such as Cochrane Clinical Trials Register (CCTR) and research registers of ongoing trials such as Current Controlled Trials. The constraints of time and resources did not allow for hand searches of key journals.

The Australian Digital Thesis Program, the System for Information on Grey Literature (SIGLE), the North West Grey Literature Service and The Networked Digital Library of Theses and Dissertations were also searched to identify other literature to elicit and describe the scope of the literature available related to the questions of interest.

Following the search, each paper considered applicable to the objectives of the review was retrieved, and the citations entered into bibliographic software (EndNote), where duplicates were identified and removed.

4.1.2 Assessment of Quality/Critical Appraisal

All research papers selected for inclusion were subjected to rigorous, independent appraisal by two critical appraisers to identify and select papers of the highest quality, i.e. those that minimised risk of bias, and had good validity and precision. The purpose of critical appraisal was to include only studies that were considered to be of a high standard, and to exclude those that were deemed to be of increased risk of bias.

Critical Appraisal Instruments

The standardised critical appraisal instruments for randomised controlled trials, cohort studies and descriptive studies, as developed by JBI and based on a synthesis of instruments used by other systematic review agencies, were used. (See Appendix 2.) Two reviewers, who conferred if any disagreement arose, undertook independent critical appraisal.

4.1.3 Data extraction and synthesis

Data were extracted from the included studies using the standardised data extraction tool developed by JBI for different types of data.

Statistical pooling was planned for appropriate data however the studies were not sufficiently homogeneous for this to be pursued and a narrative summary of the evidence was developed in each review. Key findings were identified and the level of evidence represented was assigned using a modification of the National Health and Medical Research Council levels of evidence. (Figure 1)

The textual data from the literature as a whole was discursively summarised in narrative form, although there is broad agreement that systematic reviews of evidence provide the best method available to date for synthesising the findings of high quality research. However, in fields where little such evidence exists or where there is a need to "scope" a field of knowledge, the use of a narrative review process enables reviewers to consider diverse forms of literature.⁸ Narrative review is discursive in nature and seeks to summarise the current state of knowledge in relation to a particular question through considering a wide field of sources and reaching conclusions through reason or argument. While the techniques of narrative synthesis focus on research findings, its stages in terms of developing a framework, synthesising and analysing relationships between texts guides the narrative review process which was used to inform the structure and development of the narrative components of this report. 9,10 The Guidance on the conduct of Narrative Synthesis developed for the UK Economic and Social Research Council by Popay et al (2006)⁸ suggests that reviewers should develop an organising framework from the literature; synthesise the textual data using this framework and examine and analyse the relationship between papers and their conclusions. Such a framework was developed in the early stages of the narrative review process in this project to give direction to the organisation of the review.

Level	Intervention	Diagnostic accuracy	Prognosis	Aetiology	Screening Intervention
Ι	A systematic A systematic review of level II of level studies II studies		A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
Π	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudo- randomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect.	All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect.	A pseudo- randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study • Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group	Diagnostic case- control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: • Historical control study • Two or more single arm study
IV-1	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series
IV-2	Evidence obtained from well-described analyses of case studies/ case examples; or other descriptive report generated from empirical data.	Evidence obtained from well-described analyses of case studies/ case examples; or other descriptive report generated from empirical data	Evidence obtained from well-described analyses of case studies/ case examples; or other descriptive report generated from empirical data	Evidence obtained from well-described analyses of case studies/ case examples; or other descriptive report generated from empirical data	Evidence obtained from well-described analyses of case studies/ case examples; or other descriptive report generated from empirical data

Figure 1: Modified NHMRC Levels of Evidence

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4.2 Nature of the literature reviewed

4.2.1 The Research Literature

Given the inapplicability of randomised controlled trials in this field, four general approaches were the most frequently described methods in reports on the study of hazards, risk and errors ¹¹:

- Surveying primary care providers and patients, and conducting interviews, about hazards, risks and errors observed or experienced (self reports);
- Observational studies;
- Retrospective reviews of medical records; and
- Studies of malpractice claims and complaints made against health providers.

Studies focusing on solutions to minimising risk included:

- systematic reviews;
- randomised controlled trials;
- cohort studies;
- interrupted time series studies; cross sectional studies; and
- descriptive surveys.

4.3.2 The Literature as a Whole

A large proportion of the literature reviewed represents other review literature, expert opinion and international and Australian reports. The summary of the papers referenced in this review classifies the type of evidence each represents. A simple classification system was employed:

- SR Systematic review
- R Literature review
- RCT Randomised controlled trial
- O Observational study
- Q Qualitative study
- D Descriptive study
- EO/C Expert opinion or commentary

4.4 Structure of this report

Section 5 reports on a systematic review of the evidence on safety risks relevant to primary care. Section 6 reports on a systematic review of the evidence on interventions and strategies to minimise risk in primary care. Section 7 draws on the evidence and the literature to identify gaps in knowledge related to patient safety in primary care. A summary of the review and the conclusions drawn from it are presented in Section 8.

Due to the volume of relevant literature available from the outset of the searching phase of the review process, results of individual database searches were initially rapidly scanned for relevance prior to download to EndNote. Titles and abstracts of approximately 1800 references were then screened based on relevance and applicability to the three review questions. Many publications were deemed to be irrelevant or beyond the specific scope of the review questions. Most of the references excluded prior to any retrieval were omitted on the basis of their exclusive reference to an inappropriate setting, for example the secondary or tertiary sector; their focus on risks to the healthcare provider rather than the patient, i.e. occupational hazards; their reference to issues of the 'safety net' in relation to healthcare costs throughout the international healthcare setting, and/or their lack of an abstract. Papers were also excluded if they focused on the treatment of a specific disease or detrimental patient outcome that occurred as a result of direct complications of other diagnosed medical conditions.

Approximately 750 papers judged to be relevant to the questions of interest remained. Due to time constraints, literature that was rapidly obtainable by electronic means was retrieved first with preference given to more recent publications. Bibliographies of these papers were also referred to where papers particularly relevant to one of the review questions were identified. If readily available by electronic means these papers were also retrieved. Titles of materials identified in searches of the grey literature are included in Appendix 3 to demonstrate both the scope and content of the information available related to the questions of interest.

There is an extensive literature on patient safety in health care as a broad field; a large and growing literature on quality in primary care; and a smaller, though recently expanding, literature on patient safety in primary care. Although there has been some attempt in this literature to understand the nature and distribution of hazards, risks and harms, most reported studies focus on the nature and distribution of errors regardless of whether they result in negative consequences for patients. For example, there are many studies addressing error and incidents that do not directly consider subsequent adverse outcomes or actual or potential harm to patients. The aim of much of this research into medical error has been to develop taxonomies for classification of errors in primary care.

Of interest to this review are the attempts by primary health care researchers to develop taxonomies of error (in that such taxonomies present frameworks that may be used to understand potential hazards and the risk of their occurrence); and the research and non-research literature on solutions to minimising risk in primary health care.

Taxonomies are classification systems, and a number have been developed to classify errors that occur in the delivery of healthcare, including primary care. Taxonomies related to patient safety focus on the identification and classification of errors; incidents and near misses; the reasons why these errors occur; and classifying preventative strategies that could minimise the occurrence of errors.¹² Taxonomies provide standard tools and definitions for measurement, allow the comparison of events across disciplines and suggest directions for the development of patient safety solutions. They also present a useful framework to organise the literature related to hazard, risk and harm in primary health care.

The literature addressing solutions to minimising risk identifies both specific interventions or strategies related to specific hazards, risks, errors or adverse events and more general

considerations such as the nature and reorganisation of health care systems or the promotion of psychological/attitude change to further the cause of safety in primary care.

Drawing on the literature itself, a framework that draws on taxonomies of error and solutions to minimise risk gave structure to this review. (Figure 2)

Figure 2: Framework for the Review of the Patient Safety Literature



5. Systematic Review of the Evidence: Patient Safety Risk in Primary Care

5.1 Review methods

The review methods have been described in general terms in section 4 of this report. The detailed methods for this review are in Appendix 1.

5.1.1 Review question/objective

The aim of this review was to identify the main patient safety hazards in primary care and the risk of these hazards in terms of the likelihood of their occurrence and the consequences. Specifically, the review question was:

What is the best available evidence on the hazards, risks, errors and harms associated with patients/clients receiving primary healthcare

5.2 Results

The process involved in the selection of studies for this review is shown in figure 3 below.

Figure 3: Selection of studies



Eighty-two (82) papers were identified as being potentially applicable to the review question through screening titles and abstracts of publications identified by the original search. Of these, 20 papers were unable to be retrieved due to time constraints. (See Appendix 4) Sixty-two (62) papers were retrieved. After examining the full text, 16 papers were excluded, as they did not meet the review objectives. Forty-six (46) papers were then critically appraised. Thirteen (13) papers were excluded due to poor methodological quality. The final number of studies included in the review was 33.

Four case reports that were part of the Threats to Australian Patient Safety (TAPS) Study¹³⁻¹⁶ and three case events reported in Australian Family Physician¹⁷⁻¹⁹ contributed to a clearer understanding of risk to patient safety in Australian primary care. These case event reports fell below the assessment cut-off for descriptive studies (score <5/9) due to the lack of control group, lack of assessment and adjustment for potential confounding factors. However, as they were assessed to be a useful source of information related to the awareness of issues in patient safety, these studies were included to situate the more robust evidence reviewed.

The included studies in this systematic review focused on four main areas (refer to Appendix 5):

- 1. Studies that attempted to identify and classify errors, hazards and incidents in primary care;
- 2. Studies that identified the main errors, hazards and incidents associated with the process of delivering primary care;
- 3. Studies that identified errors, hazards and incidents associated with knowledge and/or skills of clinicians delivering primary care; and
- **4.** Studies that reported both process errors and knowledge and skill errors that had contributed to harm to patients

Forty-seven (47) papers were identified as appropriate for narrative review (Section 5.3). Twelve (12) of these papers were part of the original 82 papers identified for the systematic review.

5.2.1 Identifying and classifying errors, hazards and incidents in primary care

A number of Australian and international studies have attempted to increase understandings of patient safety in primary health care by developing taxonomies classifying errors made in general practice as a basis for collecting and analysing data.²⁰⁻²⁷ The quality of these studies is variable and they are only included in this review to identify the possible hazards associated with primary care.

Of the handful of patient safety taxonomies applicable to primary care, there are two taxonomies of medical error that have been tested and appear to be the most consistently utilised and referred to in the literature.

Firstly, the Applied Strategies for Improving Patient Safety (ASIPS) taxonomy was designed by drawing on a prior conceptual taxonomy, and testing its relationship to harm based data, and making modifications in order to collect and analyse medical errors that occur in primary care ambulatory practice.²⁸⁻³⁰ The ASIPS Patient Safety Reporting System (ASIPS PSRS) collects reports of events that those who report them regard to be a threat to patient safety. Secondly, the American Academy of Family Physicians (AAFP)/Linnaeus Collaboration taxonomy was generated from the qualitative analysis of numerous error reports submitted from general practitioners and was initially developed by Dovey *et al.*^{20,25,31}

Table 1 presents data quantifying medical errors from a number of these comparable studies using themes/categories derived from the classification of error postulated by the AAFP/Linnaeus Collaboration taxonomy.^{20,25,31} Many of the Australian studies investigating medical error use this same classification system and some also represent the predominant sources behind its development and evolution whereas the ASIPS studies apply almost exclusively to the US health system.^{28-30,32} The column headings of Table 1 that are drawn from this taxonomy are used within this review to summarise information about patient safety error, hazards and incidents. (See Appendix 6)

Table 2 is also drawn from these studies and presents types and frequency of occurrence of harm related to errors in general practice.

The studies that contribute to Tables 1 and 2 all rely on completion of anonymous reports of workers in general practice, predominantly medical staff. These studies all took place in general practices, both rural and urban, across seven different countries. In some cases nurse practitioners, medical assistants and office staff submitted reports as well as the practicing GP. The AAFP/Linnaeus taxonomy, developed by Dovey *et al*,²⁰ (or a modified version of it) was used to classify errors in most studies. The taxonomy has evolved through this process.³¹

Based on these studies and the AAFP/Linnaeus taxonomy it is possible to identify two broad categories or types of risks of error that shed light on the potential patient safety risks, be they mild to severe risks of either psychological or physical harm.

Firstly, risks may stem from the organisational characteristics of primary care itself. The Linnaeus Collaboration Taxonomy, refers to 'process' errors that can be characterised this way.³¹ Those risks that fall into this first category are generally designated as such by their potential to arise without any direct patient involvement or interaction in the process itself, perhaps due to risks associated with the system or organisation itself. These failures/errors include errors in administration, design, organisation, training or maintenance.

Secondly, there are risks that arise directly from the face-to-face provision of healthcare to the patient by individual and professionally diverse, health professionals. Risks and errors applicable to this second category may include, for example, human failures that may be attributable to the knowledge and skills of the clinician or the patient. The AAFP/Linnaeus Collaboration Taxonomy specifies its second major grouping of errors related to general practice as related to the skills and knowledge of the practitioner.

The majority of reported errors in primary care (approximately 80%) can be attributed to the first category of errors, namely to system or process errors, as opposed to knowledge/skill errors of the practitioner (Table 1).^{25,26}

Reference	N subjects (GPs)	N error reports	Duration of Study	Process errors %	Administration Errors %	Investigation Errors %	Treatment Errors %	Communication Errors %	Payment Errors %	Knowledge and Skills Errors %	Diagnosis Errors %	Wrong treatment decision %	Errors in task execution %
Dovey et al., 2002 ²⁰	42	344	20 wks	86.1	30.9	24.8	23	5.8	1.2	13.9	3.9	4.2	5.8
^a Makeham et al., 2002 ²⁵	23	134	4-5 mths	79	20	13	29	15	1	21	14	2	5
^a Makeham et al., 2002 ²⁵	81	301	6-7 mths	79	19	19	24	14	1	21	12	6	2
^b Rosser et al., 2005 ²⁶	15	95	6-7 mths	87	29	18	26	9	2	13			
^b Rosser et al., 2005 ²⁶	?	413	6-7 mths	78	39	16	24	15	1	22			
^c Elder et al., 2004 ²¹	15	351			16.5			4.5		4.3			
^d Hickner et al., 2008 ²²	243	966	4 wks	98.2	17.6	68.9	1.8	5.7	0.9	1.2			
Hoffman et al., 2008 ²³	?	188	17 mths	72.9	6.9	8.5	44.7	6.9	4.3	26.1			26.1
Makeham et al., 2008 ³³	84	415	12 mths	69.5	21.3	12.4	22.9	12.9		30.5	11.8		18.7
Tilyard et al., 2005 ²⁷	20	66	8-9 mths	80.3	9.1	13.6	24.2	8.2				19.7	

Table 1. International taxonomy of errors in general practice

Frequency of different 'types' of reported error by general practitioners (GPs) classified by the American Academy of Family Physicians (AAFP)/Linnaeus Collaboration's taxonomy. Columns in bold type i.e. 'process' and 'knowledge/skills' indicate main categories of error derived from GP error reports. Columns immediately to the right of each in bold type indicate major subsets contributing to each of the two categories of error i.e. 'process' and 'knowledge/skills'. Within the category of 'process errors' sub classification was as follows: Administration errors refer to those related to patient records and handling; Investigation errors refer to those related to the ordering, receipt or

performance of laboratory tests associated with general practice; Treatment errors are those arising from the treatment process, including medication related errors; Communication errors are those related to aspects of communication in primary care, including doctor-patient, GPs-hospital and those between health care practitioners; Payment errors refer to those related to incorrect billing and/or insurance payment. Knowledge and skills errors are those classified which were directly attributable to an error made by the GP due to a lack of knowledge and/or skill. These were further sub classified as errors in diagnosis, and wrong diagnosis in particular, and those related specifically to errors in the clinical treatment administered by the GP. Where indicated (%), numbers in table refer to the percentage of total error reports made by GPs attributable to each category/type of error. The study from which the numbers are derived, the number of GPs participating, number of error reports filed, and the duration of each study is indicated in columns 1 to 4 respectively. As some of the publications from which data are derived present primary data from the country in which the study was conducted as well as data from the comparable studies conducted internationally, these data have been extracted separately where possible as detailed below.

^a First row represents data collected and reported in Australia, second from International results reported in same paper

^b First row represents data collected and reported in Canada, second from International results reported in same paper

^c number in 'no' raw represents % of patient visits in which this type of error was recorded NOT % of total errors reported

^d Study investigating 'process errors' specifically, at the exclusion of 'knowledge/skills type' error

Reference	Consequence/harm to patients %	Time/financial cost %	Delay in care %	Pain %	Emotional/psychological %	Temporary Physical %	Hospitalisation %	Permanent/very serious %	Death %
Dovey et al., 2002 ²⁰	29.2	8.8	21.2		12.1	7.0	3.0	2.4/	0.3
^a Makeham et al., 2002 ²⁵	32						4.5	/9	0.8
^a Makeham et al., 2002 ²⁵	31						3.7	/3.7	1.3
^b Rosser et al., 2005 ²⁶	39.3						0	/5.8	0
^b Rosser et al., 2005 ²⁶	29.3						3.7	/7.1	1.2
Elder et al., 2004 ²¹	23.7				6	11	0.1	0.5	
^a Hickner et al., 2008 ²²	74/46	22	24	11	1	14	4	9	8
Hoffman et al., 2008 ²³	42								

Table 2. Type of consequence/harms reported by physicians arising from error

Frequency of different consequence/harm to patients (outcomes) associated with reported error by general practitioners (GPs) classified by the American Academy of Family Physicians (AAFP)/Linnaeus Collaboration's taxonomy. Columns indicate where these errors resulted in: consequence/harm to patients (where physicians recorded any observable outcome/effect due to error); increased time/financial cost of process; delays in care; pain and suffering; emotional/psychological harm; temporary physical harm; hospitalisation; permanent harm or very serious harm; or death. Numbers (%) represent percentage of total error reports presented in Table 1.

Further characteristics of each study (i.e. number of participants, number of reported errors and duration of study) are presented in Table 1. As some of the publications from which data are derived present primary data from the country in which the study was conducted as well as data from the comparable studies conducted internationally, these data have been extracted separately where possible as detailed below.

^a First row represents data collected and reported in Australia, second from International results reported in same publication

^b First row represents data collected and reported in Canada, second from International results reported in same publication

As the elements of the AAFP/Linnaeus Collaboration Taxonomy and other taxonomies are empirically derived and there are studies of their use in the Australian context, these taxonomies offer a useful framework for conceptualising potential hazards in primary care and the scope of risk and error.

Key Finding: Evidence for Classifying Risk

The evidence suggests that the development and empirical testing of taxonomies of error may increase understandings of risks to patient safety. (Level III-3)

One systematic review³⁴ and one descriptive study²⁹ identified errors that contributed serious consequences to primary health care.

A systematic review conducted by Elder & Dovey 2002³⁴ described and classified process errors and preventable adverse events that occurred from medical care in outpatient US primary care settings. Seven small descriptive studies that described medical errors and preventable adverse events in US primary care were included in the review. Due to the descriptive nature of the design and heterogeneity in outcome, the findings were reported in narrative summary. Process errors identified in this review were classified into: clinician factors (i.e. inadequate history), communication (language or language barriers), administration (missing medical chart), and policy (Medicare regulations). Preventable adverse events are descriptors of what went wrong in the care of the patient that could have harmed or did harm a patient. These included misdiagnosis, medication errors, and procedural complication.

Apart from unclear methods for critical appraisal of included papers, and lack of explicit inclusion criteria, the review is regarded as being of good methodological quality (score 8/10).

Key Finding: Evidence for Classifying Risk

Key safety issues that contribute to patient risk can be classified as process errors in domains such as diagnosis, prescribing, communication, policy and administration (Level I)

Similarly, Pace et al 2005²⁹ identified and described medical errors and their relationship to harm in the US health system by analysing reported medical errors to the Patient Safety Reporting System. From 357 reports 608 errors were identified, and analysed with univariate, bivariate and multivariate logistic analysis. The study reported that harm was associated with therapeutic intent of an activity (OR 2.71, 95% CI 1.75, 4.17), language barriers (OR 8.35, 95% CI 2.52- 27.65), and errors of judgment, (OR 2.36, 95% CI 1.34, 4.16) communication from another office (OR 2.11, 95% CI 1.20, 3.73), mistimed procedures (OR 1.95, 95% CI 1.28, 2.95), medication errors (OR 4.14, 95% CI 2.69, 6.39). Harm was not associated with incorrectly performed procedures or failure to perform procedures or general information flow within, into, or out of the office (score 5/9).

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that the therapeutic intent of an activity, language barriers, errors of judgment, communication from another office, mistimed procedures, and medication errors are associated with harm. (Level IV-2)

5.2.2 Identifying the main errors, hazards and incidents associated with the process of delivering primary care

Administration Processes

Although the patient safety literature frequently identifies administrative processes such as documentation, reporting and information management as a source of risk to patient safety, only one descriptive study potentially relevant to the Australian context ³⁵ investigated administrative incidents that may represent risk.

The coordination or management of primary care is information-intensive and may be impeded where relevant clinical information is missing. In a cross sectional survey conducted by Smith et al³⁵ of ambulatory care physicians in the US, missing clinical information was reported in 13.6% of visits. Important missing information included laboratory results, letters, radiology results, history and physical examination documentation and information relating to patient medications. The authors reported that this missing information was likely to adversely affect patients in 44% of cases and had resulted in delayed care or a need for additional services in 60% of cases.³⁵

Variables predisposing to probability of missing clinical information were recent immigrants (odds ratio [OR], 1.78; 95% CI, 1.06-2.99), new patients (OR, 2.39; 95% CI, 1.70-3.35), or patients who had multiple medical problems compared with no problems (1 problem: OR, 1.09; 95% CI, 0.69-1.73; 2-5 problems: OR, 1.87; 95% CI, 1.21-2.89; >5 problems: OR, 2.78; 95% CI, 1.61-4.80).

The study had significant limitations due to the lack of a control group, and lack of assessment and adjustment for potential confounding factors and relates to the US system only. (Score 5/9)

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that a failure to capture and maintain accurate and comprehensive clinical information may represent a risk in primary care in US settings. (Level IV-1)

Treatment processes

Six studies investigating risks associated with treatment delivered across the primary health care sector were included in this review. ³⁶⁻⁴¹

A wide range of equipment is used in primary care and the potential exists for error in maintaining or using such equipment that may result in patient harm. Daniel and Rupert³⁶ conducted a cross-sectional survey study to investigate calibration of ultrasound units within

the physical therapy communities in Scotland and Canada. The study reported that a large percentage (44% of the 45 machines tested) of ultrasound machines in chiropractic physicians' offices delivered too much or too little dosage to the patient. Electrical safety inspections also revealed a significant failure rate as only 2 of 45 machines tested had been safety checked in the previous 12 months.

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that failure to maintain ultrasound equipment in chiropractic clinics is a potential risk to patient safety. (Level IV-1)

Two descriptive studies^{37,40} and one case event study³⁹ identified that cross-infection arising from consulting room procedures in general practice and in a chiropractic clinic[,] might be harmful to patients.

A cross sectional descriptive study by Schabrun et al 2006⁴⁰ conducted in Australia identified a potential risk of nosocomial infection with ultrasound equipment in physiotherapy clinics. The study investigated private practices, public hospitals as well as aged care facilities. The majority of ultrasound transducer heads examined were heavily contaminated with microorganisms (more than 5 CFU per cm²) and high levels of opportunistic and potentially pathogenic organisms were also identified in ultrasound gels. The levels of contamination reported in the study, and in particular, the numbers of potentially pathogenic and opportunistic organisms identified were reported to represent a risk to patient safety. (Score 5/9)

Key Finding: Evidence for Classifying Risk

The evidence suggests that contaminated ultrasound equipment in physiotherapy clinics could increase the risk of nosocomial infection in Australian primary care. (Level IV-1)

Farrow et al 1999³⁷ surveyed and telephone-interviewed 82 family practices in the US to investigate shortcomings in infection control in general practice that may represent a risk to patient safety. Ineffective decontamination of instruments, lack of understanding of the effective use of chemical disinfectants, incomplete vaccination for staff, lack of infection control guidelines, inadequate sharps policies and inadequate staff training were identified as potential threats to patient safety. The study findings were subject to limitations due to the non-random selection of the sample and relates to the US system only. (Score 5/9).

A case study report from Australia by Makeham, et al., 2008³⁹ provided a substantial, detailed description of the importance of sterilization/disinfection of equipment used in general practice. They found a lack of safety in the physical environment of general practice related to problems with the maintenance and/or proper use of equipment; and failing to have systems in place to ensure that standards for infection control or sterilisation of equipment.

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that a failure to sterilize instruments and equipment in GP clinics may represent a risk to patient safety (Level IV-2).

Processes associated with ordering, transcribing, dispensing, administering or monitoring medications

Medication error is the focus of most literature related to patient errors, hazards and incidents and potential solutions to minimise risk. Medication errors generally refer to mistakes made in the processes of ordering, transcribing, dispensing, administering or monitoring of pharmaceutical agents used in clinical practice.

Studies included in this review investigated the potential risk of polypharmacy,^{42,43} medication knowledge and literacy of patients ⁴⁴⁻⁴⁶ and the role of the pharmacist⁴⁷⁻⁵¹.

A cross sectional survey conducted by Meredith *et al* ⁴² identified potential risk associated with polypharmacy in older people. The study determined the frequency of possible medication errors in a population of older home healthcare patients in the largest urban home healthcare agencies in the United States. Participants were 6,718 home healthcare patients age 65 and older admitted to selected offices of these agencies. The study subjects took a median of five drugs; 19% were taking nine or more medications. A possible medication error was identified for 19% of patients according to Home Health Criteria, 17% according to the Beers criteria, and 30% according to either. Home Health Care Criteria for medication error defined by Meredith et al⁴² included 4 broad categories. These were: unnecessary therapeutic duplication of drugs, for example patients unnecessarily taking two drugs from the same class; possible errors for cardiovascular medications, where cardiovascular indicators were poorly controlled by medication; possible errors for psychotropic drugs, where adverse effects of the medication included confusion or falls; and possible errors with NSAIDs, particularly amongst patients at high risk of peptic ulcer and contraindication due to concurrent medications.

The Home Health Criteria identify patients with patterns of medication use and signs and symptoms that indicate sufficient likelihood of a medication-related problem to warrant reevaluating the patient. The Beers criteria identify medications that experts have deemed generally inappropriate for older patients.

Possible errors increased linearly with the number of medications taken. When patients taking one to three medications were compared with those taking nine or more drugs, the percentages with possible errors were respectively, 10% and 32% for the Home Health Criteria, 8% and 32% for the Beers criteria, and 16% and 50% for both.

The study was subject to selection bias due to an unclear sampling method. This study did highlight however, evidence of increased risk when older people were prescribed nine or more medications. (Score 6/9).

A cross sectional descriptive study by Junius-Walker et al, 2006⁴³ identified that multiple medication use entails health risks for older patients in German general practice. The study indicated that older people, in Germany, are high consumers of prescribed and over the counter (OTC) drugs. Frequency of health problems were significantly more common in the polypharmacy group (shortness of breath (OR 3.13, 95% CI 1.99-4.93, P< 0.001), syncope

(OR 2.21, 95% CI 1.26-3.85, P<0.005), depression (OR 2.29, 95% CI 1.40-3.75, P<0.001). The study is remarkable for its high methodological quality (score 8/9).

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that a failure to review and manage poly-pharmacy in older people represents a risk to patient safety in primary care. (Level IV-1)

The role of pharmacists in relation to error, unregulated alternative therapy and patient risk has also been investigated.⁴⁷⁻⁵¹

Knudsen et al 2007⁵⁰ investigated the frequency and seriousness of medication errors in 40 randomly selected Danish community pharmacies. The data included prescription correction, dispensing near misses and dispensing errors.

Most of the errors, and potentially the most serious ones, occurred in the transcription stage (wrong strength, wrong medicine, wrong dosage) of the dispensing process. Prescribing errors were the most frequent type of error reported (23/10,000). Errors that directly impacted on patients were not frequent, however most of them were potentially harmful, and the absolute number of medication errors was high.

The study is subject to bias due to unclear outcome assessment that is more likely to be subjective (score 5/9).

The danger of prescribing errors identified by Knudsen et al 2007⁵⁰ was supported by Gandhi et al 2005.⁴⁹ Rates, types, severity, and preventability of harms related to medications among outpatients at four adult primary care practices in the US (two hospital-based and two community-based) were investigated via a survey of patients and chart review. Participants were 1202 outpatients who received at least one prescription during a four-week period.

Of the 661 patients who responded to the survey (response rate, 55%), 162 had adverse drug events (25%; 95 %CI, 20 to 29 %), with a total of 181 events (27 per 100 patients). Twenty-four of the events (13%) were serious, 51 (28%) events were ameliorable, and 20 (11%) were preventable. Of the 51 ameliorable events, 32 (63%) were attributed to the physician's failure to respond to medication-related symptoms and 19 (37%) to the patient's failure to inform the physician of symptoms. The study is at risk of selection bias due to the non-representative sample. (Score 6/9)

A prospective study over a 4-week period by Ashcroft DM et al., (2005)⁴⁷ sought to determine the incidence, nature and causes of dispensing errors and near misses by pharmacists. The settings of interest were 35 community pharmacies in England and Wales (9 independent pharmacies and 26 chain pharmacies) in the UK. 125,395 prescribed items were dispensed during the study period and 330 incidents were recorded relating to 310 prescriptions. 280 (84.8%) incidents were classified as a near miss (rate per 10,000 items dispensed = 22.33, 95%CI 19.79-25.10), while the remaining 50 (15.2%) were classified as dispensing errors (rate per 10,000 items dispensed = 3.99, 95%CI 2.96-5.26). Drug selection errors were the most common types of incidents (199, 60.3%), followed by labelling (109, 33.0%) and bagging errors (wrong name on bag, wrong address on bag, item left out of bag, additional items in bag) (22, 6.6%). Most of the incidents were caused either by misreading the prescription (90, 24.5%), similar drug names (62, 16.8%), selecting the

previous drug or dose from the patient's medication record on the pharmacy computer (42, 11.4%) or similar packaging (28, 7.6%).

The study is subject to selection bias due to non-random selection of sample, and is subject to confounding due to lack of control of confounders. (Score 5/9).

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that prescribing errors developed during the dispensing process and transcription stage contribute to patient risk. (Level IV-1)

The evidential basis regarding the patient safety risk of dispensing errors in England, Wales and Denmark was further supported by Peterson et al 1999⁵¹ in a study conducted in Australia. The attitudes of pharmacists towards the issue of dispensing errors were investigated through a survey of 209 Tasmanian-registered pharmacists residing in Australia (50% response rate). The specific aim of the study was to provide an estimate of dispensing errors in the community and included pharmacists who were registered by the Pharmacy Board of Tasmania. Some participants were owners of community pharmacies.

The survey sought to establish whether the risk of dispensing errors and the actual number of errors are increasing. It also investigated the major factors contributing to the occurrence of dispensing errors, factors that may best minimise the risk of dispensing errors, the number of prescription items that one pharmacist can safely dispense in a day and whether Australia should have a regulatory maximum dispensing load. The survey also sought to provide an estimate of the number of recent errors at the pharmacist's workplace.

Most pharmacists (82%) believed that the risk of dispensing errors is increasing. The principal contributing factors nominated were: high prescription volumes, pharmacist fatigue, pharmacist overwork, interruptions to dispensing, and similar or confusing drug names. The main factors identified as being important in reducing the risk of dispensing errors were: having mechanisms for checking dispensing procedures, having a systematic dispensing workflow, checking the original prescription (duplicate) when dispensing repeats, improving the packaging and labeling of drug products, having drug names that are distinctive, counseling patients at the time of supply, keeping one's knowledge of drugs up-to-date, avoiding interruptions, reducing workloads on pharmacists, improving doctors' handwriting, and privacy when counseling patients. Most pharmacists (72%) stated that they were aware of dispensing errors that had left the pharmacy undetected, in their place of practice during the past 6 months (median value of 3, and total sample of nearly 500 errors). A median of 150 was nominated as the maximum number of prescription items that can be safely dispensed per 9-hour day (i.e. 17 items per hour) by, or in the presence of, one pharmacist. Most pharmacists (58%) stated that there should be a regulatory guideline for the safe dispensing load in Australia. Apart from selection bias because of non-random sampling, this descriptive cross sectional study design has validity (score 6/9).

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that high prescription volumes, pharmacist fatigue, pharmacist overwork, interruptions to dispensing, and similar or confusing drug names, lack of systematic dispensing workflow and lack of regulatory guideline dispensing errors may result in errors and compromise patient safety. (Level IV-2)

The potential risks of limitations in the medication knowledge and medication literacy of patients were identified in three studies. ⁴⁴⁻⁴⁶

A cross sectional study by Davis et al 2006⁴⁴ in three outpatient primary care clinics in the US presented substantial, detailed, analytical descriptions of the factors contributing to misunderstanding the instructions on five common prescription medication labels.

The study reported that low literacy (RR 2.32, 95%CI 1.26-4.28 P<0.001) and a greater number of prescription medications (RR 2.98, 95%CI 1.40-6.34, P<0.001) were significantly associated with misunderstanding of pill bottle labels.

Although the study did not examine the association between misunderstanding of label instructions and medication errors, it concluded that pharmacists need to improve the clarity and comprehensibility of labelling prescription drugs. However, due to confounding variables not being addressed and not adhering to probability sampling procedures the findings should be interpreted with caution. (Score 5/9).

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that patient's misunderstanding of label instructions is a potential risk to patient safety, particularly for patients with low literacy and those who are prescribed multiple medications. (Level IV-1)

A cross sectional descriptive study by Franks et al 2008⁴⁵ investigated readability and formatting characteristics of consumer medication information (CMI) provided with sample packaging from several primary care and physician practices within the US. The reported outcomes were instruction presentation, reading level, text size, format/layout, and comprehensibility of CMI. CMI accompanying nonsolid medication samples in this study was found to not meet recommended standards for readability and comprehensibility of patient education material according to the researchers.

This study did not examine the association between readability of label instructions, misunderstanding and medication errors, however, as with the previous study, it did support the view that pharmacists need to improve the clarity and comprehensibility of information consumers rely upon.

Most (43 of 55) products included CMI, either as a separate leaflet or directly on the packaging. The reading level of CMI leaflets ranged from the 6th- to 14th-grade level, with just 4 (16.0%) written at the recommended 6th-grade level. Text font point size was 9.48 +/- 2.14 (mean +/- SD; range 5-12). Text printed directly on sample packaging averaged 6.61 point +/- 2.62 (4-11) font size. Ninety-two percent of CMI leaflets included a combination of text and pictures; only 11.1% of CMI printed directly on the packaging used pictorial aids.

However, the study is subject to confounding due to non-random selection of sample, and not addressing confounding variables. (Score 6/9)

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that formatting and readability of consumer medication information that does not facilitate patient understanding is a potential risk to patient safety (Level IV-2).

Persell et al 2004⁴⁶ studied patients' knowledge of the indications associated with their prescription medications and sought to identify those medications that were most likely to be taken without patients understanding the correct indications for particular medications. Adult patients who received care at four primary care practices in Boston, USA were surveyed. Patients were eligible to participate if they were over 18 years old and had received a prescription from a participating physician at a clinic visit. Patients were telephoned and asked to retrieve the bottles of all medications they were currently taking, identify their medications, and state the reason they took each medicine. The primary outcome was absent or incorrect knowledge of a drug's indication.

More than 13% of patients in primary care practices did not know the indication of at least one of their prescription medications, and patients were unable to identify the indication for 6.3% of all prescribed medications. Lack of knowledge was most prevalent for cardiovascular medications.

Key Finding: Evidence for Classifying Risk

The evidence suggests that gaps in US patient medication knowledge may represent a risk to patient safety. (Level IV-2)

5.2.3 Identifying errors, hazards and incidents associated with knowledge and/or skills of clinicians delivering primary care

Three descriptive studies^{14,52,53} identified deficits in doctors' prescribing skill and competency that could have harmed a patient. Furthermore, potential risk of misdiagnosis was identified by descriptive analysis of malpractice claim data.⁵⁴

A descriptive study by Perry and Crean $(2005)^{53}$ identified potential risk of physician impairment (defined as a change that interferes with their functioning as physicians in ways that endanger patient safety). The study evaluated the neuropsychological profiles of physicians referred to an assessment program by the California Medical Board (CMB) following allegations of medical errors in USA. Misdiagnosis was the dominant reason for referral (25.8%). The profile of these physicians was compared to the various standardisation samples. The physicians generally scored in the average range across the selected subsets from the neuropsychological test, compared with the comparison reference sample on measures of picture arrangement subset score group (P<0.05); normative reference sample on non-verbal complex figure learning (P<0.001); numerical attention time (P<0.001); and symbol digit modality P<0.01). As a non-impaired physician comparison

group was not available, the results from this study must be interpreted with caution. (Score 5/9).

A case study report from the TAPS study by Makeham, Saltman, and Kidd, (2008)¹⁴ identified evidence that lack of GP skill in management of medical emergencies is a particular risk to patient health and safety. The patient in this case example ended up with hypoxic brain injury following the physician's attempted cardiopulmonary resuscitation (conducted without a clear airway) that endangered the patient life.

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that GPs may benefit from training in cardiopulmonary resuscitation techniques in order to decrease risk to patients in emergency situations in Australia. (Level IV-2)

A prospective cohort study conducted by AI, Khaja, et al 2008⁵² identified that prescription writing skills of the final year residents in a family practice residency program (FPRP) in Bahrain were suboptimal. Prescriptions issued by the participants were prospectively collected for two consecutive cohorts. Prescription errors were classified as errors of omission (minor and major), commission (incorrect information) and integration (drug-drug interactions). Approximately one quarter of the total errors were commission errors, which potentially would have been harmful to patients. These included incorrect strength/dose for systemic drugs and drugs prescribed for acute medical conditions, and incorrect length of treatment. Although this study did not address the association between these errors and serious adverse events that may occur in patients, it did facilitate the identification of rates and types of errors in the prescribing process and determined the prescribing skill competency of doctors. However, due to descriptive nature of the study design and lack of probability sampling method employed, the results should be interpreted with caution, and may relate only to the Bahrain primary care system. (score 5/9)

A descriptive cross sectional analysis of malpractice databases of the Physician Insurers Association of America (PIIA) was conducted by Philips et al 2004.⁵⁴. The study identified that one third of the underlying causes of malpractice claims were due to diagnostic errors, followed by medication errors, improper performance, failure to communicate with patients, and failure in referral.

Although the study did not fulfill all criteria (score 6/9), it did identify that for US primary care physicians, patient safety related incidents in general practice are associated with diagnostic errors.

Key Finding: Evidence for Classifying Risk

There is evidence to suggest that diagnostic errors are a particular risk to patient safety (Level IV-1).

5.3 Narrative review of other literature

Although there is broad agreement that systematic reviews of evidence provide the best method available to date for synthesising the findings of high quality research, in fields where little such evidence exists or where there is a need to "scope" a field of knowledge, the use of a narrative review process enables reviewers to consider diverse forms of literature.⁸ Narrative review is discursive in nature and seeks to summarise the current state of knowledge in relation to a particular question through considering a wide field of sources and reaching conclusions through reason or argument. ^{9,10} This narrative component of the review summarises the scope of discussion in the general literature and in reports on studies that were not of sufficient quality to be included in the main review.

Errors, hazards and incidents associated with the processes of primary care

Administration processes

Studies of adverse events and 'near misses' in family practices in the US, note that office administration errors were the most frequently reported.^{21,55} Administrative and office errors include those related to:^{21,22,25,26,33,56}

- Patient record and filing systems,
- Chart completeness,
- Patient flow/transition,
- Appointment and message handling,
- Recall events and recall system,
- Computer systems,
- After hours healthcare and staffing problems,
- Patient confidentiality, and
- Incorrect patient identification.

Computerised systems are seen by many commentators as a means to minimise risk associated with administrative process⁵⁷ however this is disputed by others. The implementation of information technology (IT) systems in primary practice to improve the organisation and handling of patient records has been in process for many years, however these systems, although designed to improve processes, are associated with unintended adverse clinical consequences by some commentators,^{58,59} particularly in the hospital setting.⁵⁹ It is suggested these unintended consequences are mainly due to the nature of healthcare work being incompatible with IT system design or implementation.⁵⁸ Other authors have similarly suggested that computerised systems may not be the source of adverse events, and that the processes of primary care rather than IT systems may be the main cause of the errors.⁵⁷

A study of Australian GPs reported that 89% of them used computers, to varying degrees, in their practice.⁶⁰ Only a third of GPs kept all patient data in electronic format, and only 22% used all of the computerised functions available to them.⁶⁰

Delays in diagnosis due to missed test results

The literature suggests that delays in diagnosis constitute a common risk and represent a significant threat to patient safety. Much of this delay can be attributed to problems in the reporting of the test results.^{61,62} In a survey of 106 primary care providers, Wahls et al.⁶² stated that 30% of respondents reported delays in diagnosis due to missed test results.

Medication processes

Medication error generally refers to mistakes made in the processes of ordering, transcribing, dispensing, administering or monitoring of pharmaceutical agents used in clinical practice. ^{4,63}

Errors in prescribing medications were the most common error described in the US and in other countries involved in developing taxonomies of error in primary care ⁶⁴. Some 70% of classifiable medication errors are due to errors in prescribing.⁶⁴ Approximately 80% of adults in the US use at least one medication (prescription, over-the-counter [OTC] or supplement) in any given week and the rate of use increases with age. ⁶⁵ Medication therapy accounts for approximately 70% of all visits to family practitioners and an average of over 2.5 medications are prescribed during these visits that involve any medication.⁶⁵

Unlike the hospital setting, where chart review is useful for identifying adverse drug events, in ambulatory care chart review reveals significantly less than GP self-reported complications.⁶⁶ Adverse drug events have been recognised to be a particular problem amongst older adults in the primary care setting, primarily due to the extensive use of medication by the older population.⁶⁷ Adverse drug events with cardiovascular agents and antibiotics showed the greatest frequency.⁶⁷

The most common form of prescribing error relates to dosage and half of the serious errors that occur appear to not be related to lack of knowledge of dosing requirements, are inadvertent and not made out of ignorance.⁶⁸

The degree to which patients adhere to the medication prescription may also increase risk in primary care. A lack of compliance with the prescribed medication regimen may increase the risk of preventable drug-related morbidities and this may be a particular issue in those groups in the older adult population where patients are prescribed multiple medications which may be confusing, especially where patients have little knowledge related to why the medicine has been prescribed.⁶⁹

Children represent a subset of the population who are at particular risk to medication errors. This risk arises because of the need for prescribers to be aware of paediatric medications and dosages applicable to children of varying ages.⁷⁰ Drug doses in paediatric populations are usually calculated individually leading to increased opportunities for dosing errors. Both descriptive research and expert opinion suggest that some healthcare professionals, including doctors and nurse prescribers, have difficulty calculating the correct dose for administration.^{70,71}

The increased use of over-the-counter (OTC) medications may also increase risk in primary care. Many commonly purchased OTCs have recognised adverse effects (e.g. NSAIDS) and general practitioners and other health professionals may not ask patients about their OTC medication use. Because of this potential problems risk being undetected.^{72 73} The use

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of OTC medications also results in a lack of complete medication records for patients and incomplete and often vital information is therefore not available for GPs.⁷⁴ It has also been suggested that the increased availability of OTC medication may result in delay among patients consulting medical practitioners for potentially serious conditions, preferring to 'self-treat' to see if symptoms are alleviated prior to making the effort to see the GP.⁷³

Communication processes

Professional opinion suggests that communication errors represent risk in primary health care.⁷⁵ Makeham et al (2008)^{33,} in their taxonomy of patient safety events in general practice, report three types of communications errors identified in their analysis:

- · Problems associated with general communication with patients,
- Problems associated with hospital discharge and other communication processes with hospitals,
- Problems associated with referral and general communication with other healthcare providers.

From the patients' perspective, breakdowns in access to and relationships with clinicians may be more prominent and have greater direct impact on the patient in terms of psychological and emotional harm, than do many technical errors.^{32,76,77}

When there are language differences (for example, between practitioners with English as their primary language and limited English-proficient patients or vice versa) communication difficulties may occur. In a qualitative study conducted in the US by Gadon et al⁷⁸ examining approaches to communicating with limited English-proficient patients, all of the physicians and office managers reported that language barriers impeded the quality and safety of patient care in their practices. Another US qualitative study by Matlow et al (2006)⁷⁹ designed to identify and compare communication issues among three paediatric outpatient clinics, identified language proficiency as a potential risk for patient safety in the ambulatory setting and suggest that further studies are needed to identify language and cultural issues that may affect patient care settings servicing a multiethnic population. Although the study populations were in the US and the study designs mean that the findings cannot be generalised to other populations, the multi-cultural nature of Australia may also present similar communication problems.

In a qualitative study of 20 general practitioners and 35 patients in the UK, investigating misunderstandings in prescribing decisions, a general lack of patient participation in the consultation and assumptions made by doctors without adequate confirmation with the patient were often the source of misunderstandings.⁸⁰ In these cases the doctor did not have adequate information about the patient and the patient did not have adequate information about the treatment being administered; this was reported to have actual or potential consequences for taking medicines.⁸⁰

Although no research-derived evidence was identified through the literature search, a number of opinion papers suggest that the literacy level of patients may impact on effective communication in primary care. One such paper of health literacy argues that patients with low heath literacy rarely leave a doctors consultation fully informed or with a clear understanding as to the nature of their health problem, what they need to do about it and
why it needs to be done.⁸¹ Another similar paper asserts that healthcare information in general is often complex, difficult to read, poorly designed and delivered in a way that does not match patients literacy and language levels.⁸² Low health literacy is also seen as a threat to patient safety, underlying misunderstandings, miscommunication, errors, increased and longer hospital admissions, poor health outcomes and higher healthcare costs.^{81,83} This problem is claimed to be most common amongst older populations, minority groups and immigrants with limited English proficiency.^{81,82}

Communication between healthcare disciplines is required to ensure safety and continuity of care. The period of patient transition from the hospital environment back to the community represents a period of risk to the patient when there is a lack of appropriate communication between the two different sectors of healthcare.^{84,85} Some 15% of all error reports from the TAPS study were related to hospital care. ⁸⁶ A review by Kripalani et al (2007).⁸⁵ found direct communication between hospital doctors and primary care doctors occurred only infrequently (3-20% of occasions).

Access to services

The increased use of the telephone for consultation and triage, particularly for after hours care, has increased over recent years and the practice has the potential for decreased physician workload.⁸⁷ A systematic review of five randomised controlled trials; one controlled trial; and three interrupted time series sought to establish the effects of telephone consultation and triage on safety, service use, and patient satisfaction. The authors concluded that although telephone consultation appeared to have the potential to reduce GP workload, questions remain about, amongst other things, patient safety. ⁸⁷

In a study of malpractice cases involving telephone consultations across a range of specialities including general practice, Katz et al (2008)⁸⁸ reported failed diagnosis to be the most common claim (68%) with death resulting in 44% of these cases. In their survey of after hours triage and the effects on patient safety, Hildebrandt et al⁸⁹ found that in 83% of the calls made to the 34 general practices studied, the patient was required to decide whether the problem was serious enough to warrant the immediate notification of the on-call doctor. Fifty per cent of the calls not forwarded on to the doctor, upon subsequent review, did in fact represent medical emergencies.⁸⁹

Although specific to the diagnosis and treatment of cancer, a study by Jiwa and colleagues (2007)⁹⁰ highlights problems encountered in ambulatory care particularly in rural Australia. As travel and distance are an issue to patients in rural communities, patients often 'save up' presenting symptoms to make the trip to see the GP worthwhile; referral to other clinics/services also often means travel of large distances.⁹⁰ The increased number of older patients in rural communities also impacts on treatment and the timely diagnosis of illness.

Risks associated with the knowledge and skills of service providers

Prompt diagnosis of poorly differentiated and potentially serious disease is one of the core competencies of the GP. Most medico-legal claims against GPs can be attributable to delay in diagnosis (greater than 50% of total) or misdiagnosis (approximately 30% of total)⁵⁴ as the underlying cause.^{91,92}

In Peterson et al (1999) ⁵¹ fatigue, high workload, overwork and interruptions all were found to have contributed to dispensing errors by pharmacists. Similar interruptions are reported as problems for GPs.⁸⁸

Informatics and computerised systems have been introduced to help with some of these issues, however even a well-designed computer system may not prevent busy clinicians from missing test results that are needed for correct and timely diagnosis.⁶²

In a study investigating predictors of diagnostic accuracy and the safe management of difficult diagnostic problems, it was found that the rate of misdiagnosis was related to the degree of difficulty of the diagnostic problem irrespective of the doctor's workload. This could include, for example, an atypical presentation of ischaemic heart disease – an ailment that the doctor might have previously encountered quite commonly in normal practice and dealt with effectively. Seventy eight percent of misdiagnoses was followed by inappropriate management, and 92% of correct diagnoses by appropriate or correct management.⁹³

Across the spectrum of primary care, inexperienced or incompetent staff present a risk to patient safety.^{93,94} The predisposition to use temporary staff has a greater impact in primary care than the hospital setting as the ongoing relationship between patient and provider is interrupted in these cases where temporary staff are employed. Rickard⁹⁵ outlines some of the risks encountered in dental practice with the use of temporary staff. Whilst operating with the best intentions, they may not be aware of the local systems or operations in place to manage risk appropriately.

5.4 Discussion

Australian and international studies with variable quality have attempted to increase understandings of patient safety in primary health care by developing taxonomies classifying errors made in primary care. The evidence from the systematic review suggests that the development and empirical testing of taxonomies of error may increase understandings of risks to patient safety.

Key safety issues (identified from the systematic review) that contribute to patient risk can be classified as process errors in domains such as diagnosis, prescribing, communication, policy and administration.

In studies that identified and described medical errors and their relationship to harm in the US health system, harm was not associated with incorrectly perform procedures or failure to perform procedures or to the general information flow into or out of the office. But, there is evidence from the systematic review to suggest that the therapeutic intent of an activity, language barriers, errors of judgment, communication from another office, mistimed procedures, and medication errors are associated with harm.

Administration Processes

Patient safety literature frequently identifies administrative processes such as documentation, reporting and information management as a source of risk to patient safety. There is evidence from the systematic review to suggest that a failure to capture and maintain accurate and comprehensive clinical information may represent a risk in primary care in US settings. Studies of adverse events in family practices in the US included in the narrative review note that office administration errors were the most frequently reported.

Diagnostic processes

The studies included in the narrative review suggests that delays in diagnosis constitute a common risk and represent a significant threat to patient safety and much of this delay can be attributed to problems in the reporting of the test results.

Treatment processes

A wide range of equipment is used in primary care and the potential exists for error in maintaining or using such equipment that may result in patient harm. There is evidence from the systematic review to suggest that failure to maintain ultrasound equipment in chiropractic clinics is a potential risk to patient safety.

There is a potential risk of nosocomial infection with ultrasound equipment. The evidence from systematic review suggests that contaminated ultrasound equipment in physiotherapy clinics could increase the risk of nosocomial infection in Australian primary care.

Processes associated with ordering, transcribing, dispensing, administering or monitoring medications

Medication error is the focus of most literature related to patient errors, hazards and incidents. There is evidence from systematic review to suggest that a failure to review and manage poly-pharmacy in older people represents a risk to patient safety in primary care.

The role of pharmacists in relation to error, unregulated alternative therapy and patient risk has also been investigated and there is evidence from systematic review to suggest that prescribing errors developed during the dispensing process and transcription stage contribute to patient risk.

There is evidence from systematic review to suggest that high prescription volumes, pharmacist fatigue, pharmacist overwork, interruptions to dispensing, and similar or confusing drug names, lack of systematic dispensing workflow and lack of regulatory guideline dispensing errors may result in errors and compromise patient safety.

The potential risks of limitations in the medication knowledge and medication literacy of patients were studied and there is evidence from systematic review to suggest that patient's misunderstanding of label instructions is a potential risk to patient safety, particularly for patients with low literacy and those who are prescribed multiple medications.

There is evidence from systematic review to suggest that formatting and readability of consumer medication information that does not facilitate patient understanding is a potential risk to patient safety

The evidence from systematic review suggests that gaps in US patient medication knowledge may represent a risk to patient safety

There is evidence from systematic review to suggest that GPs may benefit from training in cardiopulmonary resuscitation techniques in order to decrease risk to patients in emergency situations in Australia.

The literature included in the narrative review suggests that errors in prescribing medications were the most common error described in the US and in other countries involved in developing taxonomies of error in primary care.

Communication processes

Professional opinion included in the narrative review suggests that communication errors represent risk in primary health care.

Access to services

Studies of telephone consultation included in the narrative review suggest that questions remain about the effects of telephone consultation on patient safety.

Risks associated with the knowledge and skills of service providers

The literature included in the narrative review suggests that the rate of misdiagnosis is related to the degree of difficulty of the diagnostic problem irrespective of the GP workload. Also, the studies included in the narrative review note that inexperienced or incompetent staff present a risk to patient safety.

6. Systematic Review of the Evidence: Solutions to Minimising Patient Safety Risks in Primary Care

6.1 Review methods

The review methods have been described in general terms in Section 4 of this report. The detailed methods for this review are in Appendix 1.

6.1.1 Review question/objective

The objective of this review was to identify what research has been conducted regarding risks to patient safety and (where possible) assess the effectiveness of interventions suggested as solutions related to patient safety in primary healthcare. Specifically, the review question was:

What interventions (processes and activities) are effective in minimising hazards, risk, errors and harms associated with patients/clients receiving primary healthcare?

6.2 Results

6.2.1 Characteristics of included studies

A total of 51 papers were identified based on title and abstract. Following critical appraisal, a total of 28 studies were excluded on the basis of not meeting the review objectives, the remaining 22 were included in the review (refer figure 4). Retrieved papers were generally between level I – III evidence on the NHMRC levels of evidence scale and were mainly derived from the USA or UK within highly specific clinical contexts.

Figure 4: Selection of studies



The included studies considered solutions proposed in the literature to minimise risks to patient safety in primary care. In some cases solutions identified in the literature were specific and related to a particular risk, error or adverse event, whereas other research had a broader focus. Identified research broadly fell into 4 categories;

- Reporting;
- Prescribing;
- Education; and
- Communication.

6.2.2 Reporting

Two studies addressed systems for reporting and analysing incidents and error as a solution to reducing risk: one study of Level I evidence ¹² and 1 of Level III-3%. Neither study was set in Australia therefore the findings may not be applicable to Australian primary healthcare.

The role of agencies/authorities

Chang et al ¹² investigated the Joint Commission on Accreditation of Healthcare Organizations (JACAHO) patient safety event taxonomy. The authors retrieved existing patient safety terminologies and classifications from a systematic review and then used these terms to identify which ones to include within the core set of a standardised taxonomy. The authors then assessed how user friendly the taxonomy was by piloting among patient safety stakeholders in multiple disciplines – with the aim of applying a standardised terminology and classification schema for near misses and adverse events. The authors identified five fields that a useful taxonomy should include to facilitate standardisation: Impact, Type, Domain, Cause & Prevention, and Mitigation. Standardisation was important as it allowed more accurate record keeping. It also ensured that those reporting extract standardised details so that incidents can be compared.

The systematic review by Chang et al (2005) ¹² illustrates that the lack of a standardised system for organisation of information has meant that it has been difficult to make valid comparisons between the significant amounts of data that have already collected.

The role of individual healthcare practitioners

Cox and Holden ⁹⁶ undertook a retrospective review of significant events reported in one district in Northern England between 2004 and 2005. The authors used a significant event analysis (SEA) to identify learning points for the practice where they had occurred. The aim was to determine whether SEA is effective at increasing patient safety in general practice. Staff in the practices were asked to report on and grade adverse events. They then identified learning points from the events and put into practice strategies to prevent re occurrence.

Three hundred and thirty-seven events were reviewed during the study. The majority of the general practices (22/32) were able to complete SEA with no further support, four needed further support to implement and six had extreme difficulty and required further training. This study provides evidence (Level III-3) that it is feasible for a practice to discuss significant events within a SEA framework. Further data is needed to determine the effectiveness of such an undertaking.

Key Finding: Evidence on Solutions to Minimise Risk

The evidence suggests that, in UK general practice, significant event analysis is feasible. (Level III-3)

6.2.3 Prescribing medications

A total of 10 studies that examined ways to decrease prescription errors were included, however it should be noted that none of these studies were undertaken in Australia, therefore application to the Australian context has not been established.

Royal et al ⁹⁷ report on a systematic review to examine interventions in primary care to reduce medication related incidents and hospital admissions. The authors identified evidence, predominantly from the USA, to examine pharmacist led interventions and eight

interventions led by other primary care professionals and 13 interventions with a component that also addressed medication review. There is relatively weak evidence to indicate that pharmacist-led medication reviews are effective in reducing hospital admissions, however there is currently no evidence for the effectiveness of other interventions that aim at reducing admissions or preventable drug related morbidity. No significant effect was found for interventions led by nurses and doctors (OR 1.05, 95% CI 0.57 - 1.94).

Krska et al 2001 ⁹⁸ conducted a randomised controlled trial in a Scottish primary care setting in order to determine whether a multidisciplinary approach (pharmacist and GP) could reduce medication related problems in patients with chronic diseases who took multiple drugs. Medication related problems included adverse drug reactions, poor compliance with therapy and inappropriate drug selection. Pharmacists reviewed the medications of 332 patients who took at least four prescribed medications daily, with at least two chronic health conditions and two pharmacy issues (not defined). The intervention group had their medications reviewed and a pharmaceutical care plan drawn up and the control group received usual care. Seventy percent of the medication problems identified in the intervention groups were resolved after 3 months, compared with 14% in the control groups. The authors report pharmacist-led medication review can substantially reduce pharmacy issues and therefore the potential for medication-related errors. They also suggested that anyone 65 years or older ought to have a pharmaceutical review. Although this is a single study, it provides some evidence to suggest that regular review of medication is one way in which the risk of medication errors may be reduced.

Key Finding: Evidence on Solutions to Minimise Risk

The evidence suggests that there is some small benefit of pharmacist led medication review to reduce hospital admissions (Level I-II).

Computerised medication ordering systems

The majority of computerised medication ordering systems include safety features that alert the healthcare professional (prescriber) to possible drug-drug interactions within drugdisease interactions. Seven studies, of varying designs were identified that examined the effectiveness of automated alerts. The majority of the studies (5) were conducted in the USA ⁹⁹⁻¹⁰² and the remaining two in the UK ^{103,104}.

Three studies suggest that medication prescribers (largely general practitioners) will take note of computerised medication alerts, one study reported that prescribers will ignore alerts they feel are conservative and one report revealed that there are major flaws in alert systems which may leave potential medication errors undetected.

Linder et al 2006 ¹⁰⁵ performed a cross sectional study to compare an electronic diagnosis and antibiotic prescribing system to the gold standard of blinded clinician chart review in order to determine whether a computerised system would make the same diagnosis and prescription of antibiotics as a clinician. This study was conducted to assess both the accuracy of, and the potential of, these systems to generally improve electronic diagnoses and electronic antibiotic prescribing for acute infections, ARI and UTI, in primary care. Compared to usual practice (clinician visit notes), electronic antibiotic prescribing had a sensitivity of 43%, specificity of 93%, and a positive predictive value of 90%. The level of agreement between electronic antibiotic prescribing and antibiotic prescribing according to visit note varied significantly across the participating clinics, ranging from 25% to 79% (p<0.0001). The sensitivity of electronic antibiotic prescribing increased from 22% to 58% over three years (p>0.0001).

Case notes were derived from 9 US primary care clinics. Electronic ARI and UTI diagnoses showed high sensitivity and specificity. Electronic antibiotic prescribing had a sensitivity of 43%, specificity of 93% and positive predictive value of 90%. Over the three years of the study, electronic antibiotic prescribing increased from 22% to 58%. Over the same period simple agreement between electronic prescribing and physicians notes increased from 51% to 73%.

This study had limitations that should be considered. The clinician visit notes are an imperfect gold standard. There was no follow up as to whether the physician wrote a prescription for antibiotics, or that the patient actually filled the prescription or that the patient took the antibiotics. Also, there was no double-checking to determine whether the diagnosis was confirmed. The results may not be generalisable to other settings, types of electronic health records, patient conditions, and medications. The sensitivity of electronic prescribing may impinge on patient safety and therefore it is recommended that clinicians, researchers and managers understand the accuracy of electronic data and specific areas where clinical decision support system can potentially reduce error, such as with handwritten prescriptions and checking for medication interactions.

Key Finding: Evidence on Solutions to Minimise Risk

The evidence suggests accuracy in electronic prescribing is improving, but still has room to improve further (Level III)

Steele et al 2005¹⁰¹ examined the effect of automated alerts on provider ordering behaviour in a US outpatient setting. As prescribers ordered medications on a computer, an alert was displayed if a relevant drug–laboratory result interaction existed. The number and type of laboratory tests a prescriber ordered was monitored in response to automated drug alerts. Drug-laboratory interaction refers to clinically relevant laboratory determined values associated with medication use. The study focussed on interactions related to medication use that could lead to hyper or hypokalaemia, as an example. As providers ordered medications on a computer, where an "abnormal" or "missing" laboratory value was encountered using rules technology, an alert would be provided.

Adverse drug events were assessed through a random sample of chart reviews using the Naranjo scoring scale. During the post intervention period, an alert was displayed for 11.8% (1,093 out of 9,274) of the times the rule processed, with 5.6% for "missing laboratory values," 6.0% for "abnormal laboratory values," and 0.2% for both types of alerts. Focusing on 18 high-volume and high-risk medications revealed a significant increase in the percentage of time the provider stopped the ordering process and did not complete the medication order when an alert for an abnormal rule-associated laboratory result was displayed (5.6% vs. 10.9%, p=0.03, Generalized Estimating Equations test). The authors

concluded that prescribers adhere to alerts and use this information to improve patient care - specifically, in response to drug–laboratory interaction alerts, and the ordering of appropriate laboratory tests. Implementation of rules technology to prevent medication errors could be an effective tool for reducing medication errors in an outpatient setting. These results are from a single study, based in a single clinic and may not be generalisable to other types of prescriber, clinic or medications.

A Canadian study ¹⁰² examined whether immediate, online access to drug information, prescribing history and automated alerts (computerised-decision support) would improve prescribing practice and decrease medication errors. In this context the authors found computer-based access to complete drug profiles and alerts about potential prescribing problems did reduce the rate of initiation of potentially inappropriate prescriptions by 18% compared with usual care controls.

A cohort study in one Irish general practice ¹⁰³ showed that physicians would comply with computer alerts when prescribing one of three non-steroidal anti-inflammatory drugs (NSAIDs) with a good degree of compliance (84%). This resulted in a relatively low number of adverse events (10.2%). As with the Steele study above, these results are from a single study, based in a single clinic and may not be generalisable to other GPs, clinics or medications.

Fernando et al 2004 ¹⁰⁴ developed a list of 55 theoretically derived statements using a Delphi technique and used these to generate 18 potential patient safety scenarios.. These statements were related to eight broad themes covering key areas in the medicines management process: prescriber alerts, reports and clinical audit, user interface, repeat prescribing, decision support, coding, monitoring, and links to laboratories. The aim was to determine how well the UK's four most commonly used prescribing computer programs could identify patient risk situations in terms of investigating appropriate alerts when contraindicated drugs or hazardous drug-drug combinations were prescribed. None of them identified drug-drug interactions or contraindicated drugs. The best performance was 7/18, two scored 4/18 and the fourth scored 3/18. In terms of prescription of drugs with similar names, none of the systems warned for all ten drug pairs considered. The best performance was 7/18, two scored 4/18 and the fourth scored 3/18.

A survey using a convenience sample of American general practitioners was conducted to assess one of six electronic prescribing systems.¹⁰⁰ The authors reported that 40% of participants would override alerts as they considered them to be too conservative and specifically that alerts regarding drug-drug interactions were too sensitive.

Conroy et al 2007 ⁹⁹ investigated whether children were at particular risk of adverse effects and whether using an automatic/electronic system might decrease the likelihood of the risk of dose calculation errors. The authors conducted a systematic review to identify published articles reporting interventions; 28 studies were found to be relevant. The main interventions found were computerised physician order entry (CPOE) and computer-aided prescribing. Most CPOE and computer-aided prescribing studies showed some degree of reduction in medication errors, with some claiming no errors occurring after implementation of the intervention. However, one study showed a significant increase in mortality after the implementation of CPOE. The evidence therefore is equivocal with regard to computerised systems for drug dose calculations and prescribing as interventions to minimise risk among children.

Key Finding: Evidence on Solutions to Minimise Risk

The evidence suggests that IT systems that utilize alerts, impact prescribing practice and may reduce risks associated with prescribing (Level III-1).

Computerised systems that link prescribing to laboratory results and highlight drug-drug interactions may also reduce risk but there is evidence to suggest that they may also represent risk in terms of error or over-ride of system rules by clinicians (Level IV-2).

6.2.4 Education

Discussion of potential errors, or situations which increase the risk of the occurrence of an error, raising awareness of what constitutes an error, as well as analysing previously reported errors, have all been proposed as learning tools and possible interventions to reduce risk of error. Eight reports were categorised under this heading;

- addressing learning issues in US medical students (2) ^{106,107}
- addressing UK practitioner education (4) 93,108-110
- examining learning issues in Danish community pharmacies (1) ⁵⁰ and examining an education intervention delivered to UK patients (1) ¹¹¹.

Health professional education – US medical students

Two pre-post studies examined the effectiveness of education programs on the ability and confidence of US medical students to identify and discuss medical errors.

Halbach and Sullivan ¹⁰⁶ utilised a short (4 hour) multifaceted educational program designed to address patient safety issues. Students were asked to complete the same seven-item questionnaire both at the start of and after completion of the course. In addition, each student was asked to complete a 13-item evaluation of the curriculum at the end of the session. Finally, an anonymous, 12 item follow-up questionnaire was sent to all students approximately two to eight months later that asked them about subsequent experience with medical errors since their training. No student reported discussing an error directly with a patient, however they reportedly felt more aware and better equipped to identify and report errors. The authors concluded that education about patient safety and medical errors can be implemented and maintained in undergraduate medical education, however the effectiveness of a 4-hour intervention of this nature has yet to be established.

The second study (Singh et al 2005) ¹⁰⁷ also addressed patient safety from several aspects, including students attitudes and responses to medical errors; this intervention was taught as a designated unit in combination with other subjects. The authors reported that by using audits, journals and quality improvement exercises, the students were able to demonstrate improved abilities to reflect on their own practice and apply safety principles to address both actual and potential errors.

It remains to be determined whether such programs are effective solutions, as the participants were not in a position to effect change at the time of the intervention. It also remains to be determined whether such programs would be feasible in medical schools and in countries other than in the USA.

Healthcare professional education - general practitioners

Baker et al (2007) ¹⁰⁸ detail a systematic review of 53 studies, set mainly in UK general practices. The aim of the systematic review was to determine whether data concerning patient deaths (mortality data) could generate patient safety learning points.

The review examined the impact of primary care provision on mortality rates, methods of monitoring mortality, and the role of audit and death registers in treatment quality and safety improvement. The authors reported that general practitioners were interested in using mortality data but experienced difficulties in obtaining complete information. There were no experimental studies on the impact of the use of mortality data, and little evidence of long-term systematic initiatives to use mortality data in quality and safety improvement in general practice. The authors concluded that although mortality data is not used systematically in general practice, the general practitioners included in the studies did appear interested in the potential of this information in improving quality and safety.

Wallace et al 2007¹¹⁰ examined interventions within the English health authority designed to improve risk management in general practice. Educational interventions included: the practices' own initiatives, significant event audit (SEA) and the Medical Defence Union's workshops (which included significant event analysis of reported errors). The authors reported the effects of promoting education among GPs, Practice Nurses, Practice Managers and administrative staff. There was improved competence in identifying and managing patient risk over the period of the study, particularly through widening the breadth of staff involved in patient safety and in using formal recording systems. There was little evidence that these improvements were mediated by implicit organisational cultural values related to openness or acceptance of learning opportunities. A clinical audit would need to be undertaken to assess the effectiveness of the interventions in practice.

Key Finding: Evidence on Solutions to Minimise Risk

There is evidence to suggest that educational interventions increase awareness of patient safety risk in both medical students and medical practitioners, however there is no evidence to suggest that this increased awareness can be observed as a increase in patient safety (Level III-3)

Patient education

The search of the literature revealed a paper pertinent to the issue of patient education as a modality for mitigating risk to patient safety ¹¹¹. The aim of this randomised controlled trial was to determine whether providing patients with generalised leaflets would encourage them to raise any issues or queries concerning their treatment, or lead to altered interactions with their GP or a change in the number of investigations requested by the GP. The main outcomes of the study were a mean item score on the medical interview satisfaction scale, consultation time, prescribing, referral, and investigation. The authors

reported that the general leaflet caused a small non-significant increase in consultation time (0.36 minutes, 0.54 to 1.26). Although there was no change in prescribing or referral, a general leaflet increased the numbers of investigations (odds ratio 1.43, 1.00 to 2.05), this outcome persisted when controlling for the major potential confounders of perceived medical need and patient preference (1.87, 1.10 to 3.19).

This study suggests that encouraging patients to raise issues and to discuss symptoms and other health related issues in the consultation improves their satisfaction and perceptions of communication, particularly in short consultations, however there is no direct evidence that this approach improves patient safety.

6.2.5 Communication

In the course of a medical investigation, a patient may need to communicate their symptoms or treatment preferences to several healthcare professionals, who in turn may need to communicate with professionals from other disciplines. At any stage miscommunication could lead to an adverse event. Interventions that make communication more direct and simple would in theory reduce the likelihood of error. Improved communication with healthcare facilities may increase the safety of patients who are unable to access mainstream general medical services, for reasons including geographical isolation.

This section of the review identified 2 papers that examined interventions aimed at improving communication between the patient and healthcare professional ¹¹² or between healthcare professionals ¹¹³.

A proposed alternative to GP consultation is the telephone consultation line. Although some telephone consultation is done by GPs, gualified nurses using computer-based clinical decision support systems are also utilised. One of the largest telephone consultation systems in operation is the English National Health Services (NHS) Direct. This is a 24-hour nurse-led telephone advice system that aims to help callers to self manage problems and reduce unnecessary demands on other NHS services. This type of intervention could potentially offer three benefits: it could free GPs time to attend to more serious cases, offer direct access to medical help to those who are unable to attend GP services and provide direct access to medical information and advice. Bunn et al 2005 87 conducted a systematic review with the aim of assessing the effects of telephone consultation triage on patient safety, service use, and patient satisfaction. The review included nine studies, with eight set in the UK. Six studies compared telephone consultation with normal care; four by a doctor, one by a nurse, and one by a clinic clerk. Outcomes were mixed, with one study finding a significant reduction in same day GP visits (P<0.001), while two other included studies found participants subsequently required more face-to-face follow up visits. In general at least 50% (range = 25.5-72.2%) of calls were handled by telephone consultation alone. Seven studies reported on accident and emergency department visits. Of these, six showed no difference between groups and one - of nurse telephone consultation - found an increase. Two studies reported deaths and found no difference between nurse telephone consultation and normal care.

The authors concluded that immediate visits to general practice decreased, although longer term data suggest this outcome was not sustained; and that the advice provided by the helpline was at least as safe as that given by a GP.

Key Finding: Evidence on Solutions to Minimise Risk

There is some evidence to suggest that communication between patient and the healthcare professional via a telephone helpline can reduce the need for GP consultation without associated risk to patient safety. (Level III-3)

A Finnish controlled clinical trial ¹¹³ evaluated the effects of tele-radiology on diagnosis of patients in primary care. The study was conducted in two phases; in phase 1 GPs selected cases where radiographs were transmitted to a university hospital for follow up of radiological diagnosis by senior radiologists; in phase 2, all radiological examinations were transferred to the hospital for a tele-radiology consultation. During phase 1, 15% of the radiographs transmitted represented cases where pathological conditions were undiagnosed by the GP. False positives were reported in 40% of cases. The sensitivity was 0.85 and the specificity 0.62. During phase 2, 13% of pathologies were undiagnosed and 14% of cases represented false positives. The sensitivity was 0.90 and the specificity 0.86. As GPs specificity was lower than sensitivity this may result in unnecessary treatment. In almost 66% of cases in phase 1, the use of tele-radiology helped with diagnosis and in 9% of cases a completely new diagnosis was made. This compared with 31% and 4% respectively for phase 2. The authors conclude that adequate accuracy and safety cannot be achieved if the examinations sent for radiologist analysis are pre-selected by the GP as in phase 1 of this study. In most cases tele-radiology had no effect, however the general opinion of staff and patients in the primary care centre was that tele-radiology increased patient safety.

Key Finding: Evidence on Solutions to Minimize Risk

There is some evidence to suggest that the use of technology to access radiological experts may have the potential to decrease errors made in diagnosis based on radiographs by GPs in primary care. (Level III-3)

6.3 Narrative review of the literature

Where little high quality evidence or where there is a need to "scope" a field of knowledge, the use of a narrative review process enables reviewers to consider diverse forms of literature.⁸ Narrative review seeks to summarise the current state of knowledge in relation to a particular question through considering a wide field of sources and reaching conclusions through reason or argument. ^{9,10} This narrative component of the review summarises the scope of discussion in the general literature and in reports on the solutions proposed in the literature to minimise risks to patient safety in primary care that were not of sufficient quality to be included in the main review.

This section considers solutions identified in the literature that were particular and related to a specific hazard, risk, error or adverse event. Other literature reporting on research focusing on solutions to minimise risk was less pointed in its content, addressing issues encompassing systems of health care as a whole and incorporating psychological/attitude changes that were seen to need to be made to further the cause of safety in primary care. Most western countries with comparable primary care healthcare systems, including Australia, have national authorities in place to coordinate the push towards patient safety driven models of care. Such models consider the complex nature of healthcare by incorporating principles from disciplines such as psychology and systems engineering with the overall aim of establishing a centrepiece 'culture' of patient safety in health care.^{92,114,115} As an example the NHS in 2005 released it's document "7 Steps to Patient Safety in Primary Care"¹¹⁵ This model is claimed to be a valuable means to enhance patient safety.¹¹⁵

Organisations in the NHS are encouraged to integrate risk management processes and risk assessment at an institutional level incorporating all of the people, tasks and processes involved.^{92,115} Active risk assessment should enable primary care organisations to appreciate the risks they face, their likelihood of occurrence and their ability to control these risks.⁹² Agencies and authorities are encouraged to ensure that reporting and information is transformed into opportunities for healthcare workers to learn from adverse events, and that safe practice recommendations are implemented effectively.¹¹⁶ The role of national bodies in promoting and realising patient safety initiatives is exemplified (with regards to error related to medication), in Denmark via the 2003 Act on Patient Safety in the Health Service that obliges health professionals to report adverse drug events through a national reporting system. The National Board of Health is obliged to respond to these reports.^{50,117}

Safety improvement relies on a cycle where errors are continuously documented, reported and evaluated. The NPSA in the UK also set up the National Reporting and Learning System (NRLS) in 2003 to ensure that the lessons learnt from adverse events in one locality inform health services as a whole, including community and whole of health approaches.^{47,118,119}

Reporting by healthcare providers

Reporting of medical errors is a widely recognised mechanism for initiating patient safety improvement both in the hospital and in the ambulatory care setting. A recognised strength of error reporting is that it occurs at the front line of care and, therefore has the potential to increase mindfulness of safety issues as they occur in real time.¹²⁰ The Australian Incident Monitoring System or AIMS is an example of a system implemented in hospitals, where organised error reporting can form part of a risk management strategy in health care.¹²¹ It may though, be confounded by under-reporting. Many reasons have been put forward for underreporting, including lack of recognition of errors, confusion about definitions of terms, fear of blame and punishment, concerns about anonymity/confidentiality and time and effort to write incident reports.¹²² Changing the terminology associated with error reporting in acute care services from a 'near miss' to 'a good catch', having time during a shift to complete a safety report, and promoting safety incentives to acknowledge individual nurses all resulted in an increase in the amount of error reporting, and the awareness of safety issues by staff.¹²²

Another barrier has been the belief that error reporting will make no difference. Elder *et* al (2006)¹²³ describe 4 factors that were considered most important to completion of error reports amongst doctors interviewed: the burden of effort to make the report, the perceived benefit from making the report, the clarity about what to report and the properties of the specific error, such as the severity and who is responsible.¹²⁰ Although there is no empirical evidence, it may also be similar to primary care in Australia, where a lack of local level

resources increases the burden of effort and impacts negatively on the perceived benefit of reporting.

Currently, for acute care, the NPSA (UK) recommends that a significant event audit or analysis (SEA) should be utilised as a reporting mechanism if a safety incident has resulted in either no harm to a patient, or has caused 'minor' or 'moderate' harm. Root cause analysis (RCA) reporting is recommended in cases resulting in severe harm or death.¹²⁰ These types of tools have been highlighted as useful mechanisms to mediate improvements in risk management where staff can see tangible results and benefits.^{110,124} It has been argued that these tangible benefits are more effective and necessary than simply a change in safety 'culture'.¹¹⁰

Failure mode and effects analysis (FMEA) has also been identified as a reporting instrument to achieve performance improvement and prevent patient injury.¹²⁵ To have a comprehensive safety plan, Brous¹²⁴ suggests organisations must conduct both RCA and FMEA. A study by McKay et al.¹²⁶ found that the more severe the error the more likely the GP to report it due to the perceptions that others could learn from it. Studies report a distinct preference amongst GPs to not involve the patient in the event analyses to maintain anonymity or legal immunity in reporting, and preferentially report to an educational or research body.^{117,126} As well as being confidential, doctors have also reported the preference for independent, non punitive and systems orientated reporting systems related to medical error.^{127,128}

Information technology

The implementation of computerised health information systems has been viewed as a method to mitigate the widening gap between supply and demand in healthcare and to improve efficiency and safety.⁵⁷ Computers, offer the possibility to store and manage patient data (co-morbidities and past medical history) as well as information related to pharmaceutical products (dose, DDI, and side effects). Computerisation and informatics have been hailed as the answer to many 'process' errors that occur in primary care that may result in potential or actual risk to patient safety. Many errors classifiable as administrative, payment and even treatment errors can benefit from IT solutions. One such group of errors related to treatment with medication has been the focus of large volumes of literature on how informatics can reduce error and increase safety.

Computerised drug ordering systems have become regarded as "best practice" because of their reported impact on the prevention of medication errors in hospitalised patients. However, studies have found that doctors override approximately 90% of drug allergy alerts and 70-90% of high severity DDI alerts.¹²⁹ Further to these limitations, some literature questions the usefulness and design of these IT systems – in some cases their introduction has introduced new risks to patient safety.^{59,104,127,129-131} Clinical computer systems that allow audit trials for actions taken by prescribers, including overriding of drug alerts have been suggested as a means to monitor and also justify prescribing actions.¹³²

A large number of prescription errors arise as a result of mistakes made in attempting to read the handwriting of physicians.^{133,134} An updated Cochrane review of computerised advice on dosing to improve prescribing included 23 trials over 10 years and concluded that there were significant reductions in time to achieve therapeutic control using such

systems.¹³⁵ Using computerised advice for drug dosage had no effect on adverse reactions reported.¹³⁵

In a qualitative study by Avery et al (2007)¹³² general practice computer systems were again put under scrutiny by clinicians, computer system and drug database suppliers, academics and members of related representative bodies. Studies report too much unimportant irrelevant information, often lacking supporting evidence, was included which made the systems onerous to use and detracted from the relevance of the data being reported. A randomised controlled trial on the impact of computerisation on prescribing found a reduction in the initiation rate of potentially inappropriate medication.¹⁰² Only a minority of GPs who used computerised systems in practice had received instructions on the system safety features.¹³⁶

Beyond its effects on medication safety, informatics and computerisation offers the potential to avoid many other errors in primary care, particularly administration type errors. A systematic review addressing the adoption of health information systems in primary care found that the systems graphical interface design, feature functionality, project management and users previous experience with such systems affect implementation outcomes.⁵⁷ The review found interaction between technical features of the information systems and social features of the primary care work environment complicate the implementation and use of these systems.⁵⁷ The authors view was that there may be a relationship between the technical features and the interpersonal interactions needed to carry out the day-to- day clinical tasks associated with health care delivery. The authors concluded that health information systems do not significantly impact on patient safety.⁵⁷ Moreover, it was suggested that by incorporating doctor's medical knowledge and understanding of the healthcare in IT system design, and having stronger IT management by physicians themselves, the benefits would be twofold: systems would begin to achieve their intended purpose to improve efficiency; and it would also help avoid many of the errors these systems have created rather than solved in practice.^{57,58} Regardless, important clinical information was less likely to go missing where clinicians reported having full electronic records.35

Other areas where it is reported information exchange can improve safety include improving laboratory information processing by helping to ensure the indicated lab test is ordered and helping to ensure the appropriate lab tests are conducted and followed up, although the patient may have multiple care givers.¹³⁷ Proper information exchange can offset instances where safety is potentially jeopardised due to healthcare providers having little or no information about patients who present to them.¹³⁷ As electronic information exchange increases, health professionals run the risk of assuming that all information is being exchanged adequately and completely and decreasing vigilance.¹³⁷

Medication safety solutions other than IT

Adubofour *et al* (2007)⁶⁵ provided an overview of strategies that can be adopted in primary care to decrease medication errors. The authors suggest physicians should create their own "personal" formulary of frequently used medications and become familiar with up to date information regarding these agents.⁶⁵ Pham and Dickman¹³⁸ go so far as to suggest that doctors should avoid new prescriptions to avoid ADEs in older patients. Writing the

indication for use next to each drug prescribed is another possible measure, and facilitates double checking by the person dispensing the medication.^{133,134}

Multiple drug use in particular has been associated with adverse events.¹³⁹ Having patients taking multiple drugs bring medications to follow up visits can help avoid confusion. With fixed dose combination medication it is particularly important to distinguish the active ingredient to prevent potential problems.⁶⁵

Patient involvement is important, particularly where multiple doctors and pharmacies are involved, as communication breakdown between these providers can lead to error or harm. In these cases, the patient is best placed to maintain vigilance as to their therapy. It would be preferential to use a single pharmacy.⁶⁵ Education of patients enhances their role in preventing medication errors. Research suggests consumer information accompanying medication samples and many prescription drug labels are written at a reading level exceeding that of many consumers.^{44,45} Furthermore the printed text is often too small with only 11% of printed information using pictorial aids.⁴⁵

There is some evidence to suggest that pharmacist input into the prescribing process has the potential to decrease complications associated with medication therapy,⁷⁰ and that the majority of clinicians (63% in the US) use pharmacists preferentially as an information source.¹³¹ Adequate information should be provided by hospitals to community pharmacies upon discharge of patients to ensure continuity of care.⁸⁴ The involvement of pharmacists, independently, or liaising through GPs has been used to follow up patients' drug therapy in scheduled visits in between medical appointments and to review patients on long term medication. Other roles for community pharmacists include management of repeat prescriptions, which one RCT has shown can reduce ADEs.¹⁴⁰

Adubofour *et al* (2004)⁶⁵ also suggests medication reviews should be conducted periodically, with a pharmacist to ensure patients are taking the right medications safe from preventable errors. A systematic review by Royal et al (2006)⁹⁷ found only weak evidence to suggest pharmacist led medication reviews in primary care are effective in reducing hospital admissions. Interventions, particularly educational, led by other health care workers including nurses have also been found to be ineffective.⁹⁷ Further to this, distribution of educational materials has been found to be of limited use.¹⁴¹ However, performance audit and feedback was effective when existing baseline compliance with recommended practice was low.¹⁴²

It is also recommended clinicians should have knowledge of commonly used herbal/alternative therapies.⁶⁵ A systematic review by Ernst⁴⁸ suggests that many adverse events are associated with herbal medications, particularly in younger populations with whom these therapies are increasingly popular. A proper drug history should be taken to avoid unintended effects, including information on alternative medicines, supplements and OTC medications that may be uncommon in general practice.⁶⁵ Any allergy history should also be prominently displayed on the patient's chart. It has been argued that regulatory bodies, professionals and the drug industry have a responsibility to ensure that robust systems are in place to ensure the safety of OTC medications.⁷³ Given clinicians have been found to mis-categorise potentially interacting drug combinations 45% of the time,¹³⁰ recognition of potentially interacting drug pairs is essential.¹⁴³

An essential component to avoiding harmful drug reactions is to recognise and monitor patients at high risk.⁶⁵ Anticoagulants, NSAIDS and cardiovascular drugs make up over half of potentially preventable medication related events, and anti-neoplastic drugs, opiates, steroids and antibiotics also feature prominently.^{67,144} Many recommendations on the monitoring of potentially harmful drug reactions are endorsed by the WHO's regulations on appropriate drug prescribing.¹⁴⁵

Interventions to improve compliance presented in the literature may be grouped into 2 categories: educational and behavioural.^{69,146} Educational interventions aim to increase patient knowledge about the medication and/or the disease; behavioural interventions seek to incorporate drug therapy into the patients' routine. This can be via enhanced communication and counselling, including more time being spent with the dispensing pharmacist as well as the prescribing physician,⁶⁹ simplifying dosing schedules and involving patients in their own treatment via self-monitoring. Simple aids such as medication cards (with easy to read information related to new prescriptions) and medication review by a pharmacist could improve compliance particularly in older people.^{65,69} Monetary incentives have also been used to increase compliance.¹⁴⁶ In their review of the literature, Guerriero et al (2005)¹⁴⁶ suggest behavioural interventions have been more useful than educational ones.

Education

Education has been identified as an important and in many ways effective response to adequately addressing many of the issues raised in this review regarding the risks to patient safety. Improved education of both patients and healthcare providers has been identified as beneficial to patient safety. Short professional education courses have been used to address safety issues with some success in the acute care sector, application to primary care has not been established.¹⁰⁹ Trends reported in the literature suggest that there has been a push in recent years to make patient safety a larger part of medical and nursing curricula.^{52,91,109,147-149} These citations demonstrate a range of professions and models have been implemented, including undergraduate training, training in root cause analysis, and modelling techniques, however, there is no evidence regarding the effectiveness in relation to risk reduction in primary health. Again any development of a suitable and specific curricula related to patient safety is dependent on an effective and accurate reporting system being in place.¹⁴⁹ A further finding was that practices should have appropriate training manuals, guidelines, policies and rules available for staff to access; however, again this finding has not been established in relation to primary care.⁹⁵

Education of practitioners to improve safety in primary care has also received some focus, the Royal College of General Practitioners recently issued a detailed curriculum statement to guide general practice training that includes patient safety.¹⁵⁰ In 2005 the Australian Council for Safety and Quality in Healthcare published a National framework describing the knowledge, skills and behaviours that all healthcare workers need to ensure safe patient care.¹⁵¹ It provides a national guide to the required knowledge and performance needed by healthcare workers to take responsibility for patient safety. The education framework has been designed to be specific to all settings in healthcare worker needs in order to maintain patient safety.¹⁵² The topics that make up the framework include:

- Communicating effectively,
- Identifying, preventing and managing adverse events and near misses,
- Using evidence and information,
- Working safely,
- Being ethical,
- Continuing learning, and
- Specific issues

The specific details of this framework are detailed by Walton et al (2006)¹⁵²

Communication factors

Consumers and patients on the whole appear to want more information on their treatments and conditions, and to develop better relationships with health professionals.¹⁵¹ Health professionals themselves also express the desire for better information sharing with other heath care professionals.¹⁵¹ Information processing and information exchange, which ensures that the right information is available about the right patient at the right time, has been identified as a major step towards improving patient safety in healthcare.¹³⁷

Byrd and Thompson (2008)⁸¹ recommend presenting health information in clear, plain language, ensuring written information is presented at no higher than grade 5 reading level and use of supplemental graphics, cartoons and photos.^{81,82} Medical malpractice insurers have highlighted the importance of provider-patient communication and having informed patients. Consequently, undertaking specific communication skills training is a condition of being insured in the US and Australia.⁹¹ The effectiveness of this strategy in relation to patient safety in primary care has yet to be established. Canada has adopted a similar goal, but placed the focus on the consumer seeking information rather than relying upon health professional communication. A recent directive implemented in Canada⁸¹, "It's Safe to Ask" encouraged patients to ask three simple questions to overcome issues with health literacy:

- 1. What is my health problem?
- 2. What do I need to do?
- 3. Why do I need to do this?

Key to the success of such a venture is the sustained effort of managers and champions to support it with education and assistance.⁸¹ The NPSA has recently launched a similar "Please Ask" campaign in the UK with the aim of making patients more aware of their own healthcare.⁹¹

The use of interpreters has been suggested to address the problem of dealing with patients with limited English proficiency, however the cost of these services can be considerable. GPs have been reported as relying upon their staff or a patients family member, who may be proficient in the said language to aid with interpretation.⁷⁸

Kripalani et al (2007)⁸⁵ emphasised the need for urgent improvements in the processes and formats used for transferring information to primary care clinicians at hospital discharge. Patients with complex problems are often treated post-hospitalisation, before any receipt of information from the hospital leading to a greater risk of re-admission. These authors

suggest an association between the delivery and quality of discharge summaries and health information technology allowing fast extraction of information about diagnoses, medication, and test results.⁸⁵ Aside from technological solutions, giving a copy of the most pertinent data to newly discharged patients should increase the likelihood that this information will be available to the primary care physician. A combination of the two approaches has also been advocated for, albeit not demonstrated to be effective.⁸⁵

Clinician factors

In a study investigating diagnostic accuracy, additional cues or extra, important information was found to significantly increase diagnostic accuracy among family clinicians. Experience or lack thereof was not found to be a mitigating factor, though less experienced practitioners required more cues or additional information to improve diagnosis and management.⁹³ To aid in this regard computerised clinical decision support systems have been viewed as helpful and potentially useful by clinicians, if designed with flexibility and usability in mind.¹⁵³ A qualitative study of patient safety features in the GP electronic health record highlighted the potential to link information in the record with external data to provide decision support and safety alerts.¹³⁶

Reiner and Seigel (2004)¹⁵⁴ detailed aspects of a pay for performance scheme in medical imaging which they suggest, amongst other things, may improve patient safety by ensuring financial incentives are preserved for quality of service. Actual evidence to support this view was not identified.

Patient factors

It has been suggested that encouraging patients to monitor their treatment, report incidents and the like will have limited impact on specific problems with regards to safety unless it is coupled with national error reporting schemes.¹¹⁴ Patients are well placed to notice unexplained changes in their medication and in a study of medication errors patients reportedly prevented 17% of errors.⁶⁴ An automated telephone self management support program for diabetes patients resulted in the detection of significantly more adverse events and potential adverse events arising from disease management when compared with those detected by primary care providers.¹⁵⁵ Informed and engaged patients are more likely to have better health outcomes with fewer incidents or side effects. Most international initiatives related to the patients' role with regards to safety are focussed on the hospital setting.¹⁵⁶

It has been suggested that further extending the patient's role to include wider engagement in their own health care may lead to greater patient participation in safety.¹³⁷ Patients are unlikely to separate out safety issues from more general concerns about their own health. Informed patients are more likely to comply with and adhere to treatments and less likely to accept ineffective or risky procedures.¹¹⁴ A survey of clinicians and their assistants reported that they believed patients should also be provided with educational material arising from error reporting systems so they could better understand their own roles in helping reduce and manage errors.¹²⁷ Both the WHO and NPSA in the UK have made patient involvement amongst their lists of priorities to improve safety as have the JCAHO in the US.¹¹⁴ Some clinicians have expressed concern however, that disseminating information about specific errors to patients could be detrimental to physician patient interactions.¹²⁷

6.4 Discussion

It is clear that there are no easy solutions to eliminating risks to patient safety. There is little evidence examining the effectiveness of interventions that are offered as potential solutions. This review presents the best available evidence for solutions to reduce errors in areas of reporting, prescribing, education and communication. The majority of the studies were conducted either in the USA of the UK, some findings may be applicable to the context of Australian healthcare, however many will not. One overarching finding was the need of high quality research to be conducted in all of the categories within Australia in order to examine the effectiveness of potential solutions within the Australian healthcare system.

The role of agencies and authorities

The role of agencies and authorities is unambiguously described in the included literature. They are expected to require health professionals to report using national systems, promote patient safety initiatives, encourage risk management strategies across all services and health professionals, and generate opportunities for health professionals to learn from risks or adverse events. In spite of this remit, and its universal adoption in the health systems included in this review, evidence of effectiveness has not been established.

Agencies and authorities rely upon reporting by health care providers. Reporting itself has an unknown level of effectiveness, particularly in primary health. Current evidence suggests reporting in primary health is hampered by practitioner beliefs and a lack of reliable resources and systems, thus any robust analysis will require some infrastructure investment and training before further conclusions can be drawn.

The role of individual healthcare practitioners

Significant event analysis was successfully used to assist practitioners to review previous adverse patient events. The data suggests significant event analysis can be applied in the general practice setting in terms of staff ability to learn and apply the process; however, a lack of outcome data indicates that while sustainable, significant event analysis has not been demonstrated to facilitate staff learning, or prevent occurrence of patient safety risks.

Prescribing medications

Electronic prescribing systems frequently include additional features intended to increase safe prescribing practices. These additional features aim to prevent drug interactions, a benefit that has not been established in this review; and one that can be ignored or over ridden by the physician, thus creating another potential layer of risk within the system. None of the studies on prescribing were conducted in Australia; therefore the findings related to avoiding handwritten prescriptions may not be applicable in the Australian context.

Pharmacist review has been investigated for its potential benefit in decreasing medication error related hospital admissions. The evidence base is inadequate to determine the effectiveness of this as an intervention to promote patient safety. Some included studies suggest a benefit, however they tended to be lower quality designs, therefore the findings should not be considered conclusive.

Electronic systems have also been studied in relation to diagnostic accuracy, and antibiotic prescription. The evidence indicates electronic systems can facilitate sensitive and specific diagnosis of some presenting illnesses. The evidence was less clear on whether there was

a relationship between prescribing antibiotics appropriately and electronic systems for diagnosis.

Medication ordering systems provide built in alerts and are used in health systems internationally, including the UK and USA. The appropriateness of specific alerts was not investigated in the studies included in this review. The primary outcome papers reported on was physician behaviour in relation to alert systems. The evidence suggests physicians will read alerts, but tend to give greater weight to other types of information, such as their own clinical reasoning particularly if the alert is perceived to be too conservative. Where alerts are not seen to be overtly conservative, evidence suggests they impact physician behaviour, with studies indicating alerts for high volume or high-risk medications associated with specific patient laboratory results leading to a reduction in prescriptions against alert advice. The accuracy of systems in relation to specificity and sensitivity of information they provide, as well as the comprehensiveness have been investigated. More accurate, and more comprehensive systems are thought to decrease risk. The types of drugs may also be important, further research is needed to clearly identify whether focusing on a particular type of drug can successfully decrease inappropriate prescribing behaviours; NSAIDs have been studied, with limited evidence suggesting more research is needed in this area rather than that the intervention is not effective.

Immediacy of information was also investigated, with computerised systems being found to provide benefit through a more immediate access to information at the decision making point in time. Such systems have been found to introduce new risks that need to be considered. Errors within systems have been cited as a risk, although no empirical evidence was identified to support this concern. The evidence on perceived conservativeness of systems and level of physician over ride is clearer, with studies indicating physicians have a higher risk threshold than many electronic systems.

There was conflicting evidence on the role of electronic systems among children; and although advocated by pharmacists, the evidence for pharmacist led review in primary care is not sufficiently robust to form a recommendation for the intervention.

Patient information

Patient education was not well addressed in the included literature. One RCT found patients who were given paper based information related to depression had a longer consult time, and received more interventions.

Communication

The evidence in relation to the role of communication with health professionals via telephone and patient safety is unclear. The research tends to focus on the impact of communication on health professionals practice, and impact on healthcare resource utilisation rather than patient safety outcomes.

Distance based communication has shown some benefits in relation to diagnostic accuracy. Tele-radiography was found to assist remotely located practitioners decrease the risk of error where locally available technology is insufficient.

7. Knowledge and Evidence Gaps in Patient Safety in Australian Primary Care

The purpose of this review was to identify the main patient safety errors, hazards, incidents and risks relevant to primary care; describe the best available evidence related to solutions to these errors, hazards, incidents and risks; and identify the gaps in knowledge about patient safety in primary care. Gaps in the knowledge or evidence base for any field arise when there has been no research conducted or, when research findings are available, they are equivocal or they are of insufficient quality to reach an unbiased conclusion.

This review reveals numerous gaps in current knowledge about errors, hazards, incidents and risk to patient safety in primary care. This is even more the case in knowledge of interventions and strategies to improve patient safety in primary care. Although there is an emerging literature on the common hazards (drawn largely from the study of errors and incidents) and risk and a smaller literature on solutions, the field is largely unexamined in terms of rigorous inquiry. Whilst both common sense and the literature in general suggests that preventable harm occurs in primary care, reducing harm is largely dependent upon a sound knowledge base and rigorously derived evidence.

Drawing on the evidence and the literature, the apparent knowledge gaps relate to:

- The conceptual basis of patient safety in primary care
- The evidence base related to patient safety hazards; risk; error and incidents associated with primary care; and
- Solutions to improve patient safety in primary care.

7.1 The conceptual basis of patient safety in primary care

The conceptual development of patient safety and much of the evidence on the burden of harm is largely associated with the acute sector. Common understandings of the concepts central to patient safety and of the structural and process factors of primary care that may affect patient safety are fundamental to reducing risk and improving patient safety. On the basis of the literature reviewed, it can be concluded that there are substantial gaps in knowledge about the nature of patient safety in primary care settings in Australia. Obvious areas of knowledge that represents gaps warranting further examination include:

- Understandings of the relationship between hazard, risk and error within Australian primary care;
- The relationship between errors and hazards;
- The nature of "risk" in relation to patient safety in primary care;
- The burden of harm, including financial and human costs, associated with errors, hazards and incidents in primary care; and
- The structures and processes current in Australian primary care and how they relate to patient safety.

7.2 The evidence base related to patient safety hazards; risk; error and incidents associated with primary care

The literature is replete with claims that the magnitude of the problem of hazards, risk and error and their effects on safety is of greater magnitude than the data currently collected from error reporting would suggest. There is, however, a paucity of high quality research in this field. The overwhelming majority of literature is based on surveys and questionnaires, particularly of clinicians, to quantify aspects such as the incidence of error and the effectiveness of interventions to reduce error.

There are identifiable gaps in evidence related to:

- The capture and analysis of national data on the main hazards and level of risk inherent in contemporary primary care in Australia;
- Although there is a growing literature associated with patient safety in general practice, pharmacy and (to a much lesser extent) nursing, there is a notable lack of studies related to the other disciplines that deliver primary care services;
- Existing taxonomies of error have the potential to increase understandings of risk and the nature and prevalence of error in Australian primary health care but there has been insufficient empirical testing of these taxonomies;
- Although the evidence suggests that key safety issues/hazards that contribute to
 patient safety risk can be classified as process errors in domains such as diagnosis,
 prescribing, communication, policy and organisational change, the veracity of this
 evidence has yet to be established in Australian primary care;

7.3 Solutions to improve patient safety in primary care

The literature includes some evidence and discussion about means for reducing preventable harms in primary care but there are large knowledge gaps that need to be filled to develop a robust range of patient safety solutions applicable to Australian primary care. The most notable gaps relate to contemporary understandings of the extent of hazards, errors and safety outcomes in primary care and the identification, classification and evaluation of strategies and interventions designed to minimise risk and improve patient safety.

There are few patient safety solutions that have been robustly examined in primary care although a wide range have been proposed and discussed and there are numerous possible patient safety solutions that have not yet been examined including the feasibility and effects of:

- integrating and actioning patient safety strategies/interventions across all care settings including general practice, community care, private specialists rooms, public hospitals, and private hospitals;
- collecting and using data the identify the extent of errors, hazards and incidents in primary care as a baseline measure and impetus to promote improvement;

- identifying the economic costs of patient safety risk and the gains that could be made by increasing a focus on preventative strategies and involving consumers in their health care (reducing demand on the health system) and changing the way health care services are delivered (changing supply and the supply chain mechanisms);
- patient safety-related funding incentives and sanctions;
- the development and implementation of regulation for to improve patient safety; and
- involving patients/clients in driving a safety agenda.

8. Summary and Conclusions

This review, commissioned by the Australian Commission on Safety and Quality in Health Care, set out to address three questions:

- What are the main patient safety risks relevant to primary care?
- What research has been conducted regarding solutions to these risks?
- What are the gaps in the evidence base about patient safety in primary care?

Undertaken over a period of eight weeks (in March-April 2009), 188 papers were included in the review.

Overall, the quality of the evidence found in this review was poor in terms of the generalisability of findings to the Australian population. Given the inapplicability of randomised controlled trials (the so-called "gold standard" in terms of establishing the effects of specific interventions or activities on specified outcomes) in this field, most of the evidence is derived from other narrative reviews, descriptive studies, retrospective analysis of activity data and informed opinion papers.

Notwithstanding the limitations of the existing evidence, this review considers the "best available evidence" on hazards, risks, errors and harms associated with patients/clients receiving primary care; the feasibility and effects of to identify hazards and minimise risks, errors and harms associated with patients/clients receiving primary care; and the gaps in the evidence base about patient safety in primary care.

The literature suggests that key safety issues/hazards broadly relate to care-process issues in domains such as prescribing, communication, policy and organisational change. (Level I)

There is some evidence the event analysis, improving electronic documentation and support systems, strategies to improve communication between patients and healthcare professionals may represent solutions to minimise safety risk. The main challenges that warrant solutions in primary care appear to be related to organisational change, prescribing, communication and diagnosis.

Drawing on the evidence and the literature, there are significant gaps in existing knowledge and there are few patient safety solutions that have been robustly examined in primary care although a wide range have been proposed and discussed and there are numerous possible patient safety solutions that have not yet been examined.

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Appendix 1 – Protocols for the Systematic Reviews of the Evidence

Patient Safety Risks in Primary Care

Criteria for considering studies for this review

Types of studies

This review selected studies published within the last ten years (January 1999 to current) and considered any existing systematic reviews. In the absence of systematic reviews, or randomised controlled trials, other research designs such as pseudo-randomised controlled trials, before and after studies, observational cohort, time series studies with or without control group, case control studies, and descriptive studies were also considered for inclusion to identify the current best available evidence.

Types of participants

Only studies that focused on patients receiving primary care and/or primary care providers were considered.

Types of phenomena

The phenomena of interest were errors predisposing to serious adverse outcomes and/or injuries stemming from the process of healthcare.

Types of outcome measures

The outcomes of interest were any event that may have arisen from the errors with potential impact on patients.

Criteria for exclusion of studies for this review

- Studies that did not meet the review objective
- Studies with low methodological quality
- Qualitative studies
- Studies employing mixed methodology (quantitative survey and qualitative interview) where quantitative data could not be extracted and was impossible to assign to NHMRC levels of evidence
- Studies that were not reported in English
- · Studies that addressed errors or harm that arose from specific disease of patients
- Studies published before 1999

Assessment of methodological quality

Two reviewers independently assessed the methodological quality of studies using a standardised critical appraisal tool from the Joanna Briggs Institute (JBI) System for the Unified Management, Assessment and Review of Information (SUMARI) package (Appendix

2). Discussion was initiated when a low level of agreement was identified for a particular paper.

For RCTs, studies were assessed on whether the generation of the allocation sequence, allocation concealment, blinding, follow up (at least 80%), and use of intention to treat analysis were met, not met or unclear. These criteria are incorporated in the JBI critical appraisal tool for experimental studies, which consists of 10 items; each answered dichotomously, where 'yes' was allocated with one point and 'no' with zero points. Cut-off score for inclusion of studies after methodological appraisal was set at 5/10, indicating that at least 50% of the items were satisfied. Differences in opinion were resolved by discussion.

The quality of systematic reviews was appraised using the 10 item JBI appraisal tool for systematic reviews which assess transparency and clarity of study selection in terms of population, intervention, comparator and outcomes, data extraction, synthesis and quality assessment process. The cut-off score for inclusion of the systematic reviews after methodological appraisal was set at 8/10.

For observational cohort/case control studies, quality was assessed in terms of the selection of control group, the control of potential confounding factors that may influence on outcome, length of follow up, and the use of appropriate comparison statistics. These criteria are incorporated into the JBI critical appraisal tool for comparable cohort/case control studies, which consists of 9 items with a cut-off score set at 5/9.

The quality of descriptive studies was assessed using the JBI critical appraisal tool for descriptive studies which determines whether or not well-defined inclusion criteria, appropriate sample size, the control of confounding factors, the length of follow up and the use of appropriate statistics studies were met, not met or unclear. The tool consists of 9 items, and studies with a score at or above 5/9 were included.

Data extraction

Data extraction was conducted independently by the two reviewers using the data extraction tool developed by JBI in Meta Analysis of Statistics Assessment and Review of Information (MAStARI) (Appendix 7). The following data were extracted for each study:

- Research method
- Setting
- Participants
- Description of phenomena
- Outcome measures
- Results
- Author's conclusion(s)
- Reviewer's comments

The reviewers were not blinded to the authorship of the studies.

Data synthesis

Study results were double entered using the JBI data extraction tool. Due to marked heterogeneity between included studies in terms of study design, outcome variables and related phenomena, the studies included in this review were not suitable for meta-analysis. As such the results are presented in narrative form.

Solutions to Minimising Patient Safety Risks in Primary Care

Criteria for considering studies for this review

Types of studies

This review included studies published within the last ten years (January 1999 to current) and considered any existing systematic reviews. In the absence of systematic reviews, randomised controlled trials, other research designs such as pseudo-randomised controlled trials, before and after studies, observational cohort, time series studies with or without control group, case control studies, and descriptive studies were considered for inclusion to identify the current best available evidence.

Types of participants

Only studies that focused on patients receiving primary care and primary care providers were considered.

Types of Interventions/ phenomena

The interventions and phenomena of interest were interventions or activities designed to minimise: patient safety risks; errors predisposing to serious adverse outcomes; and injuries stemming from the process of healthcare.

Types of outcome measures

In addition to excluding studies that were not reported in English this review also excluded studies that were:

- Trials in progress and had not yet produced any results;
- Commentary or review papers that contained no data; and
- Experimental papers that did not include relevant control groups.

A table of excluded studies can be found in Appendix 8.

Assessment of methodological quality

Methodological quality was independently assessed by two reviewers, using a standardised critical appraisal tool from the Joanna Briggs Institute (JBI) system for the Unified Management, Assessment and Review of Information (SUMARI) package (Appendix 2). Discussion was initiated when a low level of agreement was identified for a particular paper.

For RCTs, studies were assessed on whether the generation of the allocation sequence, allocation concealment, blinding, follow up (at least 80%), and use of intention to treat analysis were met, not met or unclear. These criteria are incorporated in the JBI critical appraisal tool for experimental studies, which consists of 10 items; each answered dichotomously, where 'yes' was allocated with one point and 'no' with zero points. Cut-off score for inclusion of studies after methodological appraisal was set at 5/10, indicating that at least 50% of the items were satisfied. Differences in opinion were resolved by discussion.

The quality of systematic reviews was appraised using the 10 item JBI appraisal tool for systematic reviews which assess transparency and clarity of study selection in terms of

population, intervention, comparator and outcomes, data extraction, synthesis and quality assessment process. The cut-off score for inclusion of the systematic reviews after methodological appraisal was set at 8/10.

For observational cohort/case control studies, quality was assessed in terms of the selection of control group, the control of potential confounding factors that may influence outcome, length of follow up, and the use of appropriate comparison statistics. These criteria are incorporated into the JBI critical appraisal tool for comparable cohort/case control studies, which consists of 9 items with a cut-off score set at 5/9.

The quality of descriptive studies was assessed using the JBI critical appraisal tool for descriptive studies which determines whether or not well-defined inclusion criteria, appropriate sample size, the control of confounding factors, the length of follow up and the use of appropriate statistics studies were met, not met or unclear. The tool consists of 9 items, and studies with a score 5/9 were included.

Data extraction

Data were extracted from papers using standardised data extraction tools developed by the Joanna Briggs Institute (Appendix 7). The data extracted included specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

The following data were extracted for each study:

- Research method
- Setting
- Participants
- Description of phenomena
- Outcome measures
- Results
- Author's conclusion(s)
- Reviewer's comments

The reviewers were not blinded to the authorship of the studies.

Data synthesis

Study results were double entered using the JBI data extraction tool. On examining the included studies, it was evident that no two studies were directly comparable and therefore meta-analysis was unable to be utilised and the findings are presented in narrative form.

Narrative Review of the Literature on Patient Safety in Primary Care

Inclusion criteria

Types of participants

This narrative review considered papers that focused on patients/clients receiving primary health care

Phenomena of interest

The delivery of primary health care and the risks/harms associated with it.

Types of studies

Quantitative and qualitative peer reviewed publications and other peer reviewed and nonpeer reviewed publications, reviews, opinions, reports and guidelines

Types of outcomes

Adverse patient/health outcomes of any nature

Search strategy

Databases searched included MEDLINE, Excerpta Medica (EMBASE), CINAHL the Cochrane Database of Systematic Reviews and Google (Scholar) to source material for this scoping literature review (See Appendix 9 for full details of the search strategy). Due to the large volume of relevant literature identified from these database searches and time constraints, further searching of other databases, however relevant, was not possible. The Australian Digital Thesis Program, the System for Information on Grey Literature (SIGLE), the North West Grey Literature Service and The Networked Digital library of Theses and Dissertations were also searched.

Method of the review

Critical Appraisal

Papers identified in the search were assessed for relevance against the review questions. Following the search, each paper considered relevant to the objectives of the review was retrieved, and the citations entered into bibliographic software (EndNote), where duplicates were identified and removed.

Data Collection

Textual summaries were extracted from papers and included in the review in narrative form.

Data Synthesis

The textual data was discursively summarised in narrative form. Although there is broad agreement that systematic reviews of evidence provide the best method available to date for synthesising the findings of high quality research, in fields where little such evidence exists or where there is a need to "scope" a field of knowledge, the use of a narrative review process enables reviewers to consider diverse forms of literature.⁸ Narrative review is discursive in nature and seeks to summarise the current state of knowledge in relation to a

particular question through considering a wide field of sources and reaching conclusions through reason or argument. While the techniques of narrative <u>synthesis</u> focus on research findings, its stages in terms of developing a framework, synthesising and analysing relationships between texts informs the narrative review process which was used to inform the structure and development of this summary review. ^{9,10} The Guidance on the conduct of Narrative Synthesis developed for the UK Economic and Social Research Council by Popay et al (2006) ⁸ suggests that reviewers should develop an organising framework from the literature; synthesise the textual data using this framework and examine and analyse the relationship between papers and their conclusions. Such a framework was developed in the early stages of the narrative review process in this project to give direction to the organisation of the review.

Appendix 2 – JBI Critical Appraisal Instruments

JBI Critical Appraisal Checklist for Experimental Studies

Reviewer	Date				
Author	Year	R	ecord Num	ber	_
1. Was the assignment to tr	eatment groups truly random?		Yes	No	Unclear
2. Were participants blinded	to treatment allocation?				
3. Was allocation to treatme allocator?	ent groups concealed from the				
4. Were the outcomes of pe and included in the analysis	ople who withdrew described ?				
5. Were those assessing ou allocation?	tcomes blind to the treatment				
6. Were the control and trea entry?	tment groups comparable at				
7. Were groups treated ider interventions?	tically other than for the named				
8. Were outcomes measure groups?	d in the same way for all				
9. Were outcomes measure	d in a reliable way?				
10. Was appropriate statistic	cal analysis used?				
Overall appraisal:	Include	Exclude	See	k further in	fo.
Comments (Including reasor	ns for exclusion)				

Reviewer	Date					
Author	_ Year	Record Number				
1. Was study based on a rando	m or pseudo-	Yes	No	Unclear		
2. Were the criteria for inclusion clearly defined?	n in the sample					
3. Were confounding factors ide to deal with them stated?	entified and strategies					
4. Were outcomes assessed us	ing objective criteria?					
5. If comparisons are being made sufficient descriptions of the gro	de, was there pups?					
6. Was follow up carried out ove period?	er a sufficient time					
7. Were the outcomes of people described and included in the a	e who withdrew nalysis?					
8. Were outcomes measured in	a reliable way?					
9. Was appropriate statistical ar	nalysis used?					
Overall appraisal: Comments (Including reason fo	Include Exclude I	Seek f	Seek further info			

JBI Critical Appraisal Checklist for Systematic Reviews

Reviewer	Date				
Author	Yea	r	Record Nun	nber	_
1. Is the review question clearly	and explicitly stated?		Yes	No	Unclear
2. Was the search strategy app	ropriate?				
3. Were the sources of studies a	adequate?				
4. Were the inclusion criteria ap question?	propriate for the review	N			
5. Were the criteria for appraising	ng studies appropriate	?			
6. Was critical appraisal conduct reviewers independently?	sted by two or more				
7. Were there methods used to extraction?	minimise error in data				
8. Were the methods used to co	ombine studies appropr	iate?			
9. Were the recommendations s data?	supported by the report	ed			
10. Were the specific directives	for new research appro	opriate?			
Overall appraisal:	Include	Exclude	Seek furthe	er info. 🔲	-
Comments (Including reasons for	or exclusion)				
					=

Appendix 3 – Grey Literature Identified - Narrative Review of the Literature

Study	Study type	Design	Intervention	Setting	Outcome	Themes
Agosta, L J. 2005 ^{(Agosta,} 2005 #210	Doctor of Philosophy Thesis	Survey	Utilization of primary healthcare services delivered by a nurse practitioner	Employee Health Services department of a not for profit hospital in the Southern United States	Overall high levels of patient satisfaction with nurse practitioner delivered health care services were demonstrated.	Nurse practitioners play an integral role in achieving and maintaining safety and quality in <u>US g</u> eneral practice.
Åhlfeldt, Rose- Mharie. 2008 ¹⁵⁷	Doctor of Philosophy Thesis	Survey	Information security in healthcare	Stockholm healthcare sectors	Deficiencies both at the technical and the administrative level of security in all investigated healthcare organizations.	Entire area concerning patient information management confidentiality between different healthcare sectors is missing.
Akins, Ralitsa B. 2004 ¹⁵⁸	Doctor of Philosophy Thesis	Delphi study	Critical processes that should be included in healthcare patient safety systems Indicators of quality for the processes critical for ensuring patient safety Processes critical for patient safety in the future	Texas	 Lack of standards and infrastructure for systematic data collection Lack of standards to support judgement about error reporting, behaviour of colleagues Human factors (multitasking, distraction, interruptions, fatigue, stress) Faulty system not designed to detect errors and intercept them. Accreditation, professional and legal requirements 	Leadership Strategic planning Measurement, analysis and knowledge assessment, Staff focus and process management
Collins, N 2005 ¹⁵⁹	Conference proceedings	Review	Analysis of adverse events databases held by MACS and file review for patients requiring access to a higher level of care for the calendar year 2005	GP led hospital based service in Mcacarthur district on Sydney's south-western fringes	Hospital avoidance and hospital substitution strategies have been suggested as appropriate for certain diagnostic groups. Some have questioned the safety of such policy. For appropriately selected patients, these services can demonstrate a very low risk of adverse events and admissions to hospital during the episode of care.	General Practice is well placed to manage these CAPAC programs.

Dwan et al 2006 ¹⁶⁰	Doctor of Philosophy Thesis	Qualitative interviews	General practice nurses	New South Wales and Victoria general practice	Safety and quality in general practice	Practice nurses can play an integral role in achieving and maintaining safety and quality in <u>Australian GP</u> particularly in the area of developing practice systems and in monitoring those systems.
Hanna 2005 ¹⁶¹	Doctor of Philosophy Thesis	Survey and interview	Environmental health Impact of agricultural and veterinary chemicals (AgVets) on Australian rural communities	Australia (Victoria)	III-health is linked to exposure apparent lack of environmental health expertise especially among their GPs. Health providers demonstrated limited understanding of the health impacts of AgVet exposure. The lack of environmental health expertise among the existing primary health care workforce means that health conditions associated with exposure to AgVets are not being identified, and the absence of health intelligence hampers health planning. In Australia, the health, environment and primary industries sectors function in effect, as distinct silos, with little cross-fertilisation.	There is a need also in Australia to inject environmental health capacity into the primary health care practice. Need to develop environmental health expertise at the primary health care level to address community needs as they arise. Strategies are required in Australia to connect the environment, chemical management and health portfolios, with respect to the emerging environmental issues of chemical exposure.
Hardy 2006 ¹⁶²	Mixed method	Wollongong	1. Relationship between information exchange and communication 2. How this can impact and influence cooperation and collaboration between and among healthcare providers	Problem domain (communication): (i) care delivery model (Case Management Model of Care) and quality improvement; (ii) research methodology; (iii) the theoretical considerations around communication and social systems theories, and the use of, and contribution by (iv) Soft Systems Methodology plus (SSM+) to innovation and change management involving the use of information technology	Fundamental problem within health care	Integration and convergence of different theories related to; communication behaviours and patterns, information exchange, organisational change, and social systems.

Henderson 2007 ¹⁶³	Survey Bettering the Evaluation and Care of Health (BEACH) program	Australia GP database	Survey	Compares the practice behaviour of GPs who use a computer as a clinical tool, either by prescribing, ordering tests, or storing patient data in an electronic medical record format, with those who do not use a computer for these functions	No evidence to demonstrate that the use of a computer for clinical activity has (as yet) affected, either positively or negatively, the quality of care GPs provide to their patients	The current push to computerize general practice will mean that this method of assessment will be difficult to replicate in the future, given the absence of control groups.
Institute of Medicine 2003 ¹⁶⁴	Report	New York Academy of Medicine Library		US	Strategy to change in HC system in America	
Jones 2006 ¹⁶⁵	Using 2003 Medical Expenditure Panel Survey data		How race and SES interact to evidence for a racial gap in utilization of primary care visits affect access to primary care, which may contribute to this health status disparity	Goal of racial equality	No racial gap for low SES individuals Employed blacks may be slightly more likely than employed whites to utilize primary care	The existence and size of the racial gap in the use of primary care do not vary by socioeconomic status
Makeham 2008 ²⁴	Doctor of Philosophy Thesis	Threats to Australian Patient Safety (TAPS) study	1.To create a secure anonymous web-based error reporting system suited to the Australian general practice setting 2.Describe and quantify the errors reported by a representative random sample of Australian general practitioners		Measurement of Threats to Patient Safety in Australian GP if an anonymous, secure, web-based reporting system was provided, approximately 2 errors were reported by general practitioners per 1000 patients seen per year Processes of health care (70%), rather than errors related to the knowledge and skills of health professionals (30%).	Secure anonymous web-based error reporting system suited to the Australian general practice setting

Patterson, 2000 ¹⁶⁶	Doctor of Philosophy Thesis	Survey	Role of PN in Australia PHC	Griffith University	General practitioners and practice nurses appreciate the value of nursing services in general practice and GPs would sanction the employment of more nurses, if given financial incentives, especially for the purpose of preventive care.	PN role should be expanded to include autonomous functioning while most of the GPs were amenable to some extension of nursing practice but reticent or opposed to any independent interventions.
RegNet et al 2006 ¹⁶⁷	Doctor of Philosophy Thesis	Qualitative interviews	New South Wales and Victoria	Contribution of general practice nurses to safety and quality	Practice nurses can play an integral role in developing practice systems and in monitoring those systems	A collaborative rather than hierarchical approach between GPs and nurses
Sinclair 2006 ¹⁶⁸	Doctor of Philosophy Thesis	Survey Gay men GP	Australia	Experience of gay men and GP	Stress and depression Body image disorder Experiencing discrimination in the provision of health care Non-gay specialist GPs were less comfortable treating gay men, reported poorer communication and were more homophobic than their gay specialist counterparts.	Disclosure of sexuality is an important issue for both gay men and doctors, and has the potential to impact on the quality of health care that gay men receive. All GPs should receive additional undergraduate medical education regarding gay men's health

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Summons, and King	Conference proceedings	Report	Brisbane	Ten deadly sins that result in claims of negligence	System and doctor errors and lead to claims of negligence against GPs:	System and doctor errors and lead to claims of negligence in
2000107					1. Poor record keeping	Australia
					2. No documentation of the consent process	
					3. The altering of records when something's gone wrong	
					4. Failure to follow up referrals	
					5. Failure to follow up test results	
					6. Failure to check the history when writing scripts	
					7. Giving a diagnoses and treatment over the phone	
					8. Insufficient time / care given to establishing a sound doctor - patient relationship	
					9. Rushing consultations	
					10. Not saying anything if something's gone wrong.	
Wang	Survey	Cross-	Taipei	Major barriers of PCPs to practice	Lack of enough manpower	1) The Government should set up
2006 ¹⁷⁰		sectional questionnaire survey		these patient safety goals	Differences in PCPs' perception toward patient safety	patient safety goals drafted for primary care and provide more patient safety information and knowledge to educate the public; (2) the PCPs should assist government set up the patient safety goals appropriate for primary care and express needs of PCPs actively; (3) further researcher can focus on a national-wide research of this issue.

Young 2008 ¹⁷¹	Qualitative research methods	Master of Arts in Applied Anthropology	Oregon	How changes made to the Oregon Health Plan (OHP) in 2003 impacts those now utilizing the emergency room (ER) for primary health care in Oregon	Loss of personal agency, feelings of hopelessness, and diminished social capital. Not understanding the policy of the OHP the ER staff places blame on OHP recipients, seeing them as abusing the system	
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Appendix 4 – Studies Unable to be Retrieved

Patient Safety Risks (20)

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Solutions to Minimising Patient Safety Risks (5)

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Appendix 5 – Included Studies

Patient Safety Risks

Process errors	Number of studies	Design	Level of evidence	Evidence from Australia
Taxonomy	8	Descriptive	IV	
Admin error	1	Descriptive	IV	
Treatment	6	5 Descriptive	IV	2
		1 RCT	II	
Medication				
Polypharmcy	2	Descriptive	IV	
Patients Medication literacy	3	Descriptive	IV	
Role of pharmacist	5	4 Descriptive	IV	1
		1 systematic review	I	
Communication	2	Descriptive	IV	2
Doctors knowledge skills	4	Descriptive	IV	1
Errors combine	2	1 Descriptive	IV	
		1 systematic review	I	
Total	33			

Solutions to Minimising Patient Safety Risks

Author	Title	Solution Category	Methods	Setting	Main findings	Level of evidence
Baker et al 2007 ¹⁰⁸	Making use of mortality data to improve quality and safety in general practice: a review of current approaches.	Practitioner education	Systematic review	General practice, mainly UK	53 studies were included in the review. The studies addressed the impact of primary care provision on mortality rates, methods of monitoring mortality, and the role of audit and death registers in quality and safety improvement. General practitioners were interested in using mortality data but reported difficulties in obtaining complete information. There were no experimental studies of the impact of the use of mortality data, and little evidence of long-term systematic initiatives to use mortality data in quality and safety improvement in general practice. Conclusions: Mortality data are not used systematically in general practice although general practitioners appear interested in the potential of this information in improving quality and safety. Improved systems to provide complete data are needed and experimental studies required to determine the effectiveness of use of the data to improve general practice care. Reviewing mortality data can provide GPs with a patient safety learning resource, as well as to draw attention to GPs who have a higher than expected mortality record.	Level I
Bradbury et al 2004 ¹⁰³	How important is the role of the physician in the correct use of a drug? An observational cohort study in general practice.	Accurate prescribing	Cohort study	General practice, Ireland	The data shows that the study physicians prescribed the NSAIDs with a good degree of compliance with the information reported in each SmPCs. This fact was supported with a low number of adverse events.	Level III-2

Braithwaite et al 2006 ¹⁰⁹	Experiences of health professionals who undergo a safety improvement programme.	Practitioner education	Anonymous survery questionnaire	General practice, Australian	Respondents reported benefits from RCAs, including improved patient safety (87.9%) and communication about patient care (79.8%). SIP courses had given participants skills to conduct RCAs (92.8%) and improve their safety practices (79.6%). Benefits from the SIP were thought to justify the investment by New South Wales Health (74.6%) and committing staff resources (72.6%). Most (84.8%) of the participants wanted additional RCA training. Author conclusions: RCA participants reported improved skills and commitment to safety, but greater support from the workplace and health system are necessary to maintain momentum. Healthcare professional who underwent undertook a safety improvement course were more aware of safety issues that those that did not. They reported improved patient safety (87.9%) and communication about patient care (79.8%). SIP courses had given participants skills to conduct RCAs (92.8%) and improve their safety practices (79.6%).	Level IV
Bunn et al 2005 ⁸⁷	The effects of telephone consultation and triage on healthcare use and patient satisfaction: a systematic review.	Improved communication	Systematic review	General practice, mainly UK	Although telephone consultation appears to have the potential to reduce GP workload, questions remain about its effect on service use. Further rigorous evaluation is needed with emphasis on service use, safety, cost, and patient satisfaction. Telephone consultation appears to be effective in diverting patients away from GP and there appears to be no evidence of any safety issues, however this needs to be properly investigated. Potentially patient safety can be improved by patients accessing medical advice who would not have visited a GP.	Level I
Chang et al 2005 ¹²	The JACAHO patient safety event taxonomy: a standardised terminolpgy and classification schema for near misses and adverse events.	Improved reporting	Systematic review	Various	Standardisation is important to allow more accurate record keeping and so that information can be filtered easily from records. It also ensures that those reporting extract standardised details so that incidents can be compared. The authors identified 5 areas that a useful taxonomy should have; Impact, Type, Domain, Prevention/Mitigation. This review generates a useful model for how incident reporting can be improved, however - needs to be road tested in the field to determine if it really makes a difference to patient safety outcomes.	Level I

Conroy et al 2007 ⁹⁹	Interventions to reduce dosing errors in children: a systematic review of the literature.	Accurate prescribing	Systematic review	Various - mainly USA and Europe	Interventions to reduce the risk of dose calculation errors are therefore urgently needed. A systematic literature review was conducted to identify published articles reporting interventions; 28 studies were found to be relevant. The main interventions found were computerised physician order entry (CPOE) and computer- aided prescribing. Most CPOE and computer-aided prescribing studies showed some degree of reduction in medication errors, with some claiming no errors occurring after implementation of the intervention. However, one study showed a significant increase in mortality after the implementation of CPOE. Children are a particularly challenging group of patients when trying to ensure the safe use of medicines. The increased need for calculations, dilutions and manipulations of paediatric medicines, together with a need to dose on an individual patient basis using age, gestational age, weight and surface area, means that they are more prone to medication errors at each stage of the medicines management process. It is already known that dose calculation errors are the most common type of medication error in neonatal and paediatric patients. Computer-aided prescribing appears to be a useful intervention in reducing the number of prescribing errors in the treatment of children	Level I
Cox SJ and Holden JD. 2007 ⁹⁶	Retrospective review of significant events reported in one district in 2004-2005.	Improved reporting	Retrospective significant event analysis	General practice, UK	The aim of SEA is to identify learning points from adverse events and identify learning points to prevent re occurrence. 337 events were reviewed during 2004-2005. 22/32 practices were able to complete SEA with no further support, 4 - needed further support to implement and 6 had extreme difficulty and required further training.	Level III-3
Fernando et al 2004 ¹⁰⁴	Prescribing safety features of general practice computer systems: evaluation using simulated test cases.	Accurate prescribing	Delphi questionnaire	General practice, UK	The authors developed a list of theoretical derived statements and used these to generate potential patient safety scenarios. The aim was to determine whether the 4 most commonly used prescribing computer programs could identify risk situations. None of them identified drug-drug interactions or contra-indicated drugs. The best performance was 7/18, 2 scored 4/18 and the last was 3/18.	Level IV

Halbach JL and Sullivan LL. 2005 ¹⁰⁶	Teaching medical students about medical errors and patient safety: evaluation of a required curriculum.	Practitioner education	Pre and post study	Medical school, USA	A multifaceted educational program designed to address patient safety issues and taught as a 4 hour short course. Students were asked to complete the same seven-item questionnaire both at the start and after the course. In addition, each student was asked to complete a 13-item evaluation of the curriculum at the end of the session. Finally, an anonymous, 12 item follow-up questionnaire was sent to all students approximately two to eight months later that asked them about subsequent experience with medical errors since their training. No student reported discussing an error directly with a patient, however they reported that felt more aware and better equipped to identify and report errors. The authors conclude that education about patient safety and medical errors can be successfully implemented and maintained in undergraduate medical education.	Level IV
Kiuru et al 2002 ¹¹³	Effect of teleradiology on the diagnosis, treatment and prognosis of patients in a primary care setting.	Improved communication	Controlled trial	Finland - general practice and hospital radiology departments.	The authors suggest that radiographers diagnosed by a GP are more likely to be misinterpreted that by radiographers. Tele- radiography allows direct access to hospital radiographers can potentially can increase accuracy of diagnosis.36/446 (15%) cases were undiagnosed by a GP and false positive results were given in 40/446 cases therefore: sensitivity was 0.85 and specificity was 0.62.	Level III-3
Knudsen et al 2007 ⁵⁰	Preventing medication errors in community pharmacy: root- cause analysis of transcription errors.	Practitioner education	Root cause analysis	Community pharmacies, Denmark	RCA - Identifying risks that contributed in medication dispensing errors and suggesting strategies to combat them. The authors identified 4 main errors of risk - similarities in packaging and/or drug names, incorrect dosage dispensed, lack of effective control. Handwritten prescriptions were seen as a major source of error which could be eliminated if they were sent electronically sent to pharmacy or typed.	?
Kostopoulou et al 2008 ⁹³	Predictors of diagnostic accuracy and safe management problems in family medicine.	Practitioner education	Observational study	General practice, UK	7 scenarios including 1-4 predetermined features of difficulty. The information used to derive the scenarios was taken from legal cases, systematic reviews and interviews with GPs to determine what features of a diagnosis made it difficult and open to error. The authors conclude that as the level of difficulty of a diagnosis increases ie. more complicating factors or possibilities), the more room for error. Experience of the GP was no indicator of misdiagnosis. The authors provide a useful training tool to help family physicians recognise more features of a complex diagnosis.	Level III-3

Krska et al 2001 ⁹⁸	Pharmacist-led medication review in patients over 65: a randomised controlled trial in primary care.	Accurate prescribing	RCT	General practice, rural Scotland	Pharmacists reviewed the medications of 332 patients who took at least 4 prescribed medications daily, with at least 2 chronic health conditions and 2 pharmacy issues (not defined). The intervention group had their medications reviewed and a pharmaceutical care plan drawn up, the control group received usual care. 70% of intervention pharmacy issues were resolved after 3 months of the plan, compared with 14% of control. The authors report pharmacist-led medication review can substantially reduces pharmacy issues and therefore the potential for medication-related errors/adverse events. They also suggest that anyone 65 years ought to have a pharmaceutical review.	Level II
Lapane et al 2008 ¹⁰⁰	A mixed method study of the merits of E-prescribing drug alerts in primary care.	Accurate prescribing	Survey, convenience sample	General practice, USA	Participants were asked to assess 1 of 6 electronic prescribing systems. The authors report that 40% of participants would the alerts as they considered them to be too conservative and specifically alerts regarding drug-drug interactions were too sensitive.	Level III-3
Linder et al 2006 ¹⁰⁵	Acute infections in primary care: accuracy of electronic diagnoses and electronic antibiotic prescribing.	Accurate prescribing	Retrospective cross sectional study General practice, USA General practice, USA General practice, USA The authors compared electronic billing diagnoses and electr antibiotic prescribing to the gold standard of blinded chart rev Results: Claims-derived, electronic ARI diagnoses had a sen of 98%, specificity of 96%, and positive predictive value of 96 Claims-derived, electronic UTI diagnoses had a sensitivity of specificity of 87%, and positive predictive value of 85%. Acco the visit note, physicians prescribed antibiotics in 45% of ARI and 73% of UTI visits. Electronic antibiotic prescribing had a sensitivity of 43%, specificity of 93%, positive predictive value 90%, and simple agreement of 64%. The sensitivity of electro antibiotic prescribing increased over time from 22% in 2000 tr in 2003 (p for trend, 0.0001). Conclusion: Claims-derived, election diagnoses for ARIs and UTIs appear accurate. Although clos large gap persists between antibiotic prescribing documented		The authors compared electronic billing diagnoses and electronic antibiotic prescribing to the gold standard of blinded chart review. Results: Claims-derived, electronic ARI diagnoses had a sensitivity of 98%, specificity of 96%, and positive predictive value of 96%. Claims-derived, electronic UTI diagnoses had a sensitivity of 100%, specificity of 87%, and positive predictive value of 85%. According to the visit note, physicians prescribed antibiotics in 45% of ARI visits and 73% of UTI visits. Electronic antibiotic prescribing had a sensitivity of 43%, specificity of 93%, positive predictive value of 90%, and simple agreement of 64%. The sensitivity of electronic antibiotic prescribing increased over time from 22% in 2000 to 58% in 2003 (p for trend, 0.0001). Conclusion: Claims-derived, electronic diagnoses for ARIs and UTIs appear accurate. Although closing, a large gap persists between antibiotic prescribing documented in the visit note and the use of electronic antibiotic prescribing.	Level III-3

Little et al 2004 ¹¹¹	Randomised clinical trial of effect of leaflets to empower patients in consultations in primary care.	Patient education	RCT	General practice, UK	Main outcomes were a mean item score on the medical interview satisfaction scale, consultation time, prescribing, referral, and investigation. The authors report that the general leaflet overall caused a small non-significant increase in consultation time (0.36 minutes, – 0.54 to 1.26). Although there was no change in prescribing or referral, a general leaflet increased the numbers of investigations (odds ratio 1.43, 1.00 to 2.05), which persisted when controlling for the major potential confounders of perceived medical need and patient preference (1.87, 1.10 to 3.19). Most of excess investigations were not thought strongly needed by the doctor or the patient. The depression leaflet had no significant effect on any outcome. Conclusions Encouraging patients to raise issues and to discuss symptoms and other health related issues in the consultation improves their satisfaction and perceptions of communication, particularly in short consultations. Doctors do, however, need to elicit expectations to prevent needless investigations.	Level II
Royal et al 2006 ⁹⁷	Interventions in primary care to reduce medication related adverse events and hospital admissions: systematic review and meta-analysis.	Accurate prescribing	Systematic review	Primary care - mainly US and Europe.	All interventions related to medication problems leading to hospitalisation or drug related morbidity. Pharmacist led interventions and 8 interventions led by other primary care professionals and 13 interventions with a component of medication review. Authors Conclusion: There is relatively weak evidence to indicate that pharmacist-led medication reviews are effective in reducing hospital admissions. There is currently no evidence for the effectiveness of other interventions which aim at reducing admissions or preventable drug related morbidity. More randomised controlled trials of primary care based pharmacist-led interventions are needed to decide whether or not this intervention is effective in reducing hospital admissions. Meta-analysis showed significant positive effect of interventions on hospital admissions (OR 0.64, 95% CI 0.43-0.96). No positive effect was found with RCTs alone. No significant effect found when with interventions led by nurses and doctors. OR 1.05, 95% CI 0.57 - 1.94. Complex interventions to reduce falls in the elderly - no significant effect demonstrated. OR 0.91, 95% CI 0.68-1.21.	Level I

Singh et al 2005 ¹⁰⁷	A comprehensive collaborative patient safety residenct curriculum to address the ACGME core competencies.	Practitioner education	Pre and post study	Medical school, USA	A multifaceted educational program specifically designed to address L patient safety issues. Taught as a unit in combination with other subjects. The authors report that by using audits, journals and quality improvement exercises, the residents were able to demonstrate improved abilities to reflect on their own practice and apply safety principles to address both actual and potential errors. The authors suggest that the main strengths of the curriculum lie in the interdisciplinary faculty and the emphasis on active learning through practical exercises that complement the didactic material.	_evel IV
Steele et al 2005 ¹⁰¹	The effect of automated alerts on provider ordering behavior in an outpatient setting	Accurate prescribing	Pre and post study	Outpatient, USA	All patients seen in the clinic during the study period were eligible for L the intervention. As prescribers ordered medications on a computer, an alert was displayed if a relevant drug–laboratory interaction existed. The number and type of laboratory tests a prescriber ordered was monitored in response to automated drug alerts. Adverse drug events were assessed by doing a random sample of chart reviews using the Naranjo scoring scale. During the post-intervention period, an alert was displayed for 11.8% (1,093 out of 9,274) of the times the rule processed, with 5.6% for only "missing laboratory values," 6.0% for only "abnormal laboratory values," and 0.2% for both types of alerts. Focusing on 18 high-volume and high-risk medications revealed a significant increase in the percentage of time the provider stopped the ordering process and did not complete the medication order when an alert for an abnormal rule-associated laboratory result was displayed (5.6% vs. 10.9%, p¼0.03, Generalized Estimating Equations test). The authors conclude that prescribers will adhere to alerts and will use this information to improve patient care - specifically, in response to drug–laboratory interaction alerts, providers will significantly increase the ordering of appropriate laboratory tests. Implementation of rules technology to prevent medication errors could be an effective tool for reducing medication errors in an outpatient setting.	_evel IV

Tamblyn et al 2003 ¹⁰²	The medical office of the 21st century (MOXXI): effectiveness of computerised decision- making support in reducing inappropriate prescribing in primary care.	Accurate prescribing	RCT	General Practice, USA	Study to investigate if immediate, online access to drug information, prescribing history and automated alerts (computerised-decision support) would improve prescribing practice. Computer-based access to complete drug profiles and alerts about potential prescribing problems reduces the rate of initiation of potentially inappropriate prescriptions but has a more selective effect on the discontinuation of such prescriptions. Computer problems impinged on effectiveness of study Increase in cost of drugs at same time as study resulted in less drug use.	Level II
Wallace et al 2007 ¹¹⁰	Organisational interventions to promote risk management in primary care: experience in Warwickshire, England.	Practitioner education	Desciptive study	General Practice	This paper examines how an English health authority promoted interventions to improve RM in General Practice that included the practices' own initiatives, significant event audit (SEA) and the Medical Defence Union's workshops which included SEA. Interventions to improve risk management. Authors Conclusion: There was evidence of improved competence in risk management over the period of the study, particularly through a widening breadth of staff involved and in formal recording systems. There was little evidence that these improvements were mediated by organizational culture. Clinical audit to assess practice. the tools used for data collection where Risk management audit questionnaire and Learning organisation Cultural Questionnaire.	Level III-I

Weingart et al 2008 ¹¹²	Medication safety messages for patients via a web portal: the MedCheck intervention.	Improved communication/accurate prescribing	Retrospective survey	Outpatient, USA	MedCheck queried patients automatically 10 days after they received a new or changed prescription. The MedCheck message listed the patients' new or changed prescriptions and asked patients to select "No problems or questions" or "I have not filled or have had some problems." MedCheck triggered a traditional email message that was sent to the patient's email account indicating that he or she had received a PatientSite message and providing a link to the secure PatientSite Website (no description of the content of the message). Patients' responses were forwarded immediately to the primary care physician and to physician-designated staff. MedCheck elicited patients' medication problems and symptoms and facilitated an electronic dialogue with their clinicians. The messages served as an extension and continuation of the clinical encounter, enabling clinicians to follow up automatically on a therapeutic intervention. For this type of application to be effective, patients must review their messages in a timely way, and then provide information for physicians to review and act upon. The aim of the report was to determine whether this automated email reminder system resulted in fewer adverse drug events and quicker responses from the healthcare provider. The authors suggest that more patients use the	Level III-3
					system than would have gone to the GP.	

Appendix 6 – AAFP/Linnaeus Collaboration Taxonomy - Patient Safety Risks

	Description	N
1. Process errors	Errors in a process of the healthcare delivery system	284
-1.1. Office administration	Errors in the process of conducting an administrative task	102
- 1.1.1. Filing system	 Information filed in wrong place or wrong time 	41
- 1.1.2. Chart completeness	Unavailability of information that should have been in patients' charts	27
- 1.1.2.1. Record(s) unavailable	Entire chart or part of chart could not be accessed when needed	9
- 1.1.2.2. Care given but not documented	Care provided was not documented	10
- 1.1.2.3. Record not up to date or complete	 Item(s) of information missing from chart 	8
1.1.3. Patient flow	• Errors in patients' movement through the healthcare delivery system	7
-1.1.4. Message handling	• Errors in the taking and distributing of messages	14
1.1.5. Appointments	Errors in managing appointments for healthcare	10
-1.2. Investigations	 Errors in the process of investigating a patient's condition 	82
-1.2.1. Laboratory	Errors in the process of laboratory investigations	65
- 1.2.1.1. Ordering laboratory investigations	Wrong test ordered or test not ordered when appropriate	3
- 1.2.1.2. Implementing laboratory investigation	Errors in the process of obtaining or processing a laboratory specimen	33
- 1.2.1.3. Reporting laboratory investigations	 Error in the process of physician receiving accurate laboratory results in a timely fashion 	16
1.2.1.4. Responding to abnormal laboratory investigation results	Inappropriate response to an abnormal laboratory result	13
- 1.2.2. Diagnostic imaging	 Errors in the process of diagnostic imaging investigations 	11
- 1.2.2.1. Ordering diagnostic imaging	Wrong test ordered or test not ordered when appropriate	1
- 1.2.2.2. Implementing diagnostic imaging	Errors in the process of obtaining or processing of a diagnostic image	4
- 1.2.2.3. Reporting diagnostic imaging	 Error in the process of physician receiving accurate results of a diagnostic image in a timely fashion 	5
1.2.2.4. Responding to abnormal diagnostic imagining results	Inappropriate response to an abnormal diagnostic image	1
1.2.3. Other investigations	 Errors in the process of other investigations 	6
- 1.2.3.1. Ordering other investigations	Wrong test ordered or test not ordered when appropriate	0
- 1.2.3.2. Implementing other investigations	 Errors in the process of obtaining or processing of other diagnostic investigation 	2
- 1.2.3.3. Reporting other investigations	 Error in the process of physician receiving accurate test results of other investigation in a timely fashion 	3
1.2.3.4. Responding to abnormal results of other investigations	Inappropriate response to an abnormal result of other investigation	1
- 1.3. Treatments	 Errors in the process of treating a patient's condition 	76
-1.3.1. Medications	 Errors in the process of treating with medications 	57
- 1.3.1.1. Ordering medications	 Wrong medication or wrong dose of medication ordered or medication not ordered by physician when appropriate 	35
- 1.3.1.2. Implementing medication orders	 Error in the process of delivering a medication order or inappropriate medication order by a provider working under physician supervision 	13
1.3.1.3. Receiving medications	 Error in the process of dispensing medication as ordered 	9
1.3.2. Other treatments	 Errors in the process of treating other than by medication 	20
- 1.3.2.1. Ordering other treatments	Wrong treatment ordered or treatment not ordered when appropriate	9
1.3.2.2. Implementing other treatments	 Error in the process of providing treatment other than medication 	10
-1.4. Communication	 Errors in the process of communication 	19
-1.4.1. Communication with patients	 Errors in communication between physicians and patients 	10
1.4.1.1. Consent errors	Errors in the process of obtaining informed consent	1
- 1.4.2. Communication with non-physician colleagues	 Errors in communication between physicians and non-physician healthcare providers 	3
1.4.3. Communication with physician colleagues	Errors in communication with physicians outside the practice	6
1.5. Payment	 Errors in the process of healthcare payment systems 	4
. Knowledge and skills errors	Errors arising from lack of clinical knowledge or skills	46
-2.1. Execution of a clinical task	 Errors arising during the performance of a clinical task due to a lack of clinical knowledge or skills 	19
-2.2. Mis-diagnosis	Wrong or missed diagnosis	13
2.3. Wrong treatment decision	Wrong treatment decision arising from a lack of clinical knowledge or skills	14

Appendix 7 – JBI Data Extraction Tools

JBI Data Extraction Form for Experimental/Observational Studies

Reviewer		_ Date	
Author		Year	
		Record Numbe	;I
Study Method	RCT	Quasi-RCT	Longitudinal
Participants Setting Population	Retrospective	Observational	Other
Sample size Intervention 1 Interventions	Intervention 2	e Interver	tion 3
Intervention 1			
Intervention 2			
Intervention 3			-
			-

Clinical outcome measures

Outcome Description	Scale/measure

Study results

Dichotomous data

Intervention ()	Intervention ()
number / total number		number / total number	
	Intervention (number / total number	Intervention () number / total number	Intervention () Intervention (number / total number number / total number

Continuous data

Intervention ()	Intervention ()
number / total number		number / total number	

Authors conclusions

Appendix 8 – Excluded Studies

Patient Safety Risks

Studies that did not meet the review objectives (16)

- Bunn F, Byrne G, Kendall S. The effects of telephone consultation and triage on healthcare use and patient satisfaction: A systematic review. British journal of General Practice. 2005;55:956-61.
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- Nabhan A, Ahmed-Tawfik MS. Understanding and attitudes towards patient safety concepts in obstetrics. Int J Gynaecol Obstet. 2007 Sep;98(3):212-6.
- Pandhi N, Schumacher J, Flynn KE, Smith M. Patients' perceptions of safety if interpersonal continuity of care were to be disrupted. Health Expect. 2008 Dec;11(4):400-8.
- Pitkanen M, Hurn J, Kopelman MD. Doctors' health and fitness to practise: performance problems in doctors and cognitive impairments. Occup Med (Lond). 2008 Aug;58(5):328-33.
- Sarkar U, Handley MA, Gupta R, Tang A, Murphy E, Seligman HK, et al. Use of an interactive, telephone-based self-management support program to identify adverse events among ambulatory diabetes patients. J Gen Intern Med. 2007 Apr;23(4):459-65.

- Van Vorst RF, Araya-Guerra R, Felzien M, Fernald D, Elder N, Duclos C, et al. Rural community members' perceptions of harm from medical mistakes: a High Plains Research Network (HPRN) Study. J Am Board Fam Med. 2007 Mar-Apr;20(2):135-43.
- Weingart SN, Gandhi TJ, Seger AC, Seger DL, Borus J, Burdick E, et al. Patient-reported medication symptoms in primary care. Archives of Internal Medicine. 2005;165:234-40.

Studies excluded following critical appraisal (13)

- Gandhi TJ, Weingart SN, Borus J, Seger AC, Peterson J, Burdick E, et al. Adverse drug events in ambulatory care. The New England Journal of Medicine. 2003;348:1556-64. Reason for Exclusion: The study did not fulfil enough quality criteria (score 4/9).
- Gurwitz JH, Field TS, Harrold LR, Rothschild J, Debellis K, Seger AC, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA. 2003;289(9):1107-16. Reason for Exclusion: The study did not fulfil enough quality criteria (score 3/9).
- Hansen L, Fernald D, Araya-Guerra R, Westfall JM, Pace W. Pharmacy clarification of prescription ordered in primay care: a report from the applied strategies fro improving patient safety collaborative. JABFM. 2006;19(1):24-30.
 Reason for Exclusion: The study made conclusions about safety, but isn't really investigating/defining

issue. In addition, it did not fulfil enough quality criteria (score 4/9).

- Katz HP, Kaltsounis D, Halloran L, Mondor M. Patient safety and telephone medicine : some lessons from closed claim case review. J Gen Intern Med. 2008 May;23(5):517-22.
 Reason for Exclusion: The study did not fulfil enough quality criteria (score 4/9).
- Knudsen P, Herborg H, Mortensen AR, Kaltsounis M, Hellebek A. Preventing medication erros in community pharmacy: root-casue analysis of transcrition errors. Qual Saf Health Care. 2009;16:285-90. Reason for Exclusion: The study did not fulfil enough quality criteria, very poor design (score 1/9).
- Kostopoulou O. From cognition to the system: developing a multilevel taxonomy of patient safety in general practice. Ergonomics. 2006 Apr 15-May 15;49(5-6):486-502. Reason for Exclusion: The study did not fulfil enough quality criteria (score 3/9).
- Matlow AG, Wishen A, Wishen A, Raboud JM. A study of provider-caregiver communication in paediatric ambulatory care. Paediatr Child Health. 2006 Apr;11(4):217-21. Reason for Exclusion: The study did not fulfil enough quality criteria (score 3/9).
- Millward LJ, Bryan K, Everatt J, Collins R. Clinicians and dyslexia--a computer-based assessment of one of the key cognitive skills involved in drug administration. Int J Nurs Stud. 2004 Mar;42(3):341-53. Reason for Exclusion: The study did not fulfil enough quality criteria (score 4/9).
- Rubinstein SM, Leboeuf-Yde C, Knol DL, de Koekkoek TE, Pfeifle CE, van Tulder MW. The Benefits Outweigh the Risks for Patients Undergoing Chiropractic Care for Neck Pain: A Prospective, Multicenter, Cohort Study. J Manipulative Physiol Ther. 2007;30:408-18.

Reason for Exclusion: The study did not fulfil enough quality criteria (score 4/9).
- Stevenson C, Ernst E. Risks associated with spinal manipulation. The American Journal of Medicine. 2002;112:566-71. Reason for Exclusion: The study did not fulfil enough quality criteria (score 3/9).
- Vila H, Soto R, Cantor AB, Mackey D. Comparative Outcomes analysis of procedures performed in physicians offices and ambulatory surgery centers. Archives of Surgery. 2003;138:991-5.
 Reason for Exclusion: The study did not fulfil enough quality criteria, very poor design (score 2/9).
- Wahls TL, Cram PM. The frequency of missed test results and associated treatment delays in a highly computerized health system. BMC Fam Pract. 2007;8:32.
 Reason for Exclusion: The study did not fulfil enough quality criteria (score 3/9).
- Weingart SN, Toth M, Sands DZ, Aronson MD, Davis RB, Phillips RS. Physicians' decisions to override computerized drug alerts in primary care. Archives of Internal Medicine. 2003;163:2625-31. Reason for Exclusion: The study did not fulfil enough quality criteria (score 4/9).

Solutions to Minimising Patient Safety Risks

Excluded studies that did not meet the review objectives (10)

- Altavela, J., M. Jones, and M. Ritter, A prospective trial of a clinical pharmacy intervention in a primary care practice in a capitated payment system. J Manag Care Pharm 2008. 14: p. 831-843. ¹⁷²
- Sorensen, L., et al., *Medication reviews in the community: results of a randomized, controlled effectiveness trial.* . Br J Clin Pharmacol, 2004. 58: p. 648-664. ¹⁷³
- de Lusignan, S. and S. Teasdale, Achieving benefit for patients in primary care informatics: the report of a international consensus workshop at Medinfo 2007. Inform Prim Care. 2007;15(4):255-61.¹⁷⁴
- Kirk, S., et al., *Patient safety culture in primary care: developing a theoretical framework for practical use.* Qual Saf Health Care, 2007. 16(4): p. 313-20. ¹⁷⁵
- McKay, J., et al., *Levels of agreement on the grading, analysis and reporting of significant events by general practitioners: a cross-sectional study.* Qual Saf Health Care, 2008. 17(5): p. 339-45. ¹²⁶
- Mikkelsen, T.H., I. Sokolowski, and F. Olesen, *General practitioners' attitudes toward reporting and learning from adverse events: results from a survey.* Scandinavian Journal of Primary Health Care, 2006. 24(1): p. 27-32.¹¹⁷
- Rosenthal, T.C., *The medical home: growing evidence to support a new approach to primary care.* Journal of the American Board of Family Medicine, 2008. 21(5): p. 427-440. ¹⁷⁶
- Singh, R., et al., *Estimating impacts on safety caused by the introduction of electronic medical records in primary care*. Inform Prim Care, 2004. 12(4): p. 235-42. ¹⁷⁷
- Singh, R., et al., *Prioritising threats to patient safety in rural primary care.* The Journal of Rural Health, 2007. 23(2): p. 173-178. ¹⁷⁸
- Williams, S.K. and S.S. Osborn, *The development of the National Reporting and Learning System in England and Wales, 2001-2005.* Med J Aust, 2006. 184(10 Suppl): p. S65-8. ¹¹⁸

Studies excluded following critical appraisal (15)

- Bond C, Matheson C, Williams S, Donnan P. Repeat prescribing: a role for community pharmacists in controlling and monitoring repeat prescriptions. *British Journal of General Practice*. 2000;50(453):271-5.
 Reason for exclusion: Unclear on many aspects. Doesn't fulfil appropriate criteria.
- Bonnabry P, Despont-Gros C, Grauser D, Casez P, Despond M, Pugin D, et al. A risk analysis method to evaluate the impact of a computerized provider order entry system on patient safety. *J Am Med Inform Assoc*. 2008 Jul-Aug;15(4):453-60.
 Reason for exclusion: Study performed in inpatient setting
- Chen J, Kresnow MJ, Simon TR, Dellinger A. Injury-prevention counseling and behavior among US children: results from the second Injury Control and Risk Survey. *Pediatrics*. 2007 Apr;119(4):e958-65. Reason for exclusion: This is managing risk, but not arising from the process of healthcare.

- Davis R, Jacklin R, Sevdalis N, Vincent C. Patient involvement in patient safety: what factors influence patient participation and engagement? *Health Expectations*. 2007;10:259-67.
 Reason for exclusion: Lit review, not systematic, no specifics about studies included to suggest quality of evidence
- Derkx H, Rethans JJ, Maiburg B, Winkens R, Knottnerus A. New methodology for using incognito standardised patients for telephone consultation in primary care. *Med Educ*. 2009 Jan;43(1):82-8. Reason for exclusion: Study does not use TISPS as a solution intervention
- Durieux P, Trinquart L, Colombet I, Nies J, Walton RT, Rajeswaran A, et al. Computerized advice on drug dosage to improve prescribing practice. *The Cochrane Database of Systematic Reviews*. 2008(3). Reason for exclusion: Outcome measures not relevant to the review
- Essex B, Ashworth M, Crichton N. Performance concerns in primary care: a Delphi consensus on risk and investigation. *Quality in Primary Care*. 2007;15(5):293-300.
 Reason for exclusion: Performance concerns in primary care: a Delphi consensus on risk and investigation.
- Galt KA, Rich EC, Young WW, Markert RJ, Barr C, Houghton B, et al. Impact of hand-held technologies on medication errors in primary care. *Topics in Health Information Management*. 2002;23(2):71-81. Reason for exclusion: Protocol - no results to add to review.
- Hoffmann B, Beyer M, Rohe J, Gensichen J, Gerlach FM. "Every error counts": a web-based incident reporting and learning system for general practice. *Quality & Safety in Health Care*. 2008;17(4):307-12.
 Reason for exclusion: This is data collection and subjective classification i.e taxonomy
- Ludwick DA, Doucette J. Adopting electronic medical records in primary care: lessons learned from health information systems implementation experience in seven countries. *Int J Med Inform*. 2009 Jan;78(1):22-31. Reason for exclusion: Literature review.
- Mick JM, Wood GL, Massey RL. The Good Catch Pilot Program: increasing potential error reporting. *Journal of Nursing Administration*. 2007;37(11):499-503. Reason for exclusion: inpatient setting
- Pearson S-A, Ross-Degnan D, Payson A, Soumerai SB. Changing medication use in managed care: A critical review of available evidence. *American Journal of Managed Care*. 2003;9:715-31.
 Reason for exclusion: About quality not safety
- Robertson H, MacKinnon N. Development of a list of consensus-approved clinical indicators. *Clinical therapeutics*. 2002;24(10):1595-613. Reason for exclusion: No clear intervention
- Sarkar U, Handley MA, Gupta R, Tang A, Murphy E, Seligman HK, et al. Use of an interactive, telephone-based self-management support program to identify adverse events among ambulatory diabetes patients. *J Gen Intern Med.* 2007 Apr;23(4):459-65. Reason for exclusion: non-generalisable target audience
- Schutz AL, Counte MA, Meurer S. Assessment of patient safety research from an organizational ergonomics and structural perspective. *Ergonomics*. 2007;50(9):1451-84.
 Reason for exclusion: Literature review

Appendix 9 - Search Strategy - Narrative Review of the Literature

Approach to the questions

The PICO question (Population, Intervention, Comparison, Outcome) developed to operationalise the review is as follows:

Population of interest

Any patient (children and adults) receiving care in any primary care setting

Interventions of interest

Any intervention delivered by health professionals within the primary health care setting including:

- 1. Physiotherapy
- 2. Chiropractic
- 3. Occupational Therapy
- 4. Pharmacy
- 5. Dentistry (dental nurses)
- 6. Psychology
- 7. Primary Medical Care
- 8. Nursing
- 9. Midwifery
- 10. Home Care
- 11. Podiatry
- 12. Speech therapy
- 13. Optometry

Comparison

As described by the literature retrieved.

Outcome

Any measure of risk/harm/adverse event/benefit/safety.

Methods for assessment, management and minimising risks and harms.

Search strategy

The search for the literature began with general searches of the Internet with Google and Google Scholar. These initial searches were very broad, simply focussing on "patient safety"/"primary care". Once websites and pertinent literature had been identified, some papers were retrieved to provide a background/introduction to the topic of interest and also aid in the development of keywords of interest. A similar, preliminary, search of MEDLINE via PubMED was also performed to this end.

The topic of review in question being broad, did not lend itself to a singular, focussed, "systematic" search strategy. Rather, the search was 'scoping' in nature and modified dependent on the nature/pertinence/validity of the results obtained from the database in question. Keywords were kept to a minimum so as not to limit the search.

For example in a MEDLINE search, using the PUBMED interface. The search strategy focussed on the *Outcomes* of interest that were consistent across all searches; hence they were dealt with first. The search below (#1-#9) attempts to isolate general components of the question. The "risk" to "safety", represented by as broad a collection of "error/adverse" terms as possible.

#1 adverse or error*

#2 harm* or injur*

#3 incorrect or inappropriate

#4 iatrogen*

#5 #1 or #2 or #3 or #4

#6 risk* #7 #5 and #6

#8 safety

#9 #7 and #8

Following this the specific interventions of interest will be introduced in the subsequent 1-4 search strings. For example:

#10 physiotherapy or (physical therapy)

#10 chiropractic

#11 (chiropractic care)

#12 #10 or #11

#10 (occupational therap*)

#11 (occupational rehabilitation)

#10 psychology

#11 (psychological assessment) or psychotherapy

#10 dentistry

#11 (dental care)

#10 pharmacy

#11 (pharmacy practice)

#12 dispensing or dispensary

#13 polypharmacy

- #10 (family practice) or (family medicine) or (general practice)
- #11 (general practitioner*) or (family physician*)

#12 (primary medical care)

#10 Midwi*

#11 prenatal or postnatal

#12 pregnancy or birth

- #10 (home care) or (respite care)
- #11 (domestic acre) or (domestic assistance)

#12 rehabilitation

#10 podiatr* or chiropod*

#10 (speech therap*)

#11 (speech patholog*)

#10 optometr* or optician

#11 lenses or (visual aid*)

The *population* of interest will then be introduced if the results require further refining depending on number and content.

#13 (primary care) or ambulatory

if results need more specificity the population will be further defined by,

#14 patient

The 'general' above search will be reordered and terms reintroduced dependent on the number and validity of returned results.

Upon examining the results following the keyword search combining the *outcome*, *intervention* and *population*, where there appear to be search results pertinent to the questions of the review however many irrelevant papers are included also. The nature of list will be examined to see how it can be refined further, for example by inclusion of NOT operators. For example,

#17 (#16) NOT (hospital)

#18 (#17) NOT (intensive care) etc.

Specific searches will then be followed with searches conducted using more general/generic keywords applicable to the questions directing the review topic. Using this approach, it is anticipated there will be some degree of overlap/duplication in the results obtained from the search. These duplications will be filtered out when importing into an Endnote library. For example,

#1 (patient safety) and (primary care)

#5 (patient safety) and risk etc

Before any retrieval of literature, the 'titles' of the entire retrieved database from the keyword search were screened, and papers that obviously did not fit the inclusion criteria dictated by the scope of the review were not marked for transfer to a 'final' endnote library of relevant literature. Abstracts were referred to where it was unclear from the title if the paper was relevant or not.

All search the results were limited by date to between 1999 – 2009 and in the English language only.

Example search

The basic search of the MEDLINE database for the PHYSIOTHERAPY aspect of patient safety reads:

#1 adverse or error*

#2 harm* or inju*

#3 incorrect or inappropriate
#4 iatrogen*
#5 #1 or #2 or #3 or #4
#6 risk*
#7 #5 and #6

#8 safety #9 #7 and #8

#10 physiotherapy or (physical therapy) #11 #9 and #10

#12 (primary care) or ambulatory#13 #11 and #12

as this search returned only 14 (with limits applied) results, the search was approached again, using a diff strategy,

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#15 physiotherapy or (physical therapy)#16 #15 and #9#17 #16 and patient
```

With limits 182 results. After looking over the results, the search was further refined by,

#18 (#17) NOT (hospital*)
#19 (#18) NOT (clinical)
#20 (#19) NOT (medication)
#21 (#20) NOT (medication or administration)
With limits 68 results. Downloaded to Endnote library

Appendix 10 – Included Studies - Narrative Review of the Literature

Included Papers

- Abbott RL, Weber P, Kelley B. Medical professional liability insurance and its relation to medical error and healthcare risk management for the practicing physician. *Am J Ophthalmol.* 2005 Dec;140(6):1106-11.
- Adubofour K, Keenan C, Daftary A, Mensah-Adubofour J, Dachman W. Strategies to reduce medication errors in ambulatory practice. *Journal of the National Medical Association*. 2004;96:1558-64.
- Agosta LJ. Patient satisfaction with nurse practitioner primary health care services. 2006.
- Ahlfeldt R-M. Information security in distributed healthcare; Exploring the needs for achieving patient safety and patient privacy: Stockholm University; 2008.
- Akins RB. Critical processes and performance measures for patient safety systems in healthcare institutions: a Delphi study: Texas: A & M University; 2004.
- Al Khaja KAJ, Sequeira RP, Al-Ansari TM, Damanhori AHH. Prescription writing skills of residents in a family practice residency programme in Bahrain. *Postgraduate Medical Journal*. 2008;84(990):198-204.
- Ashcroft DM, Morecroft C, Parker D, Noyce PR. Likelihood of reporting adverse events in community pharmacy: an experimental study. *Qual Saf Health Care*. 2006 Feb;15(1):48-52.
- Ashcroft DM, Quinlan P, Blenkinsopp A. Prospective study of the incidence, nature and causes of dispensing errors in community pharmacies. 2005.
- Avery AJ, Savelyich BS, Sheikh A, Morris CJ, Bowler I, Teasdale S. Improving general practice computer systems for patient safety: qualitative study of key stakeholders. *Qual Saf Health Care*. 2007 Feb;16(1):28-33.
- Bajramovic J, Emmerton L, Tett SE. Perceptions around concordance--focus groups and semi-structured interviews conducted with consumers, pharmacists and general practitioners. *Health Expectations*. 2004;7(3):221-34.
- Barber N. Designing information technology to support prescribing decision making. *Qual Saf Health Care*. 2004 Dec;13(6):450-4.
- Barnett JR, Coyle P, Kearns RA. Holes in the safety net? Assessing the effects of targeted benefits upon the health care utilization of poor New Zealanders. *Health Soc Care Community*. 2000 May;8(3):159-71.
- Beasley JW, Escoto KH, Karsh B-T. Design elements for a primary care medical error reporting system. *Wisconsin Medical Journal*. 2004;103(1):56-9.
- Becher E, Chassin M. Improving Quality, Minimizing Error: Making It Happen. *Health Affairs*. 2001;20(3):68-81.
- Benner P, Sheets V, Uris P, Malloch K, Schwed K, Jamison D. Individual, practice, and system causes of errors in nursing. A taxonomy. *Journal of Nursing Administration*. 2002;32(10):509-23.
- Bird S. Missing test results and failure to diagnose. Australian Family Physician. 2004 360-361;33(5).
- Bond C, Hannaford P. Issues related to monitoring the safety of over-the-counter (OTC) medicines. *Drug Saf.* 2003;26(15):1065-74.
- Bond C, Matheson C, Williams S, Donnan P. Repeat prescribing: a role for community pharmacists in controlling and monitoring repeat prescriptions. *British Journal of General Practice*. 2000;50(453):271-5.

- Boston-Fleischhauer C. Enhancing healthcare process design with human factors engineering and reliability science, Part 2: Applying the knowledge to clinical documentation systems. *The Journal of Nursing Administration*. 2008;38(2):84-9.
- Bradley E, Hynam B, Nolan P. Nurse prescribing: reflections on safety in practice. *Social Science & Medicine*. 2007;65(3):599-609.
- Braithwaite J, Westbrook MT, Mallock NA, Travaglia JF, Iedema RA. Experiences of health professionals who conducted root cause analyses after undergoing a safety improvement programme. *Qual Saf Health Care*. 2006 Dec;15(6):393-9.
- Britten N, Stevenson FA, Barry CA, Barber N, Bradley CP. Misunderstandings in prescribing decisions in general practice: qualitative study *BMJ: British Medical Journal*. 2000;320:484-8.
- Brous E. The criminalization of unintentional error: implications for TAANA. *Journal of Nursing Law*. 2008;12(1):5-12.
- Bunn F, Byrne G, Kendall S. The effects of telephone consultation and triage on healthcare use and patient satisfaction: A systematic review. *British journal of General Practice*. 2005;55:956-61.
- Byrd J, Thompson L. "It's safe to ask": promoting patient safety through health literacy. *Healthc Q.* 2008;11(3 Spec No.):91-4.
- Chang A, Schyve PM, Croteau RJ, O'Leary D, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *International Journal for Quality in Health Care* 2005;17(2):95-105.
- Chua SS, Wong ICK, Edmondson H, Allen C, Chow J, Peacham J, et al. A feasibility study for recording of dispensing errors and 'near misses' in four UK primary care pharmacies.
- Collins N. Community acute and post-acute care: sounds like a good idea, but is it safe? 49th Annual Scientific Convention; 2005; Brisbane, Australia; 2005.
- Daniel DM, Rupert RL. Calibration and electrical safety status of therapeutic ultrasound used by chiropractic physicians. 2003.
- Davis R, Jacklin R, Sevdalis N, Vincent C. Patient involvement in patient safety: what factors influence patient participation and engagement? *Health Expectations*. 2007;10:259-67.
- Davis TC, Wolf MS, Bass PF, 3rd, Thompson JA, Tilson HH, Neuberger M, et al. Literacy and misunderstanding prescription drug labels. *Ann Intern Med.* 2006 Dec 19;145(12):887-94.
- Davis TC, Wolf MS. Health Literacy: Implications for family medicine. Family Medicine. 2004;36:595-8.
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- Dennison RD. A medication safety education program to reduce the risk of harm caused by medication errors. *Journal of Continuing Education in Nursing*. 2007;38(4):176-84.
- Derkx H, Rethans JJ, Maiburg B, Winkens R, Knottnerus A. New methodology for using incognito standardised patients for telephone consultation in primary care. *Med Educ*. 2009 Jan;43(1):82-8.
- Doggett J. A new approach for primary care for Australia; 2007.
- Dopson A. Confidence and competence in paediatric drug calculations. *Nurse Prescribing*. 2008;6(5):208-14.
- Dovey S. Advancing Understanding of medical errors in general practice: A discussion of recent research from the American Academy of Family Physicians. *New Zealand Journal of Family Practice*. 2003;30:242-6.
- Dovey SM, Meyers DS, Phillips RL, Jr., Green LA, Fryer GE, Galliher JM, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care*. 2002 Sep;11(3):233-8.

- Durieux P, Trinquart L, Colombet I, Nies J, Walton RT, Rajeswaran A, et al. Computerized advice on drug dosage to improve prescribing practice. *The Cochrane Database of Systematic Reviews*. 2008(3).
- Dwan ea. Role of practice nurse in New South Wales and Victoria general practice. 2006.
- Elder N, Vonder Meulen M, Cassedy A. The identification of Medical errors by family physicians during outpatient visits. *Annals of Family Medicine*. 2004;2(2):125-9.
- Elder NC, Graham D, Brandt E, Hickner J. Barriers and motivators for making error reports from family medicine offices: a report from the American Academy of Family Physicians National Research Network (AAFP NRN). J Am Board Fam Med. 2007 Mar-Apr;20(2):115-23.
- Elder NC, Pallerla H, Regan S. What do family physicians consider an error? A comparison of definitions and physician perception. *BMC Fam Pract.* 2006;7:73.
- Ernst E. Serious adverse effects of unconventional therapies for children and adolescents: a systematic review of recent evidence. *Eur J Pediatr.* 2003 Feb;162(2):72-80.
- Essex B, Ashworth M, Crichton N. Performance concerns in primary care: a Delphi consensus on risk and investigation. *Quality in Primary Care*. 2007;15(5):293-300.
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- Flanagan P, MacKinnon NJ, Hanlon N, Robertson H. Identification of intervention strategies to reduce preventable drug morbidity in older adults. *Geriatrics Today Journal of the Canadian Geriatrics Society*. 2002;5:76-80.
- Francis SA, Barnett N, Denham M. Switching of prescription drugs to over-the-counter status: is it a good thing for the elderly? *Drugs Aging*. 2005;22(5):361-70.
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- Gluck PA. Patient safety in women's health care: a framework for progress. Best Pract Res Clin Obstet Gynaecol. 2007 Aug;21(4):525-36.
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- Hickner J, Graham DG, Elder NC, Brandt E, Emsermann CB, Dovey S, et al. Testing process errors and their harms and consequences reported from family medicine practices: a study of the American Academy of Family Physicians National Research Network. *Quality & Safety in Health Care*. 2008;17(3):194-200.
- Hildebrandt DE, Westfall JM, Smith PC. After-hours telephone triage affects patient safety. *J Fam Pract.* 2003 Mar;52(3):222-7.
- Hoffman JM, Proulx SM. Medication errors caused by confusion of drug names. Drug Safety. 2003;26(7):445-52.
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Sandars J, Esmail A. The frequency and nature of medical error in primary care: understanding the diversity across studies. Fam Pract. 2002 Jun: 20(2):221	Research purpose: This review had two objectives; first, to identify the frequency and nature of error in primary care, and, secondly, to consider the possible causes for the diversity in the stated rates and nature of error in primary care. Method: Literature searches of English language studies identified in the National Patient Safety Foundation bibliography database, in Medline and in Embase were carried out. Studies that were relevant to the purpose of the study were included. Additional information was obtained from a specialist medico-legal database.
6. ⁴	Sample size: N/A
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Studies identified that medical error occurs between five and 80 times per 100000 consultations, mainly related to the processes involved in diagnosis and treatment. Prescribing and prescription errors have been identified to occur in up to 11% of all prescriptions, mainly related to errors in dose. There are a wide variety of definitions and methods used to identify the frequency and nature of medical error. Incident reporting, systematic identification and medico-legal databases reveal differing aspects, and there are additional perspectives obtained from GPs, primary health care workers and patients.
	An understanding of the true frequency and nature of medical error is complicated by the different definitions and methods used in the studies.
	Study type: R

Summary of literature included in the narrative review

Doggett J. A new approach for primary care for Australia; 2007.5	Research purpose: Not Stated
	Method: N/A
	Sample size: N/A
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: The author recommends the reorientation of Australia's health system towards primary care, to be achieved through the roll-out of around 200 integrated Primary Health Care Centres, each servicing a polulation of 100 000 on average.
	A wealth of international evidence shows that health systems oriented towards primary care achieve better health outcomes than systems focused on hospital care.
	Study type: EU/C
Becher E, Chassin M.	Research purpose: Not Stated
Minimizing Error	Method: N/A
Making It Happen.	Sample size: N/A
Health Affairs.	Risk adjustment/ confounders controlled for: N/A
2001;20(3):68-81.6	Confidence interval: N/A
	Findings: If we are to reduce errors and improve quality substantially, we must create systems and care processes that anticipate inevitable human errors and either prevent them or compensate for them before they cause harm. Success will require a multifaceted strategy, including public education, government investment and regulation, payment system restructuring, and leadership from within the delivery system.
	Study type: EO/C
Hammons T, Piland	Research purpose: review of the state of knowledge about ambulatory safety.
N, Small S, Hatlie M,	Method: N/A
Ambulatory patient	Sample size: N/A
safety. What we	Risk adjustment/ confounders controlled for: N/A
know and need to	Confidence interval: N/A
know. Journal of Ambulatory Care Management. 2003;26(1):63-82. ⁷	Findings: The current (2003) state of knowledge about ambulatory safety is reviewed. A research agenda in ambulatory safety is proposed. A series of potential interventions that could be used to improve safety in the ambulatory setting is proposed. Study type: R
Dovey S. Advancing	Research purpose: summarise the key advances in understanding of medical errors in
Understanding of medical errors in general practice: A discussion of recent research from the	primary care settings contributed by the American Academy of Family Physicians AAFP's research.
	Method: N/A
	Sample size: N/A
American Academy	Risk adjustment/ confounders controlled for: N/A
of Family Physicians. New Zealand Journal of Family Practice. 2003;30:242-6. ¹¹	Confidence interval: N/A
	Findings : Medical errors are as much an issue for primary care providers as they are for hospital-based providers. Patients in primary care settings are at risk from poorly managed messaging and appointment systems, from inadequate communication systems, and from dysfunctional pre- scribing and investigation processes (among other problems). There is taxonomy describing more than 500 different types of errors occurring in primary care practices. There is a list of some 185 practical solutions to reported errors in primary care.
	Study type: R

Benner P, Sheets V, Uris P, malloch K, Schwed K, Jamison D. Individual, practice, and system causes of errors in nursing. A taxonomy. Journal of Nursing Administration. 2002;32(10):509- 23. ¹⁸⁵	Research purpose: To analyse data from State Boards to explore the potential for developing new strategies to reduce dangerous errors Method: Case studies of nursing errors from State Boards of Nursing files were analyzed Sample size: 21 case studies of nursing errors from 9 State Boards of Nursing files Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: With the guiding rationale being identification of categories central to the nurse's role and function in healthcare delivery errors, Eight categories of nursing errors representing a broad range of possible errors and contributive or causative factors were identified: lack of attentiveness; lack of agency/fiduciary concern; inappropriate judgment; lack of intervention on the patient's behalf; medication errors; lack of prevention; missed or mistaken MD/healthcare provider's orders; and documentation errors. Causes for the error, at the system and practice responsibility levels, were identified in each case. The categories, an assessment of causes of errors, and an examination of the remediation actions taken were the first steps in devising a taxonomy of nursing error, designed with prevention in mind. The authors discuss their work and present the taxonomy Study type: O
Pace W, Fernald D, Harris D, Dickinson LM, Araya-Guerra R, Staton E, et al. Developing a Taxonomy for Coding Ambulatory Medical Errors: A Report from the ASIPS Collaborative. Advances in Patient Safety. 2005;2:63- 73 ²⁹	Research purpose: briefly describe the development and modification of the Dimensions of Medical Outcomes DMO based on actual primary care patient safety events reported to Applied Strategies for Improving Patient Safety ASIPS; describe the use of the ASIPS DMO3 to identify individual codes and patterns of codes within events that resulted in patient harm; describe the ability of the ASIPS DMO to provide a multidimensional description of events that allows for easy grouping of error processes across various clinical activities or errors within specific clinical activity across various types of processes. Method: Individuals in 34 primary care practices reported medical errors to a Patient Safety Reporting System. Based on the first 357 reports, a modified multi-axial taxonomy was developed to improve the description of primary care errors. 337 of 421 available taxonomy codes were applied to 608 error reports. Analyses included basic frequencies, cross tabulations, and odds ratios to examine the ability of the taxonomy and its underlying constructs to describe patient safety events and their relationship to harm. Sample size: 608 fully coded events were considered for analysis. Risk adjustment/ confounders controlled for: N/A Confidence interval: Yes Findings: Four individual codes were associated with harm, including therapeutic intent of an activity, language barriers, and errors of judgment. Harm was also associated with 10 constructs within the taxonomy hierarchy and 8 derived constructs. These constructs included communication from another office, mistimed procedures, medication errors, and involvement of the treating clinician. Harm was not associated with incorrectly performed procedures or failure to perform procedures or general information flow within, into, or out of the office. Study type: O

Fernald DH, Pace WD, Harris DM, West DR, Main DS, Westfall JM. Event reporting to a primary care patient safety reporting system: a report from the ASIPS collaborative. Ann Fam Med. 2004	Research purpose: to describe types of errors reported and differences between anonymous and confidential reports.
	Method: The ASIPS project collects event reports from 2 practice-based research networks: the Colorado Research Network (CaReNet) and the High Plains Research Network (HPRN). The participating practices are located across Colorado and care for a diverse patient population in terms of age, race, ethnicity, socioeconomic status, and medical problems. The entire ASIPS project includes (1) a voluntary reporting system, (2) analysis of reported events, (3) analysis of data from such secondary sources as insurance claims, (4) educational feedback to practices, and (5) implementation of interventions to improve patient safety.
Jul-Aug;2(4):327- 32. ²⁸	Sample size: 2 practice-based research networks: the Colorado Research Network (CaReNet) and the High Plains Research Network (HPRN). 33 practices with a total of 475 clinicians and staff have participated in ASIPS.
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Communication problems (70.8%), diagnostic tests (47%), medication problems (35.4%), and both diagnostic tests and medications (13.6%) were the most frequently reported errors. Confidential reports were significantly more likely than anonymous reports to contain codable data.
	Study type: O
Parnes B, Fernald D, Quintela J, Araya-	Research purpose: To present a novel examination of how error cascades are stopped (ameliorated) before they affect patients.
Guerra R, Westfall J,	Method: Qualitative analysis of reported errors in primary care.
Harris D, et al. Stopping the error	Sample size: 754 coded events voluntarily reported to the ASIPS reporting system.
cascade: a report on	Risk adjustment/ confounders controlled for: N/A
ameliorators from the	Confidence interval: N/A
ASIPS collaborative. Qual Saf Health Care. 2007 Feb;16(1):12-6. ³⁰	Findings: Of 754 codeable reported events, 60 were classified as ameliorated events. In these events, a participant stopped the progression of the event before it reached or affected the patient. Ameliorators included doctors, nurses, pharmacists, diagnostic laboratories and office staff. Additionally, patients or family members may be ameliorators by recognising the error and taking action. Ameliorating an event after an initial error requires an opportunity to catch the error by systems, chance or attentiveness. Correcting the error before it affects the patient requires action either directed by protocols and systems or by vigilance, power to change course and perseverance on the part of the ameliorator. Study type: D
Dovey SM, Meyers	Research purpose: To develop a preliminary taxonomy of primary care medical errors.
DS, Phillips RL, Jr., Green LA, Fryer GE,	Method: Qualitative analysis to identify categories of error reported during a randomized controlled trial of computer and paper reporting methods.
Galliner JIVI, et al. A	Sample size: Forty two physicians made 344 reports.
of medical errors in	Risk adjustment/ confounders controlled for: N/A
family practice. Qual	Confidence interval: N/A
Saf Health Care. 2002 Sep;11(3):233- 8. ²⁰	Findings: Forty two physicians made 344 reports: 284 (82.6%) arose from healthcare systems dysfunction; 46 (13.4%) were errors due to gaps in knowledge or skills; and 14 (4.1%) were reports of adverse events, not errors. The main subcategories were: administrative failures (102; 30.9% of errors), investigation failures (82; 24.8%), treatment delivery lapses (76; 23.0%), miscommunication (19; 5.8%), payment systems problems (4; 1.2%), error in the execution of a clinical task (19; 5.8%), wrong treatment decision (14; 4.2%), and wrong diagnosis (13; 3.9%). Most reports were of errors that were recognized and occurred in reporters' practices. Affected patients ranged in age from 8 months to 100 years, were of both sexes, and represented all major US ethnic groups.
l	ראוווטארחמוו נווב ובעטרנא שביב טו בעבוונא שוווטד וומע מעעבואל נטוואלעעבוונבא. דפון פווטוא

Study type: D Makeham MA, Dovey Research purpose: To develop an international laxonomy describing errors reported by S, County M, Kidd Head practitioners in Australia and five other countries. Makeham MA, Dovey Search purpose: To develop an international laxonomy describing errors reported by jant and fue United States reported errors in an observational pilot study. Anonymous reports Method: GPs in Australia, Canada, the Netherlands, New Zealand, the United Kingdom and the United States reported errors in an observational pilot study. Anonymous reports and international investigators. Sample size: 23 GPs in Australia, and between 8 and 20 in the other participating countries. In Australia, 17 doctors reported 134 errors, compared with 301 reports by 63 doctors in the other five countries. Sample size: 23 GPs in Australia, and between 8 and 20 in the other participating countries. In Australia, 17 doctors reported 134 errors, compared with 301 reports by 63 doctors in the other five countries. Sample size: 23 GPs in Australia, and stilla and stillas reports. NA Confidence interval: NA Findings: The final taxonomy was a five-level system encompassing 171 error types. The first-level classification was reported an 28% of reports from Australia and 30% from other countries. Study Neores: 20% The Linneus-PC Research purpose: A taxonomy was created to code and classify the medical errors reported by family physicians. Method: The taxonomy was created from the actual words used in the free text portions of reports. As well as		resulted in patients being admitted to hospital and one patient died.
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experts.		experts.
Confidence interval: N/A		Confidence interval: N/A

	Findings: Three areas may affect how physicians make decisions about error: the process that occurred vs. the outcome that occurred, rare vs. common occurrences and system vs. individual responsibility. Study type: SR
Chang A, Schyve PM, Croteau RJ,	Research purpose: To develop a common terminology and classification schema (taxonomy) for collecting and organizing patient safety data.
O'Leary D, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. International Journal for Quality in Health Care 2005;17(2):95- 105. ¹²	Method: The project comprised a systematic literature review; evaluation of existing patient safety terminologies and classifications, and identification of those that should be included in the core set of a standardized taxonomy; assessment of the taxonomy's face and content validity; the gathering of input from patient safety stakeholders in multiple disciplines; and a preliminary study of the taxonomy's comparative reliability. Sample size: A total of 512 distinct references were identified from the Medline search. The Embase search resulted in 15 additional unique references. The titles and/or abstracts of these articles were initially scanned, and inclusion/exclusion decisions made. Based on the review of the abstracts, 429 articles were eliminated. Of the 96 full articles that were reviewed, 73 were eliminated. Eleven formal classification schemes identified in the remaining 23 articles that address the frequencies, types, causes and contributing factors, consequences, and prevention of medical/medication errors. Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Elements (terms) and structures (data fields) from existing classification schemes and reporting systems could be grouped into five complementary root nodes or primary classifications: impact, type, domain, cause, and prevention and mitigation. The
	root nodes were then divided into 21 subclassifications which in turn are subdivided into more than 200 coded categories and an indefinite number of uncoded text fields to capture narrative information. An earlier version of the taxonomy (111 coded categories) demonstrated acceptable comparability with the categorized data requirements of the ICU safety reporting system.
	Study type: SR
Van Vorst RF, Araya- Guerra R, Felzien M,	definitions and types of harm from medical mistakes.
Fernald D, Elder N, Duclos C, et al. Rural community members' perceptions of harm from medical mistakes: a High Plains Research Network (HPRN) Study. J Am Board Fam Med. 2007 Mar- Apr;20(2):135-43. ³²	Method: Mixed methods study using community-based participatory research (CBPR). The High Plains Research Network (HPRN) with its Community Advisory Council (CAC) designed and distributed an anonymous survey through local community newspapers. Survey included open-ended questions on patients' experiences with medical mistakes and resultant harm. Qualitative analysis was performed by CAC and research team members on mistake descriptions and types of reported harm. Patient Safety Taxonomy coding was performed on a subset of surveys that contained actual medical errors.
	Sample size: A total of 286 surveys were returned, with 172 respondents (60%) reporting a total of 180 perceived medical mistakes. Quantitative analysis showed that 41% of perceived mistakes (n = 73) involved only unanticipated outcomes.
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Reported types of harm included emotional, financial, and physical harm. Reports suggest that perceived clinician indifference to unanticipated outcomes may lead to patients' loss of trust and belief that the unexpected outcome was a result of an error. CBPR methodology is an important strategy to design and implement a community- based survey. Community members reported experiencing medical mistakes, most with harmful outcomes. The response they received by the medical community may have influenced their perception of mistake and harm.
	Study type: D

Rubin G, George A, Chinn DJ, Richardson C. Errors in general practice: development of an error classification and pilot study of a method for detecting errors. Quality & Safety in Health Care. 2003;12(6):443-7. ¹⁸⁶	Research purpose: To describe a classification of errors and to assess the feasibility and acceptability of a method for recording staff reported errors in general practice. Method: An iterative process in a pilot practice was used to develop a classification of errors. This was incorporated in an anonymous self-report form which was then used to collect information on errors during June 2002. The acceptability of the reporting process was assessed using a self completion questionnaire. Sample size: Ten general practices in the North East of England. 101 events were used to create an initial error classification. Subsequently, 940 errors were recorded in a single 2 week period from 10 practices, providing additional information. Risk adjustment/ confounders controlled for: No Confidence interval: Yes
	Findings: 42% of errors (397/940) were related to prescriptions, although only 6% (22/397) of these were medication errors. Communication errors accounted for 30% (282/940) of errors and clinical errors 3% (24/940). The overall error rate was 75.6/1000 appointments (95% CI 71 to 80). The method of error reporting was found to be acceptable by 68% (36/53) of respondents with only 8% (4/53) finding the process threatening. Study type: O
Makeham MAB, Kidd MR, Saltman DC, Mira M, Bridges- Webb C, Cooper C, et al. The threats to Australian Patient Safety (TAPS) study: Incidence of reported errors in general practice. Medical Journal of Australia. 2006;185:95-8. ⁸⁶	Research purpose: To determine the incidence of errors anonymously reported by general practitioners in NSW. Method: The Threats to Australian Patient Safety (TAPS) study used anonymous reporting of errors by GPs via a secure web-based questionnaire for 12 months from October 2003. Sample size: 84 GPs from a stratified random sample of the population of 4666 NSW GPs - 41 (49%) from RRMA 1, 22 (26%) from RRMA 2-3, and 21 (25%) from RRMA 4-7. Participants were representative of the GP source population of 4666 doctors in NSW (Medicare items billed, participant age and sex). Risk adjustment/ confounders controlled for: Stratified sample, anonymous participants Confidence interval: N/A Findings: 84 GPs submitted 418 error reports, claimed 490 864 Medicare patient encounter items, and saw 166 569 individual patients over 12 months. The incidence of
	reported error per Medicare patient encounter item per year was 0.078% (95% CI, 0.076%-0.080%). The incidence of reported errors per patient seen per year was 0.240% (95% CI, 0.235%-0.245%). No significant difference was seen in error reporting frequency between RRMA groupings. Study type: O
Rosser W, Dovey S, Bordman R, White D, Crighton E, Drummond N. Medical errors in primary care: results of an international study of family practice. Can Fam Physician. 2005 Mar;51:386-7. ²⁶	Research purpose: To describe errors Canadian tamily physicians found in their practices and reported to study investigators. To compare errors reported by Canadian family physicians with those reported by physicians in five other countries. Method: Analytical study of reports of errors. The Linnaeus Collaboration was formed to study medical errors in primary care. General practitioners in six countries, including a new Canadian family practice research network (Nortren), anonymously reported errors in their practices between June and December 2001. An evolving taxonomy was used to describe the types of errors reported. Sample size: In Canada, 15 family doctors reported 95 errors. In the other five countries, 64 doctors reported 413 errors. Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Although the absence of a denominator made it impossible to calculate rates of errors, Canadian doctors and doctors from the other countries reported similar

	skills. All countries reported similar proportions of laboratory and prescribing errors. Canadian doctors reported harm to patients from 39.3% of errors; other countries reported harm from 29.3% of errors. Canadian physicians considered errors "very serious" in 5.8% of instances; other countries thought them very serious in 7.1% of instances. Hospital admissions and death were among the consequences of errors reported in other countries, but these consequences were not reported in Canada. Study type: O
Sandars J. Recent	Research purpose: Not stated
developments in	Method: N/A
patient safety in	Sample size: N/A
in Primary Care.	Risk adjustment/ confounders controlled for: N/A
2007;15(3):165-7. ⁹¹	Confidence interval: N/A
	Findings: The main dangers to patient safety in primary care are delayed diagnosis, inappropriate treatment and the use of medication. Between 60% and 83% of these threats to patient safety are preventable. Delayed diagnosis is the commonest cause (54%) of malpractice claims. Between 13% and 51% of all reported adverse incidents that occur in primary care are related to medication. An important aspect of improving patient safety in primary care is education, especially specialty training for general practice registrars and continuing medical education for GPs.
	Study type: EO/C
Woodward S. Patient	Research purpose: Not stated
safety in primary care	Method: N/A
challenge. Clinical	Sample size: N/A
Risk. 2005;11(4):142-	Risk adjustment/ confounders controlled for: N/A
4.92	Confidence interval: N/A
	Findings: By far the most common error in primary care (50% of cases) was a failure or delay in diagnosis. Other common errors included medication prescription errors, failure or delay in referral and failure to recognise or warn of side effects of medication (each around 5%); The most common recorded outcome of these errors in primary care was the death of the patient (21% of cases). Other outcomes included deterioration in clinical condition (6%) and unnecessary pain (4%). A fundamental characteristic of any organization with a culture of safety is that it is open and fair. For primary care organizations, staff, teams and practices this means that people are: Open about incidents they have been involved in; Able to talk to their colleagues and superiors about any incident; Accountable for their actions; Open and honest with patients, their families or carers, and feel that they can apologize when things have gone wrong; Supported and treated fairly when an incident happens. Primary care organizations and practices can help ensure a two-way dialogue exists between the health service and patients by developing a local policy on <i>Being Open</i> . A <i>Being Open</i> policy should include: A description of how the information will be treated in accordance with privacy and confidentiality guidelines, and in line with data protection and freedom of information legislation; A description of the incident process, including how incidents are detected and reported, responded to, managed and investigated; Defined roles and responsibilities of the health care team and identification of the individual who should make the explanation; Guidance on the content of the initial discussion about the incident with the patient, their relatives or carers; Details of external reporting requirements; Details of the support and follow up required for both the patient and staff.

Phillips RL, Jr.,	Research purpose: Not stated
Bartholomew LA, Dovey S, Fryer GE, Miyoshi TJ, Green LA. Learning from malpractice claims	Method: Physician Insurers Association of America malpractice claims data (1985–2000) were analyzed for proportions of negligent claims by primary care specialty, setting, severity, health condition, and attributed cause. Risks of a claim for condition-specific negligent events relative to the prevalence of those conditions in primary care were calculated.
about negligent, adverse events in	Sample size: Of 49 345 primary care claims, 26 126 (53%) were peer reviewed.
primary care in the	Risk adjustment/ confounders controlled for: Yes
United States. Qual	Confidence interval: No
Saf Health Care. 2004;13:121-6. ⁵⁴	Findings: 5921 primary care claims (23%) were assessed as negligent; 68% of claims were for negligent events in outpatient settings. No single condition accounted for more than 5% of all negligent claims, but the underlying causes were more clustered with "diagnosis error" making up one third of claims. The ratios of condition-specific negligent event claims relative to the frequency of those conditions in primary care revealed a significantly disproportionate risk for a number of conditions (for example, appendicitis was 25 times more likely to generate a claim for negligence than breast cancer). Study type: O
Eldor N. Vondor	Decearch numbers To deceribe errors and proventable adverse events identified by
Meulen M, Cassedy A. The identification	family physicians during the office-based clinical encounter and to determine the physicians' perception of patient harm resulting from these events.
of Medical errors by family physicians during outpatient visits. Annals of Family Medicine. 2004;2(2):125-9. ²¹	Method: Sampled Cincinnati area family physicians representing different practice locations and demographics. After each clinical encounterphysicians completed a form identifying process errors and preventable adverse events. Brief interviews were held with physicians to ascertain their perceptions of harm or potential harm to the patient. Sample size: Fifteen physicians in 7 practices completed forms for 351 outpatient visits. Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Errors and preventable adverse events were identified in 24% of these visits. There was wide variation in how often individual physicians identified errors (3% to 60% of visits). Office administration errors were most frequentky noted. Harm was believe to have occurred as a result of 24% of the errors, and was a potential in another 70%.
	Study type: D
Hickner J, Graham DG, Elder NC, Brandt	Research purpose: To describe types, predictors and outcomes of testing errors reported by family physicians and office staff.
E, Emsermann CB, Dovey S, et al. Testing process errors and their harms and consequences reported from family medicine procestings a	Method: Offices were purposefully selected from a list of 58 volunteers to maximize practice diversity. Physicians, residents, nurse practitioners, physician assistants and office staff submitted anonymous reports of errors they recognised or experienced during the course of their work day. Only errors related to the testing process, including lab tests, diagnostic imaging and other tests such as pulmonary function tests and electrocardiograms.Each office completed a survey describing their testing processes prior to event reporting.
study of the American	Sample size: 243 clinicians and office staff of eight family medicine offices.
Academy of Family Physicians National Research Network. Quality & Safety in Health Care. 2008;17(3):194- 200. ²²	Risk adjustment/ confounders controlled for: Yes
	Confidence interval: Yes
	Findings: Errors occurred in ordering tests (12.9%), implementing tests (17.9%), reporting results to clinicians (24.6%), clinicians responding to results (6.6%), notifying patient of results (6.8%), general administration (17.6%), communication (5.7%) and other categories (7.8%). Charting or filing errors accounted for 14.5% of errors. Significant associations (p.0.05) existed between error types and type of reporter (clinician or staff), number of labs used by the practice, absence of a results follow-up system and patients' race/ethnicity. Adverse consequences included time lost and financial consequences (22%), delays in care (24%), pain/suffering (11%) and adverse

	clinical consequence (2%). Patients were unharmed in 54% of events; 18% resulted in some harm, and harm status was unknown for 28%. Usingmultilevel logistic regression analyses, adverse consequences or harm were more common in events that were clinician-reported, involved patients aged 45–64 years and involved test implementation errors. Minority patients were more likely than white, non-Hispanic patients to suffer adverse consequences or harm. Study type: O
Hoffmann B, Beyer M, Rohe J, Gensichen J, Gerlach FM. "Every error counts": a web-based incident reporting and learning system for general practice. Quality & Safety in Health Care. 2008;17(4):307-12 ²³ .	Research purpose: describes the development, structure and initial results of an incident reporting system for general practices in German speaking countries. Method: Jeder Fehler Zaehlt (JFZ; www.jeder-fehlerzaehlt. de) is a web-based reporting system that receives incident reports from anonymous German-speaking users. Two physicians both experts in the field of patient safety and general practice, classified each report independently. When results varied, a consensus was found. The incident reports were analysed for underlying errors in accordance with the Institute of Medicine's definition ("failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim"). The reports were categorised according to the International Taxonomy of Medical Errors in Primary Care (version August 2004) with its four domains (error type, impact, contributing factors, prevention strategies). Each domain has two to four levels. Since several reports contained more than one item in one or more of the three domains error type, contributing factors and prevention strategies, the respective domain was classified up to three times rather than once.
	In 44.7% and males in 38.3% of the reports (17% of reports did not specify). Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: 130 incidents occurred for the first time, 29 occurred once a year, 16 occurred once a month, 5 occurred once a week and another 5 occurred daily (3 were not specified). Nearly three-quarters of the reports were classified as process errors. In the reports of treatment errors, 92 different drugs were identified; those most often involved were anticoagulants (21 times), vaccines (18), analgesics (17), antihypertensives (9), antibiotics (8) and antidiabetics (4). In 101 reports the most frequent contributing factors were provider factors ("relying on computer", "seeing what you expect to see", "lack of attention to detail") and in 25 reports these were patient factors (eg, "patient presenting with many health problems"). Other contributing factors occurred rarely (provider team, task, working conditions, organisation, physical environment, regulatory/payment system factors). JFZ is an efficient incident reporting system in an early stage of development. Study type: D
Makeham MAB, Stromer S, Bridges- Webb C, Mira M, Saltman DC, Cooper C, et al. Patient safety events reported in general practice: a taxonomy. Quality & Safety in Health Care. 2008;17(1):53-7. ³³	Research purpose: To develop a taxonomy describing patient safety events in general practice from reports submitted by a random representative sample of general practitioners (GPs), and to determine proportions of reported event types. Method: 433 reports received by the Threats to Australian Patient Safety (TAPS) study were analysed by three investigating GPs, classifying event types contained. Agreement between investigators was recorded as the taxonomy developed. Sample size: 84 volunteers from a random sample of 320 GPs, previously shown to be representative of 4666 GPs in New South Wales, Australia. Risk adjustment/ confounders controlled for: None Confidence interval: N/A Findings: A three-level taxonomy resulted. At the first level, errors relating to the processes of healthcare (type 1; n = 365 (69.5%)) were more common than those relating to deficiencies in the knowledge and skills of health professionals (type 2; n = 160 (30.5%)). At the second level, five type 1 themes were identified: healthcare systems (n = 112 (21 3%)): investigations (n = 65 (12 4%)): modications (n = 107 (20 4%)): other

	treatments (n = 13 (2.5%)); and communication (n = 68 (12.9%)). Two type 2 themes were identified: diagnosis (n = 62 (11.8%)) and management (n = 98 (18.7%)). The third level comprised 35 descriptors of the themes. Good inter-coder agreement was demonstrated with an overall kappa score of 0.66. A least two out of three investigators independently agreed on event classification in 92% of cases.
Tilyard M, Dovey S, Hall K. Avoiding and fixing medical errors	Research purpose: To report tactics for avoiding and remedying medical errors observed by general practitioners in New Zealand, Australia, Canada, England, the Netherlands, and the United States and five other countries.
in general practice: prevention strategies	Method: Reports from the Primary Care International Study of Medical Errors in these countries were compared.
reported in the Linnaeus Collaboration's primary care	Sample size: 66 reports of medical errors in New Zealand and 363 reports from general practitioners in Australia, Canada, England, the Netherlands, and the United States. Risk adjustment/ confounders controlled for: N/A
international study of medical errors. The New Zealand Medical Journal. 2005;118(1208). ²⁷	Confidence interval: N/A Findings: In all New Zealand reports and 336 (92.6%) reports from other countries, doctors offered at least one error prevention idea. The largest category of suggestions was 'more diligence' (New Zealand: 69.7% of reports, other countries: 55.3%). Other strategies were: 'provide care differently' (New Zealand 22.7%, other countries 36.4%); 'improve communication' (19.7% and 17.8% of reports); 'education' (7.8% and 11.0% of reports); and 'more resources' (12.1% and 14.0% of reports).
	In general practitioners' medical errors reports, a culture of individual blame is more evident than recognised need for systems design. A minority of reports contained specific, pragmatic suggestions for changing healthcare systems to protect patients' safety. Error reporting systems may be a practical way to generate innovative solutions to potentially harmful problems facing general practice patients.
	Study type: R
Kostopoulou O, Delaney B.	Research purpose: To classify events of actual or potential harm to primary care patients using a multilevel taxonomy of cognitive and system factors
Confidential reporting of patient safety events in primary care: results from a multilevel classification of cognitive and system factors. Qual Saf Health Care. 2007 Apr;16(2):95-100. ⁵⁵	Method: Observational study of patient safety events obtained via a confidential but not anonymous reporting system. Reports were followed up with interviews where necessary. Events were analysed for their causes and contributing factors using causal trees and were classified using the taxonomy. General medical practices in the West Midlands were selected to represent a range of sizes and types of patient population. All practice staff were invited to report patient safety events. Main outcome measures were frequencies of clinical types of events reported, cognitive types of error, types of detection and contributing factors; and relationship between types of error, practice size, patient consequences and detection.
	Sample size: Five general medical practices in the West Midlands of UK
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: 78 reports were relevant to patient safety and analysable. They included 21 (27%) adverse events and 50 (64%) near misses. 16.7% (13/71) had serious patient consequences, including one death. 75.7% (59/78) had the potential for serious patient harm. Most reports referred to administrative errors (25.6%, 20/78). 60% (47/78) of the reports contained sufficient information to characterise cognition: "situation assessment and response selection" was involved in 45% (21/47) of these reports and was often linked to serious potential consequences. The most frequent contributing factor was work organisation, identified in 71 events. This included excessive task demands (47%, 37/71) and fragmentation (28%, 22/71).
	Even though most reported events were near misses, events with serious patient consequences were also reported. Failures in situation assessment and response selection, a cognitive activity that occurs in both clinical and administrative tasks, was

	related to serious potential harm.
	Study type: D
Jacobs S, O'Beirne M, Derfiingher LP, Vlach L, Rosser W,	Research purpose: To develop a taxonomy of errors derived solely from the content of error reports using Canadian data from the Primary Care International Study of Medical Errors.
Drummond N. Errors and adverse events	Method: Secondary analysis of data from a descriptive, cross-sectional, self-report survey.
In family medicine:	Sample size:
validating a Canadian	Risk adjustment/ confounders controlled for: N/A
taxonomy of errors.	Confidence interval: N/A
Can Fam Physician. 2007 Feb;53(2):271- 6, 0. ⁵⁶	Findings: Six types of errors or adverse events (administrative, communication, diagnostic, documentation, medication, and surgical or procedural) and 10 causal factors (case complexity, discontinuity of care, failure to follow protocol or accepted practice, fatigue, gap in knowledge, high workload, insufficient information on pharmacologic properties of medication, medication side effects, relationship dynamics, and structural problems) were identified.
	Study type: D
Smith PC, Araya- Guerra R, Bublitz C,	Research purpose: To describe primary care clinicians' reports of missing clinical information.
Parnes B, Dickinson LM, Van Vorst R, et al. Missing clinical information during primary care visits. Jama. 2005 Feb 2;293(5):565-71. ³⁵	Method: Cross-sectional survey conducted in primary care clinics within State Networks of Colorado Ambulatory Practices and Partners (SNOCAP), a consortium of practice- based research networks participating in the Applied Strategies for Improving Patient Safety medical error reporting study. For every visit during 1 half-day session, each clinician completed a questionnaire about patient and visit characteristics and stated whether important clinical information had been missing. Clinician characteristics were also recorded.
	Reports of missing clinical information frequency, type, and presumed location; perceived likelihood of adverse effects, delays in care, and additional services; and time spent looking for missing information. Multivariate analysis was conducted to assess the relationship of missing information to patient, visit, or clinician characteristics, adjusting for potential confounders and effects of clustering.
	Sample size: 32 primary care clinics within State Networks of Colorado Ambulatory Practices and Partners (SNOCAP). Two hundred fifty-three clinicians were surveyed about 1614 patient visits between May and December 2003.
	Risk adjustment/ confounders controlled for: Cross-sectional survey
	Confidence interval: 95%
	Findings: Clinicians reported missing clinical information in 13.6% of visits; missing information included laboratory results (6.1% of all visits), letters/dictation (5.4%), radiology results (3.8%), history and physical examination (3.7%), and medications (3.2%). Missing clinical information was frequently reported to be located outside their clinical system but within the United States (52.3%), to be at least somewhat likely to adversely affect patients (44%), and to potentially result in delayed care or additional services (59.5%). Significant time was reportedly spent unsuccessfully searching for missing clinical information was more likely when patients were recent immigrants (odds ratio [OR], 1.78; 95% confidence interval [CI], 1.06-2.99), new patients (OR, 2.39; 95% CI, 1.70-3.35), or had multiple medical problems compared with no problems (1 problem: OR, 1.09; 95% CI, 0.69-1.73; 2-5 problems: OR, 1.87; 95% CI, 1.21-2.89; >5 problems: OR, 2.78; 95% CI, 0.29-0.92) and when individual clinicians reported having full electronic records (OR, 0.40; 95% CI, 0.17-0.94). Primary care
	consume time and other resources, and may adversely affect patients.

	Study type: D
Ludwick DA, Doucette J. Adopting electronic medical records in primary care: lessons learned from health information systems implementation experience in seven countries. Int J Med Inform. 2009	Research purpose: The purpose of this review was to identify the current state of knowledge about health information systems adoption in primary care. The goal was to understand factors and influencers affecting implementation outcomes from previous health information systems implementations experiences.
	Method: A comprehensive systematic literature review of peer reviewed and grey literature was undertaken to identify the current state of knowledge regarding the implementation of health information systems.
	Sample size: A total of 6 databases, 27 journal websites, 20 websites from grey sources, 9 websites from medical colleges and professional associations as well as 22 government/commission websites were searched. The searches returned almost 3700 article titles. Eighty-six articles met the inclusion and exclusion criteria.
541,70(1).22 51.	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Articles show that systems' graphical user interface design quality, feature functionality, project management, procurement and users' previous experience affect implementation outcomes. Implementers had concerns about factors such as privacy, patient safety, provider/patient relations, staff anxiety, time factors, quality of care, finances, efficiency, and liability. The review showed that implementers can insulate the project from such concerns by establishing strong leadership, using project management techniques, establishing standards and training their staff to ensure such risks do not compromise implementation success. The review revealed the concept of socio-technical factors, or "fit" factors, that complicate health information systems deployment. The socio-technical perspective considers how the technical features of a health information system interact with the social features of a health care work environment.
	not, positively or negatively, affected by systems implementation. The fact that no articles were found reviewing the benefits or drawbacks of health information systems accruing to patients should be concern to adopters, payers and jurisdictions. No studies were found that compared how provider–patient interactions in interviews are effected when providers used electronic health information systems as opposed to the paper equivalent. Very little information was available about privacy and liability.
Stead WW	Research purpose: To describe options and implementation strategies for IT to improve
Rethinking electronic health records to better achieve quality and safety goals. Annu Rev Med. 2007;58:35-47. ⁵⁸	patient safety
	Method: Expert opinion
	Sample size: N/A
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: By matching technological approach to task and staging introduction into practice, initial benefit can be obtained more quickly, at reduced cost, while managing risk of a misfit. A staged approach to turning direct access by patients to their health information into more effective care is presented as an example of this strategy. Study type: EO/C

Cohen A, Abaluck B, Localio AR, Kimmel SE, et al. Role of computerized physician order entry systems in facilitating medication errors. JAMA. 2005;293:1197-203. ⁵⁹ Method: We performed a qualitative and quantitative study of house staff interaction with a CPOE system at a tertiary-care teaching hospital (2002-2004). Main Outcome Measure: examples of medication errors caused or exacerbated by the CPOE system. Sample size: We surveyed house staff (N = 261; 88% of CPOE users); conducted 5 focus groups and 32 intensive one-on-one interviews with house staff, information technology leaders, pharmacy leaders, attending physicians, and nurses; shadowed house staff and nurses; and observed them using CPOE. Participants included house staff, nurses, and hospital leaders. Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: We found that a widely used CPOE system facilitated 22 types of medication error risks. Examples include fragmented CPOE displays that prevent a coherent view of patients' medications, pharmacy inventory displays mistaken for dosage guidelines, ignored antibiotic renewal notices placed on paper charts rather than in the CPOE system, separation of functions that facilitate double dosing and incompatible orders, and inflexible ordering formats generating wrong orders. Three quarters of the house staff reported observing each of these error risks, indicating that they occur weekly or more
Localio AR, Kimmel SE, et al. Role of computerized physician order entry systems in facilitating medication errors. JAMA. 2005;293:1197-203. ⁵⁹ Method: We performed a qualitative and quantitative study of house staff interaction with a CPOE system at a tertiary-care teaching hospital (2002-2004). Main Outcome Measure: examples of medication errors caused or exacerbated by the CPOE system. Sample size: We surveyed house staff (N = 261; 88% of CPOE users); conducted 5 focus groups and 32 intensive one-on-one interviews with house staff, information technology leaders, pharmacy leaders, attending physicians, and nurses; shadowed house staff and nurses; and observed them using CPOE. Participants included house staff, nurses, and hospital leaders. Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: We found that a widely used CPOE system facilitated 22 types of medication error risks. Examples include fragmented CPOE displays that prevent a coherent view of patients' medications, pharmacy inventory displays mistaken for dosage guidelines, ignored antibiotic renewal notices placed on paper charts rather than in the CPOE system, separation of functions that facilitate double dosing and incompatible orders, and inflexible ordering formats generating wrong orders. Three quarters of the house staff reported observing each of these error risks, indicating that they occur weekly or more
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often. Use of multiple qualitative and survey methods identified and quantified error risks not previously considered, offering many opportunities for error reduction. In this study, we found that a leading CPOE system often facilitated medication error risks, with many reported to occur frequently. As CPOE systems are implemented, clinicians and hospitals must attend to errors that these systems cause in addition to errors that they prevent. Study type: Q
Hendersen J. Britt H. Research purpose: To assess the availability of computers to general practitioners and
Miller G. Extent and individual GPs' use of computers for clinical functions.
utilisation of computerisation in Australian general practice. Medical Journal of Australia. Utilisation of Method: A secondary analysis of data from a random sample of Australian GPs who participated in the Bettering the Evaluation and Care of Health (BEACH) survey, a continuous cross-sectional survey of general practice activity, between November 2003 and March 2005. Participants reported the availability of computers at their major practice address and the clinical functions for which they used the computers.
2006;185(84-87). ⁶⁰ Main outcome measures were the proportion of practices with computers available; proportion of individual GPs who used computers for clinical purposes.
Sample size: 1319 Australian GPs
Risk adjustment/ confounders controlled for: N/A
Confidence interval: N/A
Findings: The proportion of GPs not using a computer was 11.2% (6% did not have a computer at their major practice address and a further 5.2% chose not to use an available computer). The majority of GPs using a computer at work used it for electronic prescribing (94.7%), ordering tests (82.2%) and keeping some patient data in an electronic medical record (79.5%). Of those with clinical software available (n = 1114), 6.6% chose not to use it. A third of GPs (32.8%) kept all patient information in an electronic format. The proportion of GPs keeping all data electronically and using all clinical functions available in their computer was 21.7%.
While the physical presence of computers has increased significantly over the past decade, GPs are still reluctant to fully embrace the technology. Study type: D

Daniel DM, Rupert RL. Calibration and electrical safety status of therapeutic ultrasound used by chiropractic	Research purpose: To determine whether ultrasound machines used by chiropractic physicians met established calibration and electrical safety standards, and to assess frequency of ultrasound therapy use.
	Method: This cross-sectional study tested 45 ultrasound units for ultrasonic output and electrical safety. Additionally, doctors were asked to complete a short survey relating to education, usage, and maintenance of their ultrasound equipment.
physicians. 2003.36	Sample size: 45 ultrasound units
	Risk adjustment/ confounders controlled for:
	Confidence interval: p<0.05
	Findings: Of the 45 machines tested, 44% failed either calibration or electrical safety inspection. Failure rate was age dependent (P <= .05). Only 2 of the 45 machines tested had been safety checked within the last year. A large percentage of ultrasound machines in chiropractic physicians' offices deliver too much or too little dosage to the patient. Electrical safety inspections also revealed a significant failure rate. Chiropractic physicians must become more aware of the requirement for yearly calibration and safety inspections, and understand that failure to maintain their equipment could result in loss of therapeutic effectiveness and pose a threat to the safety of their patients and staff. Study type: D
Singh H, Petersen LA, Thomas EJ. Understanding	Research purpose: Argues for situational awareness as a model that is primarily used in aviation human factors research that can encompass both the cognitive and the systems roots of such errors.
diagnostic errors in	Method: Expert opinion
from aviation Quality	Sample size: N/A
and Safety in Health	Risk adjustment/ confounders controlled for: N/A
Care. 2006;15:159-	Confidence interval: N/A
64. ⁶¹	Findings: It is possible that the use of such a model in medicine could help reduce errors in diagnosis and lead to significant improvements in patient care.
	Study type: EO/C
Wahls TL, Cram PM. The frequency of missed test results and associated treatment delays in a highly computerized health system. BMC Fam Pract. 2007;8:32. ⁶²	Research purpose: The primary objective of the current study was to assess the frequency of missed results and resulting treatment delays encountered by primary care providers in VA clinics.
	Method: An anonymous on-line survey of primary care providers was conducted as part of the health systems ongoing quality improvement programs. Information was collected from providers concerning their clinical effort (e.g., number of clinic sessions, number of patient visits per session), number of patients with missed abnormal test results, and the number and types of treatment delays providers encountered during the two week period prior to administration of our survey.
	Sample size: 106 out of 198 providers (54 percent response rate).
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Respondents saw an average of 86 patients per 2 week period. Providers encountered 64 patients with missed results during the two week period leading up to the study and 52 patients with treatment delays. The most common missed results included imaging studies (29 percent), clinical laboratory (22 percent), anatomic pathology (9
	percent), and other (40 percent). The most common diagnostic delays were cancer (34 percent), endocrine problems (26 percent), cardiac problems (16 percent), and others (24 percent).
	Missed results leading to clinically important treatment delays are an important and likely underappreciated source of diagnostic error.
	Study type: D

Bird S. Missing test results and failure to diagnose. Australian Family Physician.	Research purpose: This article outlines a method of analysing near misses in general practice with the aim of minimising the risk of an adverse incident, complaint or claim arising from failure to diagnose.
	Method: Case study and expert opinion
2004 360-	Sample size: N/A
301;33(3).107	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Claims alleging 'failure to diagnose' account for up to 50% of medical negligence claims against GPs. These claims commonly arise from a failure in a practice's test result and patient tracking systems. Cause and effect diagrams are a useful tool to assist timely diagnosis.
	Study type: EO/C
Makeham MAB,	Research purpose: To present clinical lessons resulting from the TAPS study.
Saltman DC, Kidd	Method: Synthesis of findings
the TAPS study:	Sample size: 648 anonymous reports about threats to patient safety from a representative random sample of Australian general practitioners.
systems. Australian	Risk adjustment/ confounders controlled for: N/A
Family Physician.	Confidence interval: N/A
2008;37(11):923-4. ¹⁶	Findings: See other papers by these authors
	Study type: D
Farrow SC, Zeuner D, Hall C. Improving	Research purpose: This paper describes one district's collaborative approach between public health and GPs to assess and improve local infection control standards
infection control in	Method: Survey and telephone interviews
general practice. The	Sample size: 82 Family practices
Society for the	Risk adjustment/ confounders controlled for: N/A
Promotion of Health.	Confidence interval: N/A
1999;119(1):17-22. ³⁷	Findings: A number of infection control shortcomings were identified
	Study type: Q
Bradley E, Hynam B, Nolan P. Nurse prescribing: reflections on safety in practice. Social Science & Medicine.	Research purpose: To ascertain the conditions that foster the highest levels of safety and how nurses can be supported in prescribing practice. To investigate how recently qualified nurse prescribers describe, and rate, the safety of their prescribing.
	Method: An in-depth interview that sought to elicit responses to various aspects of prescribing work. The nurses came from a variety of specialities and from hospital, community and general practice backgrounds.
2007;65(3):599-	Risk adjustment/ confounders controlled for: N/A
009.03	Confidence interval: N/A
	Findings: On completion of their training nurses were acutely aware of the responsibility that prescribing imposed on them. Although this awareness was thought to encourage caution and safety, it may also account for the fact that 26% of the nurses (n=8) had not prescribed since qualifying. Nurses felt that the multidisciplinary team had a vital role to play in supporting their prescribing practice as did collaborative working. It is concluded that those working in specialty areas that are less well-defined in terms of scope of practice (e.g. older adult nursing and learning disability) would benefit in particular from ongoing mentoring relationships with experienced prescribers and the development of individual formularies.
	Study type: Q

Duncimon WP	Decearch nurness. To review information about adverse drug events (ADEs) and
Runciman WB, Roughead EE, Semple SJ, Adams RJ. Adverse drug events and modication errors in	medication errors in Australia.
	Method: Synthesis of systematic literature reviews and reports from data collections of the Australian Bureau of Statistics, Institute of Health and Welfare, Council for Health Care Standards and Patient Safety Foundation.
Australia, 2003, ¹⁴⁴	Sample size: N/A
	Risk adjustment/ confounders controlled for: No
	Confidence interval: N/A
	Findings:
	 (routine data collections): Routine death certificate and hospital discharge data coded using the International Classification of Diseases capture less than half as many ADEs as medical record reviews. Of coded adverse events that contributed to death, 27% involved an ADE, as did 20% of adverse events identified at discharge and 43% at general practice encounters. There is a strong correlation between increases in medication use and rates of adverse drug reactions (ADRs) associated with hospitalization.
	2. (drugs implicated): These were similar in all the above studies: anticoagulants, anti- inflammatory drugs, opioids, anti-neoplastics, antihypertensives, antibiotics, cardiac glycosides, diuretics, hypoglycaemic agents, steroids, hypnotics, anticonvulsants, and antipsychotics. Results (clinical indicators): An ADE is reported in 1% of hospital admissions, while some hospitals do not report ADRs to the national collection. Only three-quarters of patients with acute myocardial infarction receive thrombolytics within 1 hour of presentation. Five per cent of patients on warfarin record an international normalized ratio >5, and 1%, 0.05%, and 0.2% suffer abnormal bleeding, cerebral haemorrhage, or death, respectively.
	 (the Australian Incident Monitoring System): Twenty six per cent of 27 000 hospital- related incidents were medication-related, as were 36% of 2000 anaesthesia-related incidents, and 50% of 2500 general practice incidents.
	 (errors): Errors occur in 15-20% of drug administrations when ward stock systems arc used and 5-8% when individual patient systems are used. Previous allergic reactions to drugs may not be recorded more than 75% of the time.
	Study type: D
Kuo GM, Philips RL, Graham D, Hickner J. Medication errors reported by US family physicians and their office staff. Qual Saf Health Care. 2008;17:286-90. ⁶⁴	Research purpose: To describe medication errors reported by family physicians and their office staff and to estimate their preventability using currently available electronic prescribing and monitoring tools.
	Method: In two error reporting studies conducted by the American Academy of Family Physicians (AAFP) National Research Network (NRN), 1265 medical errors were voluntarily reported by >440 primary care clinicians and staff from 52 physician offices. The error reports related to medications were abstracted and analysed using a medication error coding toolMedication Error Types, Reasons, and Informatics Preventability (METRIP). Main outcome measures were the type, severity and preventability of medication errors and associated adverse drug events (ADEs).
	Sample size: 194 error reports related to medications were abstracted
	Risk adjustment/ confounders controlled for: None
	Confidence interval: N/A
	Findings: 126 (70%) of the medication errors were prescribing errors, 17 (10%) were medication administration errors, 17 (10%) documentation errors, 13 (7%) dispensing errors and 5 (3%) were monitoring errors. ADEs resulted from 16% of reported medication errors. The severity of harm from reported errors were: prevented and did not reach patients, (72, 41%), reached patients but did not require monitoring (63, 35%), reached patients and required monitoring (15, 8%), reached patients and required intervention (23, 13%) and reached patients and resulted in hospitalisation (5, 3%). No
	deaths were reported. Of the errors that were prevented from reaching patients, 29 (40%)

	were prevented by pharmacists, 14 (19%) by physicians, 12 (17%) by patients and 5 (7%) by nurses. 102 (57%) of the reported errors might have been prevented with enhanced electronic prescribing and monitoring tools. ConclusionsMost medication errors reported from US family physician offices were related to prescribing errors and more than half of the errors reached patients. The errors were prevented by pharmacists, patients and physicians. More than half of the errors could be prevented by electronic tools. Study type: D
Adubofour K, Keenan	Research purpose: This article provides an overview of strategies that can be adopted
C, Daftary A, Mensah-Adubofour J, Dachman W. Strategies to reduce medication errors in	by primary care physicians to decrease medication errors in ambulatory practice.
	Method: Synthesis of literature
	Sample size: N/A US studies and audience
	RISK adjustment/ confounders controlled for: N/A
lournal of the	Confidence Interval: N/A
National Medical Association. 2004;96:1558-64. ⁶⁵	Findings: Physicians engaged in ambulatory practice need to be proactive in making the use of medications safer. It is only through constant vigilance that doctors can decrease the incidence of ADR and medication errors. They should work with patients and other healthcare providers to reduce the number of errors in prescriptions and drug administration. They must also participate in the post-marketing surveillance program established by the FDA. The MedWatch program (1-800-FDA- 1088, http://www.fda.gov/medwatch/report/hcp.htm) is the safety information and adverse event reporting program of the FDA. MedWatch is important since the data generated can only lead to more prudent prescribing.
	Study type: R
Gandhi TJ, Burstin H, Cook EF, Puopolo AL, Haas JS, Brennan TA, et al. Drug complications in	Research purpose: This paper sought to assess the incidence and characteristics of outpatient drug complications, identify their clinical and non-clinical correlates, and evaluate their impact on patient satisfaction.
	Method: Retrospective chart reviews and patient surveys in eleven Boston-area ambulatory clinics.
of General Internal	Sample size: 2,248 outpatients, 20 to 75 years old, randomly selected
Medicine.	Risk adjustment/ confounders controlled for: None
2000;15:149-54.66	Confidence interval: p<.0001, 95% CI
	Findings: Among 2,248 patients reporting prescription drug use, 394 (18%) reported a drug complication. In contrast, chart review revealed an adverse drug event in only 64 patients (3%). In univariate analyses, significant correlates of patient-reported drug complications were number of medical problems, number of medications, renal disease, failure to explain side effects before treatment, lower medication compliance, and primary language other than English or Spanish. In multivariate analysis, independent correlates were number of medical problems (odds ratio [OR] 1.17; 95% confidence interval [95% CI] 1.05 to 1.30), failure to explain side effects (OR 1.65; 95% CI, 1.16 to 2.35), and primary language other than English or Spanish (OR 1.40; 95% CI, 1.01 to 1.95). Patient satisfaction was lower among patients who reported drug complications ($P < .0001$). In addition, 48% of those reporting drug complications sought medical attention and 49% experienced worry or discomfort. On chart review, 3 (5%) of the patients with an adverse drug event required hospitalisation and 8 (13%) had a documented previous reaction to the causative drug.
	documented in the medical record. These complications increased use of the medical system and correlated with dissatisfaction with care. Our results indicate a need for better communication about potential side effects of medications, especially for patients with multiple medical problems. Study type: O

Gandhi TJ, Weingart SN, Borus J, Seger AC, Peterson J, Burdick E, et al. Adverse drug events in ambulatory care. The New England	Research purpose: This study aimed to determine the rates, types, severity, and preventability of adverse events related to drugs among outpatients and to identify preventive strategies. Method: A prospective cohort study, including a survey of patients and a chart review, at
	four adult primary care practices in Boston (two hospital-based and two community- based). Prescriptions were computerized at two of the practices and handwritten at the other two.
2003;348:1556-64. ¹³⁹	Sample size: 1202 outpatients who received at least one prescription during a four-week period.
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Of the 661 patients who responded to the survey (response rate, 55 percent), 162 had adverse drug events (25 percent; 95 percent confidence interval, 20 to 29 percent), with a total of 181 events (27 per 100 patients). Twenty-four of the events (13 percent) were serious, 51 (28 percent) were ameliorable, and 20 (11 percent) were preventable. Of the 51 ameliorable events, 32 (63 percent) were attributed to the physician's failure to respond to medication-related symptoms and 19 (37 percent) to the patient's failure to inform the physician of the symptoms.
	The medication classes most frequently involved in adverse drug events were selective serotonin-reuptake inhibitors (10 percent), beta-blockers (9 percent), angiotensin-converting–enzyme inhibitors (8 percent), and nonsteroidal antiinflammatory agents (8 percent). On multivariate analysis, only the number of medications taken was significantly associated with adverse events.
	Adverse events related to drugs are common in primary care, and many are preventable or ameliorable. Monitoring for and acting on symptoms are important. Improving communication between outpatients and providers may help prevent adverse events related to drugs.
	Study type: O
Gurwitz JH, Field TS, Harrold LR, Rothschild J, Debellis K, Seger AC, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA. 2003;289(9):1107- 16. ⁶⁷	Research purpose: To assess the incidence and preventability of adverse drug events among older persons in the ambulatory clinical setting.
	Method: Cohort study using multiple methods, including reports from health care providers; review of hospital discharge summaries; review of emergency department notes; computer-generated signals; automated free-text review of electronic clinic notes; and review of administrative incident reports concerning medication errors.
	Sample size: all Medicare enrollees (30 397 personyears of observation) cared for by a multispecialty group practice during a 12-month study period (July 1, 1999, through June 30, 2000), in which possible drug-related incidents occurring in the ambulatory clinical setting were detected
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: There were 1523 identified adverse drug events, of which 27.6% (421) were considered preventable. The overall rate of adverse drug events was 50.1 per 1000 personyears, with a rate of 13.8 preventable adverse drug events per 1000 person-years. Of the adverse drug events, 578 (38.0%) were categorized as serious, life-threatening, or fatal; 244 (42.2%) of these more severe events were deemed preventable compared with
	preventable adverse drug events occurred most often at the stages of prescribing (n=246, 58.4%) and monitoring (n=256, 60.8%), and errors involving patient adherence (n=89, 21.1%) also were common. Cardiovascular medications (24.5%), followed by diuretics (22.1%), nonopioid analgesics (15.4%), hypoglycemics (10.9%), and anticoagulants (10.2%) were the most common medication categories associated with
	preventable adverse drug events. Electrolyte/renal (26.6%), gastrointestinal tract (21.1%), hemorrhagic (15.9%), metabolic/endocrine (13.8%), and neuropsychiatric

	(8.6%) events were the most common types of preventable adverse drug events.
	Study type: O
AI Khaja KAJ, Sequeira RP, AI- Ansari TM, Damanhori AHH. Prescription writing skills of residents in a family practice residency programme in Bahrain. Postgraduate Medical Journal. 2008;84(990):198- 204. ⁵²	Research purpose: To evaluate the prescription writing skill of final year residents in a family practice residency programme (FPRP) in Bahrain, and to compare skill of residents who have graduated from medical schools with problem based learning (PBL) versus traditional (non-PBL) curricula.
	Method: Prescriptions issued by the residents were prospectively collected for two consecutive cohorts in May 2004 and May 2005. Prescription errors were classified as errors of omission (minor and major), commission (incorrect information) and integration (drug-drug interactions).
	Sample size: Prescriptions issued by FPRP residents were collected by the pharmacists in charge in response to a request from the chief pharmacist for primary care from the three health centres designated for training year 4 FPRP residents. All prescriptions issued by 12 final year residents (a batch of 13 residents) in May 2004 and another 14 final year residents (a batch of 14 residents) in May 2005 were collected.
	Risk adjustment/ confounders controlled for: None
	Confidence interval: p<.05
	Findings: In 69.6% of medications with major omission errors, dosage form (39.4%) and length of treatment (18.5%) were not specified. In 24.7% of medications with commission errors, dosing frequency (19.9%) and incorrect strength/dose (2.2%) were the most common errors. Integration errors comprised 5.7% of all prescribing errors. No significant differences were observed between PBL and non-PBL graduates with regard to the total number of prescriptions with errors, drugs per prescriptions with a potential for drug-drug interactions was comparable between PBL and non-PBL graduates. PBL graduates prescribed medications using brand names at a rate greater than non-PBL, whereas non-PBL graduates prescribed medications on inappropriate "as required" basis, and injections at a rate greater than PBL residents.
Barber N. Designing	Research nurnose: This naner discusses the sort of characteristics that a decision
information	support system should have.
technology to support	Method: Opinion and referenced literature
prescribing decision making. Oual Saf	Sample size: N/A
Health Care. 2004	Risk adjustment/ confounders controlled for: N/A
Dec;13(6):450-4.68	Confidence interval: N/A
	Findings: The system should slot into a wider vision of good prescribing, not conflict with it, and should be based on our understanding of the causes of error. As yet there is little evidence that decision support is effective in changing patient outcome, and the evaluation in this field is of limited quality and generalisability. It is proposed that software design should target high risk patients and drugs, trap dosing errors, have standardised methods of production and evaluation, be congruent with good prescribing, focus on the tasks that computers do well, individualise treatment, and ensure that prescribers enjoy using the final product. Study type: EO/C
Schulmeister L. Look-	Research purpose: To discuss the effect of Confusing medication names and
alike, sound-alike	packaging on medication error
medications. Clinical	Nethod: Informed opinion and literature review
Journal of Oncology	Sample Size: N/A
Nursing.	KISK aujustment/ confounders controlled for: N/A
2000;10(1):35-41.134	Confidence Interval: N/A
	medication errors. Look-alike, sound-alike errors cannot be attributed solely to similar
	medication names and packaging; additional root causes and contributing factors usually exist. Nurses, especially those who prepare chemotherapy in addition to administering it, play a major role in preventing or averting look-alike, sound-alike medication errors. The potential for errors caused by look-alike, sound-alike medications may be reduced by using generic drug names, CPOE, and computer alerts; limiting the type or number of dose formulations of high-risk medications; placing warning labels on stock bins; and storing high-risk medication errors. To reduce the potential for this type of error, nurses also need to maintain awareness of problematic product names and implement the error prevention recommendations advocated by the ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).
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Meredith S, Feldman	Research purpose: To determine the frequency of possible medication errors in a
PH, Frey D, Hall K,	population of older home healthcare patients according to expert panel objective criteria
et al. Possible	Method: A cross-sectional survey with two of the largest urban home healthcare agencies in the United States.
home healthcare	Sample size: 6,718 home healthcare patients age 65 and older admitted to selected offices of these agencies between October 1996 and September 1998
the American Geriatrics Society	Risk adjustment/ confounders controlled for: 400 (4.7%) were excluded from the analysis because of missing data.
2001;49:719-24. ⁴²	Confidence interval: N/A
	Findings: The study subjects took a median of five drugs; 19% were taking nine or more medications. A possible medication error was identified for 19% of patients according to Home Health Criteria, 17% according to the Beers criteria, and 30% according to either. Possible errors increased linearly with number of medications taken. When patients taking one to three medications were compared with those taking nine or more drugs, the percentages with possible errors were, respectively, 10% and 32% for the Home Health Criteria, 8% and 32% for the Beers criteria, and 16% and 50% for both. Nearly one-third of the home healthcare patients surveyed had evidence of a potential medication problem or were taking a drug considered inappropriate for older people.
	Study type: O
Mason A. New medicines in primary care: a review of	Research purpose: This review aimed to explore the determinants of uptake, the causes of geographical variations, and the influence of price, cost and financial incentives on prescribing behaviour.
influences on general practitioner prescribing. Journal of Clinical Pharmacy & Therapeutics. 2008;33(1):1-10. ¹⁸⁸	Method: Two separate searches were conducted on nine electronic databases. Strategy 1, an update of a previous review, used key terms for primary care physicians, uptake, medicines and 'new'. Strategy 2 focussed on terms relating to incentives and prescribing. Records were screened for eligibility and data from relevant papers were extracted using Bonair and Persson's typology for determinants of the diffusion of innovation, which classified influences into three groups: actors, structural/environmental characteristics and product characteristics.
	Sample size: N/A
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: The searches identified 550 records and 28 studies were included in the updated review. Prescribing of new medicines needs to be understood in the context of individual patient-centred care, which is characterized by stability and continuity. Hospital doctors, pharmaceutical representatives and prescribing advisers are all influential, but GP attitudes towards these actors vary and there are notable differences between high and low prescribers of new pharmaceuticals. Support systems can help provide appropriate guidance and increase the uptake of new medicines by identifying patients who may benefit from pharmaceutical therapy. There is evidence of a shift in GP

	attitudes towards central policy initiatives, with doctors slowly accepting the need for external scrutiny and national standards. Although cost does appear to inform prescribing decisions, it is typically of lower importance than both safety and efficacy concerns and does not represent a significant barrier to uptake of new medicines. The impact of financial incentives on prescribing behaviour remains unclear, but is unlikely to be straightforward. No evidence exploring the reasons for geographical variations in GP uptake of new medicines was found. Study type: R
Persell SD, Heiman HL, Weingart SN, Purdick E, Porus L	Research purpose: Patients' knowledge of the indications of their prescription medications was studied and those medications that were most likely to be taken without nations understanding the correct indication were identified.
Burdick E, Borus J, Murff HJ, et al. Understanding of drug indications by ambulatory care patients. American Journal of Health-	Patients understanding the correct indication were identified. Method: Adult patients who received care at four primary care practices were surveyed. Patients were eligible to participate if they were over 18 years old and had received a prescription from a participating physician at a clinic visit. Patients were telephoned and asked to retrieve the bottles of all medications they were currently taking, identify their medications, and state the reason they took each medicine. The primary outcome was absent or incorrect knowledge of a drug's indication.
2004;61(1):2523-7. ⁴⁶	whose data were analyzed.
	Risk adjustment/ confounders controlled for: Covariates included
	Confidence interval: 95%
	Findings: Eighty-three patients (13.5%) lacked knowledge of the indication for at least one of their prescription medications. They did not know the indication for 148 medications (6.3%). After multivariable adjustment, lack of knowledge was more common for cardiovascular drugs (odds ratio [OR], 1.50; 95% confidence interval [CI], 1.03-2.19) and less common for diabetes medications (OR, 0.37; 95% CI, 0.16-0.84) and analgesics (OR, 0.23; 95% CI, 0.05-1.01) compared with all other medications, and more common if the patient taking these medications was older, black, or had a high school education or less.
	one of their prescription medications. Lack of knowledge was most prevalent for cardiovascular medications.
	Study type: D
Birdsall R, Deng T,	Research purpose: To identify the types of medicine compliance issues that occur among older people.
Man L, Ross A, et al. Identifying compliance issues with prescription medicines among older people: a pilot study. Drugs Aging. 2008;25(2):153-62. ⁶⁹	Method: The study was undertaken in suburbs of the city of Auckland, New Zealand. Semi-structured interviews and observation were used to determine how older people were managing their medicines. Observation of the interaction between the pharmacist and older person was performed to gather baseline information and semi-structured interviews were undertaken within 1 month to determine how older people were using their medicines and to identify compliance issues surrounding their use of medicines. Observation of the pharmacist-older person interaction was undertaken in the pharmacy where the older people usually collected their medicines, and participants were subsequently interviewed in their homes. The main outcome measure was compliance issues associated with the use of medicines.
	Sample size: A sample of 31 older people (> or = 65 years of age) living in the community consented to participate in the study.
	Risk adjustment/ confounders controlled for: None – convenience sample
	Confidence interval: N/A
	Findings: The main issues identified were alteration of labelled medicine instructions; transferring medicine into other containers and the associated labelling and safety issues; and patients not taking medicines for various reasons, including swallowing difficulties, expense, difficulty in opening packaging, confusion about the regimen and

	adverse effects experienced and personal reasons. There was an average of five compliance issues per participant. This study identified intentional and non-intentional compliance issues that could hinder the optimal use of medicines by older people who are at greater risk of medicine-related adverse effects. Large quantities of medicines, confusion, and lack of knowledge as to why a medicine had been prescribed contributed to non-compliance. Appropriate communication between the pharmacist and patient, patient education and aids such as medication cards and referral for medication review could improve compliance in this age group. Study type: Q
Wong ICK, Wong LYL, Cranswick NE. Minimising medication errors in children. Archives of Disease in Childhood. 2009;94:161-4. ⁷⁰	Research purpose: This paper reviews the factors contributing to paediatric medication errors, including lack of appropriate paediatric formulations, communication issues between health professionals, dose calculation mistakes and inadequate clinical practice. This review also discusses risk reduction strategies such as electronic prescribing and computerised physician order entry (CPOE) systems which can significantly reduce paediatric medication errors in conjunction with pharmacist monitoring, improved communication and environments which promote best practice. Method: Literature Review Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: refer to paper
	Study type: R
Dopson A. Confidence and competence in paediatric drug calculations. Nurse Prescribing. 2008;6(5):208-14. ⁷¹	Research purpose: This article aims to reassure nurse prescribers of their competence in drug calculations Method: Review of literature and explanation of practice Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: This risk of medication error by nurse prescibers is increased if the individual prescriber is not confident in his/her ability to perform drug calculations, particularly in relation to another susceptible group, namely babies and children. Combining the roles of prescriber, dispenser and drug administrator removes potential safety nets for identifying
	error and therefore leads to increased risk.
Knudsen P, Herborg	Research purpose: This study investigated the frequency and seriousness of
H, Mortensen AR, Knudsen M, Hellebek A. Preventing medication errors in community pharmacy: frequency	medication errors. Method: Randomly selected Danish community pharmacies collected data for a defined period. The data included four types of written report of incidents, three of which already existed at the pharmacies: prescription correction, dispensing near misses and dispensing errors. Data for the fourth type of report, on adverse drug events, were collected through a web-based reporting system piloted for the project.
medication errors.	Sample size: 40 pharmacies
Qual Saf Health	Risk adjustment/ confounders controlled for: N/A
Care. 2007 Aug:16(4):291-6.50	Confidence Interval: N/A Eindings: There were 076 cases of prescription corrections, 200 cases of peer misses
	203 cases of dispensing errors and 198 cases of adverse drug events. The error rate was 23/10,000 prescriptions for prescription corrections, 1/10,000 for dispensing errors and 2/10,000 for near misses. The errors that reached the patients were pooled for separate analysis. Most of these errors, and the potentially most serious ones, occurred in the transcription stage of the dispensing process. Prescribing errors were the most frequent type of error reported. Errors that reached the patients were not frequent, but most of them were potentially harmful, and the absolute number of medication errors was

	high, as provision of medicine is a frequent event in primary care in Denmark.
	Study type: O
Ashcroft DM, Quinlan P, Blenkinsopp A. Prospective study of the incidence, nature and causes of dispensing errors in community	Research purpose: This study sought to determine the incidence, nature and causes of dispensing errors and near misses occurring in community pharmacies in England and Wales.
	Method: This was a prospective study over a 4-week period. Pharmacists recorded details of all incidents that occurred during the dispensing process, including information about: the stage at which the error was detected; who found the error; who made the error; type of error; reported cause of error and circumstances associated with the error.
pharmacies. 2005.47	Sample size: 35 community pharmacies (9 independent pharmacies and 26 chain pharmacies) in the UK
	Risk adjustment/ confounders controlled for:
	Confidence interval:
	Findings: 125 395 prescribed items were dispensed during the study period and 330 incidents were recorded relating to 310 prescriptions. 280 (84.8%) incidents were classified as a near miss (rate per 10 000 items dispensed =22.33, 95%Cl 19.79-25.10), while the remaining 50 (15.2%) were classified as dispensing errors (rate per 10000 items dispensed =3.99, 95%Cl 2.96-5.26). Selection errors were the most common types of incidents (199, 60.3%), followed by labeling (109,33.0%) and bagging errors (22,6.6%). Most of the incidents were caused either by misreading the prescription (90,24.5%), similar drug names (62, 16.8%), selecting the previous drug or dose from the patient's medication record on the pharmacy computer (42, 11.4%) or similar packaging (28, 7.6%).
	Study type: O
Chua SS, Wong ICK, Edmondson H, Allen C, Chow J, Peacham J, et al. A feasibility	Research purpose: The main aim of this study was to investigate the feasibility of a self- reporting system for dispensing errors and near misses in primary care (community) pharmacies. It was also to identify the types of errors or near misses commonly encountered in community pharmacies.
study for recording of dispensing errors and 'near misses' in four UK primary care pharmacies. ¹⁸⁹	Method: A data collection form was designed and modified for use after a pilot study. Community pharmacies volunteered to participate in this feasibility study. The data collection was conducted in two phases each of 4 weeks' duration. Any dispensing errors and near misses that occurred during the study periods were recorded by the pharmacy staff in a standard data collection form. A focus group discussion was held with the dispensing staff of participating pharmacies to identify and evaluate the feasibility of the reporting system.
	Sample size: Four community pharmacies
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Out of a total of 51 357 items dispensed during the two phases of the study, 39 dispensing errors (0.08%) and 247 near misses (0.48%) were detected. The results show that near misses occurred six times more often than dispensing errors, indicating the importance of final checking in pharmacies. The most common types of dispensing errors or near misses appeared to be incorrect strength of medication, followed by incorrect drug, incorrect quantity, incorrect dosage form and incorrect label. Feedback during the focus group discussion indicated that the outcome of the self-reporting scheme was more important than the incidence of errors or near misses. Participating pharmacies also agreed that the self-reporting scheme used was feasible and they would
	continue using the scheme although some incentives would be helpful.

Wazaify M, Hughes CM, McElnay JC. The implementation of a harm minimisation model for the identification	Research purpose: This study tested an intervention model which sought to minimise over-the-counter (OTC) drug misuse and abuse in community pharmacies.
	Method: The intervention model consisted of client identification and recruitment, treatment and referrals, and finally follow-up data collection and outcome measurements. All pharmacists participated in semi-structured interviews to explore their views and experiences of the study.
and treatment of	Sample size: six community pharmacies in the Greater Belfast area
misuse and abuse in	Risk adjustment/ confounders controlled for: N/A
community	Confidence interval: N/A
pharmacies in Northern Ireland. Patient Education & Counseling. 2006;64(1-3):136- 41. ⁷²	Findings: Pharmacists identified 196 cases of suspected abuse/misuse. Pharmacists approached 70 of the identified clients during the six-month study; some clients agreed to stop using the product of abuse/misuse, used an alternative, or had been switched to a maintenance prescription under general practitioner (GP) supervision. No client proceeded to completion of the follow-up phase (e.g. health-related quality of life). Analysis of the interviews revealed that pharmacists had encountered some difficulties in approaching potential clients, but had used skills gained in the study in other aspects of their practice.
	Some difficulties were encountered in implementing the harm minimisation model, but these may be alleviated by further training and greater collaborative working. Practice implications Notwithstanding the challenges faced in the study, this approach to harm minimisation should be considered for wider implementation in community pharmacy.
	Study type: Q
Francis SA, Barnett	Research purpose: Discusses safety risks of Over-the-Counter drugs (OTC) for older
N, Dennam M. Switching of	
prescription drugs to	
over-the-counter	Sample size: N/A
status: is it a good	Risk adjustment/ confounders controlled for: N/A
thing for the elderly?	
2005;22(5):361-70. ⁷³	Findings: OTC drug use implies a mutual responsibility for communication between patients and health professionals that in practice is not always achieved. Epidemiological research is needed to investigate patterns of OTC use and evaluate the potential risks of OTC medicines in older people. Governments, regulatory bodies, professionals and the drug industry have a responsibility to ensure that robust systems are in place if the increased use of OTC medicines by older people is to be safe and effective.
	Study type: R
Bond C, Hannaford P. Issues related to	Research purpose: To compare a community pharmacist-managed repeat prescribing system with established methods of managing repeat prescribing.
monitoring the safety of over-the-counter (OTC) medicines. Drug Saf. 2003;26(15):1065- 74. ⁷⁴	Method: A randomised controlled intervention study involving general medical practices, patients, community pharmacists. Patients on repeat medication were given sufficient three-monthly scripts, endorsed for monthly dispensing, to last until their next clinical review consultation with their general practitioner (GP). The scripts were stored by a pharmacist of the patient's choice. Each monthly dispensing was authorised by the pharmacist, using a standard protocol. The cost of the drugs prescribed and dispensed was calculated. Data on patient outcomes were obtained from pharmacist-generated patient records and GP notes.
	Sample size: 19 general medical practices, 3074 patients, 62 community pharmacists
	Risk adjustment/ confounders controlled for: Age, gender
	Confidence interval: regression used
	Findings: A total of 12.4% of patients had compliance problems, side-effects, adverse drug reactions, or drug interactions identified by the pharmacist. There were significantly more problems identified in total in the intervention group. The total number of consultations, deaths, and non-elective hospital admissions was the same in both

	groups. Sixty-six per cent of the study patients did not require their full quota of prescribed drugs, representing 18% of the total prescribed costs (estimated annual drug cost avoidance of 43 Pounds per patient). CONCLUSION: This system of managing repeat prescribing has been demonstrated to be logistically feasible, to identify clinical problems, and to make savings in the drugs bill. Study type: RCT
Leonard M, Graham S, Bonacum D. The	Research purpose: Argues for the value of teamwork and communication in providing safe care.
human factor: The	Method: Expert opinion and case study
critical importance of	Sample size: N/A
and communication	Risk adjustment/ confounders controlled for: N/A
in providing safe	Confidence interval: N/A
care. Quality and Safety in Health Care. 2004;13(Suppl 1):i85-i90. ⁷⁵	Findings: Effective communication and teamwork is essential for the delivery of high quality, safe patient care. Communication failures are an extremely common cause of inadvertent patient harm. The complexity of medical care, coupled with the inherent limitations of human performance, make it critically important that clinicians have standardised communication tools, create an environment in which individuals can speak up and express concerns, and share common "critical language" to alert team members to unsafe situations.
	Study type: EO/C
Pandhi N, Schumacher J, Flynn KE, Smith M.	Research purpose: To determine if patients vary in perceptions of safety if interpersonal continuity were to be disrupted. If so, which characteristics are associated with feeling unsafe?
Patients' perceptions of safety if	Method: Observational study (Wisconsin Longitudinal Study Graduate and Sibling Survey)
interpersonal continuity of care	Sample size: 6827 respondents (most aged 63-66 years)
were to be disrupted.	Risk adjustment/ confounders controlled for: Stated
Health Expect. 2008	Confidence interval: As below.
Dec;11(4):400-8. ⁷⁶	Findings: Twelve percent of respondents felt unsafe. After adjustment, as compared to those who felt safe, those who felt unsafe were more likely to be women (Odds ratio=1.65, 95% confidence interval=1.35-2.01), have more chronic conditions (1.27, 1.08-1.50) and have a longer relationship with a usual provider: 5-9 years (1.53, 1.11-2.10) 10-14 years (1.41, 1.02-1.95) and 15 or more years (1.62, 1.20-2.17) compared to 0-4 years. Those who preferred active participation in decision-making and had trust in their physician were less likely to feel safe (1.63, 1.10-2.41). Certain older adults perceive being unsafe if not seeing their usual physician. Further research should investigate reasons for perceptions of safety if continuity were disrupted and any implications for care.
	Study type: O
Kuzel AJ, Woolf SH, Gilchrist VJ, Engel JD, LaVeist TA, Vincent C, et al. Patient reports of preventable problems and harms in primary health care. Ann Fam Med. 2004 Jul-	Research purpose: The principal aims of this study were to develop patient-focused typologies of medical errors and harms in primary care settings and to discern which medical errors and harms seem to be the most important.
	Method: In-depth anonymous interviews of adults from rural, suburban, and urban locales in Virginia and Ohio were conducted to solicit stories of preventable problems with primary health care that led to physical or psychological harm. Transcriptions were analyzed to identify, name, and organize the stories of errors and harms.
	Risk adjustment/ confounders controlled for: N/A
Aug;2(4):333-40.77	Confidence interval: N/A
	Findings: The 38 narratives described 221 problematic incidents that predominantly
	involved breakdowns in the clinician-patient relationship ($n = 82, 37\%$) and access to clinicians ($n = 63, 29\%$). There were several reports of perceived racism. The incidents

	were linked to 170 reported harms, 70% of which were psychological, including anger, frustration, belittlement, and loss of relationship and trust in one's clinician. Physical harms accounted for 23% of the total and included pain, bruising, worsening medical condition, and adverse drug reactions. The errors reported by interviewed patients suggest that breakdowns in access to and relationships with clinicians may be more prominent medical errors than are technical errors in diagnosis and treatment. Patients were more likely to report being harmed psychologically and emotionally, suggesting that the current preoccupation of the patient safety movement with adverse drug events and surgical mishaps could overlook other patient priorities.
Davis TC, Wolf MS, Bass PF, 3rd,	Research purpose: To examine patients' abilities to understand and demonstrate instructions found on container labels of common prescription medications.
Thompson JA, Tilson HH, Neuberger M, et al. Literacy and	Method: Cross-sectional study using in-person, structured interviews. Measurements were made of correct understanding of instructions on 5 container labels; demonstration of 1 label's dosage instructions.
misunderstanding prescription drug labels. Ann Intern	Sample size: 3 primary care clinics serving mostly indigent populations in Shreveport, Louisiana; Jackson, Michigan; and Chicago, Illinois. A total of 395 English-speaking adults waiting to see their providers.
19;145(12):887-94.44	Risk adjustment/ confounders controlled for:
	Confidence interval: 95%
	Findings: Correct understanding of the 5 labels ranged from 67.1% to 91.1%. Patients reading at or below the sixth-grade level (low literacy) were less able to understand all 5 label instructions. Although 70.7% of patients with low literacy correctly stated the instructions, "Take two tablets by mouth twice daily," only 34.7% could demonstrate the number of pills to be taken daily. After potential confounding variables were controlled for, low (adjusted relative risk, 2.32 [95% CI, 1.26 to 4.28]) and marginal (adjusted relative risk, 1.94 [CI, 1.14 to 3.27]) literacy were significantly associated with misunderstanding. Taking a greater number of prescription medications was also statistically significantly associated with misunderstanding (adjusted relative risk, 2.98 [CI, 1.40 to 6.34] for > or =5 medications).
Koutantii M. Davis	Study type. O Desearch purpose: To provide an overview of the notential roles nationts might play in
RB, Vincent C, Coulter A. The	ensuring the safety of their own care and in contributing to the safety of health care generally.
patient's role in	Method: Synthesis of literature and informed opinion
patient safety:	Sample size: N/A
their representatives,	Risk adjustment/ confounders controlled for: N/A
and health	Confidence interval: N/A
professionals. Clinical Risk. 2005;11:99- 104. ¹¹⁴	Findings: There is much to be gained by seeing such initiatives in the broader context of empowering patients in health care systems and indeed in broader attempts to engage people in looking after their health. This will assist in the formulation of further studies in this new area and in the development of interventions. Future research should explore knowledge, attitudes, values and beliefs of patients or their representatives about medical error, and identify factors amenable to interventions that affect their willingness to actively engage with patient safety issues. The role of staff in promoting patient engagement in patient safety should also be examined. Specific interventions addressing these factors could then be formulated, taking into account both patients' and health care staff 's perspectives and needs.

Gadon M, Balch GI, Jacobs EA. Caring for patients with limited English proficiency: the perspectives of small group practitioners. J Gen Intern Med. 2007 Nov;22 Suppl 2:341-6. ⁷⁸	Research purpose: To learn about current approaches to communicating with limited English-proficient (LEP) patients and the associated financial and nonfinancial constraints that private practice physicians and managers perceive in providing these services. Method: Computer-assisted telephone focus groups with open-ended discussion guide administered to small private practices in geographic areas that have experienced recent dramatic increases in LEP populations. Participants were primary care physicians, specialists, and practice managers. Focus group transcripts were systematically coded using grounded theory analysis. The research team then identified common themes that arose across the groups. Sample size: 67 individuals (24 PCPs, 21 specialists and 22 office managers) Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Citing the cost, inaccessibility, and inconvenience of using professional interpreters, physicians commonly used family and friends as interpreters. Few recalled any actual experience with professional interpreters or were well-informed about the cost of their services. Physicians and office managers voiced uniform concern about how language barriers. However, perceived barriers to implementing cost-effective strategies to these barriers are high. Physicians in private practice would benefit from information about how to best overcome language barriers in their practices efficiently and affordably.
Matlow AG, Wishen A, Read SE, Raboud JM. A study of provider-caregiver communication in paediatric ambulatory care. Paediatr Child Health. 2006 Apr;11(4):217-21. ⁷⁹	Research purpose: To identify and compare communication issues among three paediatric outpatient clinics. Method: In this prospective, qualitative study, a questionnaire was used to survey physicians, nurse practitioners and caregivers at three different infectious diseases clinics. Sample size: three ID clinics and their respective physicians and NPs. If more than one sibling in a family were patients in the same clinic at the same time, only one questionnaire per family was included in the study. Risk adjustment/ confounders controlled for: demographic factors Confidence interval: 95% Findings: There was a statistically significant preponderance of families in the tuberculosis clinic for whom English was not the mother tongue and who were not fluent in English. Patients in the HIV clinic were less likely to be at their first appointment than were patients attending the other clinics. Patients in the general clinic were less likely to have been seen by the same physician on the previous visit. Parents from all three clinics were satisfied with the care they received, with communication and with rapport with their clinic visit and less likely to complain about the wait time. Language proficiency and lack of continuity of provider care were identified as potential risks for patient safety in the ambulatory setting. Further studies are necessary to identify language and cultural issues that may affect patient care in a tertiary paediatric hospital servicing a multiethnic population.

Britten N, Stevenson FA, Barry CA, Barber N, Bradley CP. Misunderstandings in prescribing decisions in general practice: qualitative study BMJ: British Medical Journal. 2000;320:484-8. ⁸⁰	Research purpose: To identify and describe misunderstandings in prescribing decisions in general practice: Method: Qualitative study Sample size: 20 general practices Risk adjustment/ confounders controlled for: no Confidence interval: not stated Findings: 14 categories of misunderstanding were identified relating to patient information unknown to the doctor, doctor information unknown to the patient, conflicting information, disagreement about attribution side of side effects, failure of communication about doctor's decision, and relationship factors. All the misunderstandings were associated with lack of patients' participation in the consultation in terms of the voicing of expectations and preferences or the voicing of responses to doctors' decisions and actions. Patients participation in the consultation and the adverse consequences o flack of participation are important. Study type: Q
Byrd J, Thompson L.	Research purpose: To describe a communication and health literacy initiative
"It's safe to ask":	Method: Description of program
promoting patient	Sample size: 65 sites across Manitoba
safety through health	Risk adjustment/ confounders controlled for: N/A
literacy. Healthc Q.	Confidence interval: N/A
2008;11(3 Spec	Findings: N/A
No.):91-4.81	Study type: D
Davis TC, Wolf MS. Health Literacy: Implications for family medicine. Family Medicine. 2004;36:595-8. ⁸²	Research purpose: In this issue of Family Medicine, several articles address health literacy in family medicine. Method: Article review Sample size: N/A Risk adjustment/ confounders controlled for: Confidence interval: Findings: Wallace and Lennon examined the readability of American Academy of Family Physicians patient education materials available via the Internet. They found that three of four handouts were written above the average reading level of American adults. Rosenthal <i>et al</i> surveyed residents and found they lacked the confidence to screen and counsel adults about literacy. They used a Reach Out and Read program with accompanying resident education sessions to provide a practical and effective means for incorporating literacy assessment and counseling into primary care. Chew <i>et al</i> presented an alternative to existing health literacy. Likewise, Shea <i>et al</i> reviewed the prospect of shortening the Rapid Estimate of Adult Literacy in Medicine (REALM), a commonly used health literacy screening tool. Both the Chew and Shea articles highlight the need for improved methods for recognizing literacy problems in the clinical setting. Study type: D
Weiss BD, Mays MZ,	Research purpose: To develop a quick and accurate screening test for limited literacy
Martz W, Castro KM,	available in English and Spanish.
DeWalt DE, Pignone	Method: Candidate items were administered for the new instrument and also the Test of
MP, et al. Quick	Functional Health Literacy in Adults (TOFHLA) to English-speaking and Spanish-
assessment of	speaking primary care patients. We measured internal consistency with Cronbach's
literacy in primary	alpha and assessed criterion validity by measuring correlations with TOFHLA scores.
care: The newest	Using TOFLHA scores <75 to define limited literacy, we plotted receiver-operating
vital sign. Annals of	characteristics (ROC) curves and calculated likelihood ratios for cutoff scores on the new
Family Medicine.	instrument.
2005;3(6):514-22. ⁸³	Sample size: 492 patients

	Risk adjustment/ confounders controlled for: Power of 0.9 for an independent samples t-test Confidence interval: 95%, p<.001 Findings: The final instrument, the Newest Vital Sign (NVS), is a nutrition label that is accompanied by 6 questions and requires 3 minutes for administration. It is reliable (Cronbach alpha >0.76 in English and 0.69 in Spanish) and correlates with the TOFHLA. Area under the ROC curve is 0.88 for English and 0.72 for Spanish versions. Patients with more than 4 correct responses are unlikely to have low literacy, whereas fewer than 4 correct answers indicate the possibility of limited literacy. NVS is suitable for use as a quick screening test for limited literacy in primary health care settings. Study type: D
Layson-Wolf C, Morgan JA. Pharmacy continuity of care: what do community pharmacists need from an acute care hospital to improve continuity of pharmaceutical care? Disease Management & Health Outcomes. 2008;16(4):199- 203. ⁸⁴	Research purpose: To identify what community pharmacists need from an acute care hospital to improve continuity of pharmaceutical care Method:Opinion paper Sample size: Not stated Risk adjustment/ confounders controlled for: Not stated Confidence interval: Not stated Findings: The success of continuity of care in optimizing the transition of the patient from the inpatient setting to the community setting is highly dependent on the effective cooperation and communication between all components of the healthcare system. More studies are needed to evaluate the impact of cost due to the additional resources needed to appropriately implement an effective continuity of care system. Study type: EO/C
Kripalani S, LeFevre F, Phillips CO, Williams MV, Basaviah P, Baker DW. Deficits in communication and information transfer between hospital- based and primary care physicians: implications for patient safety and continuity of care. JAMA. 2007 Feb 28;297(8):831-41.85	Research purpose: To characterize the prevalence of deficits in communication and information transfer at hospital discharge and to identify interventions to improve this process. Method: Review of observational studies. Data Sources MEDLINE (through November 2006), Cochrane Database of Systematic Reviews, and hand search of article bibliographies. Data from observational studies were extracted on the availability, timeliness, content, and format of discharge communications, as well as primary care physician satisfaction. Results of interventions were summarized by their effect on timeliness, accuracy, completeness, and overall quality of the information transfer. Sample size: Observational studies investigating communication and information transfer at hospital discharge (n = 55) and controlled studies evaluating the efficacy of interventions to improve information transfer (n = 18). Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Direct communication between hospital physicians and primary care physicians occurred infrequently (3%-20%). The availability of a discharge summary at the first postdischarge visit was low (12%-34%) and remained poor at 4 weeks (51%- 77%), affecting the quality of care in approximately 25% of follow-up visits and contributing to primary care physician dissatisfaction. Discharge summaries often lacked important information such as diagnostic test results (missing from 33%-63%), treatment or hospital course (7%-22%), discharge medications (2%-40%), test results pending at discharge (65%), patient or family counseling (90%-92%), and follow-up plans (2%-43%). Several interventions, including computer-generated discharge summaries and using patients as couriers, shortened the delivery time of discharge communications. Use of standardized formats to highlight the most pertinent information improved the perceived

	Deficits in communication and information transfer at hospital discharge are common and may adversely affect patient care. Interventions such as computer-generated summaries and standardized formats may facilitate more timely transfer of pertinent patient information to primary care physicians and make discharge summaries more consistently available during follow-up care. Study type: R, O
Bunn F, Byrne G, Kendall S. The effects of telephone consultation and triage on healthcare use and patient satisfaction: A systematic review. British journal of General Practice. 2005;55:956-61.87	Research purpose: To assess the effects of telephone consultation and triage on safety, service use, and patient satisfaction Method:Systematic review Sample size: Nine studies met review inclusion criteria: five randomised controlled trials; one controlled trial; and three interrupted time series Risk adjustment/ confounders controlled for: Not stated. Confidence interval: Not stated. Findings: Among 9 studies: six studies compared telephone consultation with normal care; four by a doctor, one by a nurse, and one by a clinic clerk. Three of five studies found a significant decrease in visits to GPs but two found an increase in return consultations. In general at least 50% (range = 25.5-72.2%) of calls were handled by telephone consultation alone. Of seven studies reporting accident and emergency department visits, six showed no difference between the groups and one - of nurse telephone consultation - found an increase. Two studies reported deaths and found no difference between nurse telephone consultation appears to have the potential to reduce GP workload, questions remain about its effect on service use. Further rigorous evaluation is needed with emphasis on service use, safety, cost, and patient satisfaction. Study type: SR
Katz HP, Kaltsounis D, Halloran L, Mondor M. Patient safety and telephone medicine : some lessons from closed claim case review. J Gen Intern Med. 2008 May;23(5):517- 22. ⁸⁸	Research purpose: To describe medical errors involving the telephone in patient- clinician encounters that significantly impacted medical care and medico-legal outcomes. Method: Descriptive, retrospective case review of telephone-related closed malpractice claims that included depositions, expert witness testimony, medical records, allegations, injuries, and outcomes. Sample size: 40 Risk adjustment/ confounders controlled for: Not stated. Confidence interval: Not stated. Findings: Telephone-related claims were costly; injuries were catastrophic. Poor documentation and faulty triage were major factors influencing care and legal outcome. Telephone errors may represent the tip of the iceberg in patient safety in ambulatory practice; however, these preliminary results need to be confirmed in a larger sample of cases. Study type: D
Hildebrandt DE, Westfall JM, Smith PC. After-hours telephone triage affects patient safety. J Fam Pract. 2003 Mar;52(3):222-7.89	Research purpose: To describe the management of after-hours calls to primary care physicians and identify potential errors that might delay evaluation and treatment. Method: Survey of primary care practices and audit of after-hours phone calls. Sample size: Ninety-one primary care offices (family medicine, internal medicine, obstetrics, and pediatrics) Risk adjustment/ confounders controlled for: Not stated. Confidence interval: Not stated. Findings: More than two thirds of the offices used answering services to take their calls. Ninety-three percent of the practices required the patient to decide whether the problem was emergent enough to require immediate notification of the on-call physician. Physician reviewers reported that 50% (range, 22%-77%) of the calls not forwarded to the on-call physician represented an emergency needing immediate contact with the

	physician. The authors concluded that after-hours call systems in most primary care offices impose barriers that may delay care. All clinical patient calls should be sent to appropriately trained medical personnel for triage decisions. We urge all clinicians that use an answering service to examine their policies and procedures for possible sources of medical error.
	Descereb numbers. To investigate the secondiction of superioness of violance and
Sibbritt DW, Joy E,	perceptions of risk of violence with provision of after-hours GP care and home visits.
	Method: A questionnaire-based cross-sectional survey of GPs
on Australian general	Sample size: Five hundred and twenty-eight GPs
practitioners'	Risk adjustment/ confounders controlled for: logistic regression
provision of home visits and after-hours	Confidence interval: GP who provided consultation vs not provided in relation to age groups -95%CI-47.5- 50.3 50.8- 53.1
care: a cross- sectional study. J	If GP had experienced violence, they were more likely (OR=1.52; 95% CI 0.96-2.40) to provide home visits.
Eval Clin Pract. 2008 Apr;14(2):336-42. ¹⁹⁰	Findings: Five hundred and twenty-eight GPs completed the survey (response rate 49%). Of the GPs surveyed, 63.7% were subjected to some form of violence in the previous 12 months. Risk of violence influenced 10.2% of GPs' delivery of in-hours home visits and 22.0% of GPs' delivery of after-hours home visits. A further 4.7% of GPs reported not performing after-hours home visits at all during the previous 12 months because of safety concerns. On logistic regression, gender, location of practice and country of medical qualification were significantly associated with provision of in-hours and after-hours home visits. Experience of violence during the previous 12 months was not significantly associated with provision of home visits. This study's finding of GPs' self-reported restriction of practice and withdrawal from home visits and after-hours calls in response to risk of violence represents a significant primary health care issue. GPs' decision to provide after-hours calls and home visits is complex, and the finding of lack of significant association of experiences of violence with provision of home visits and after-hours calls is likely to be due to the cross-sectional nature of the study.
liwa M. Halkett G	Research nurnose: The aim of this study is to further explore the factors that impact on
Aoun S, Arnet H, Smith M, Pilkington	the speed of diagnosis in rural Western Australia with direct reference to General Practitioners (GPs) working in this setting.
M, et al. Factors	Method: a structured discussion of specific cases.
of cancer diagnosis in	Sample size: GPs based in two rural locations in Western Australia were asked to identify up to eight clinical cases for discussion.
Australia: a general	Risk adjustment/ confounders controlled for: None
practice perspective.	Confidence interval: N/A
BMC Family Practice. 2007;8:1-7. ⁹⁰	Findings: A number of factors affecting the speed of diagnosis were identified: the demographic shift towards a frailer and older population, presenting with multiple and complex diseases, increases the challenge to identify early cancer symptoms; seasonal and demanding work patterns leading to procrastination in presenting for medical care; unhelpful scheduling of specialist appointments; and the varying impact of informal networks and social relationships. Within the limitations of this study we have generated a number of hypotheses that require formal evaluation: (1) GPs working within informal professional and social networks are better informed about their patients' health needs and have an advantage in making early diagnosis; (2) Despite the other differences in the population characteristics decentralising services would improve the prospect for timely diagnosis; and (3) Careful coordination of specialist appointments would improve the speed of diagnosis for rural patients.
	Study type: U

Barnett JR, Coyle P, Kearns RA. Holes in the safety net? Assessing the effects of targeted benefits upon the health care utilization of poor New Zealanders. Health Soc Care Community. 2000 May;8(3):159-71. ¹⁹¹	Research purpose: This paper examines the issue of targeting primary health-care benefits in favour of low-income recipients and other high users of health care. The study sought to determine the extent to which price barriers remain important by comparing patient utilization of a free community health clinic with a low-income control sample of patients who continue to use conventional (for New Zealand) fee-for-service providers Method: A case study was conducted in the city of Christchurch. Survey-based research design Sample size: Users of the free community health clinic (n = 202) and conventional (for New Zealand) fee-for-service providers (n = 148). Risk adjustment/ confounders controlled for: Chronic users excluded Confidence interval: 95% Findings: That a large proportion of respondents delayed seeking care because of cost. Further, for respondents using the fee-for-service providers, levels of use were not related to need, whereas at the free clinic there was an inverse relationship between income and consultation rates. It was concluded that if a universality of benefits is not possible, then there is a need for better targeting of primary care benefits. There is a danger in such initiatives being evaluated primarily in terms of their validity as funding mechanisms, rather than in terms of their success in meeting the health-care needs of the disadvantaged.
Brous E. The criminalization of unintentional error: implications for TAANA. Journal of Nursing Law. 2008;12(1):5-12. ¹²⁴	Research purpose: Reviews the issues relating to criminal law and error reporting Method: Expert opinion Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Recent criminal charges against nurses create worrisome implications for patient safety. Unintentional human errors occur in clinical practice and are inevitable. The vast majority of errors reflect system problems that need to be addressed. Harm to patients can only be reduced or avoided when modern safety theory is used to respond to adverse events. It is essential that errors be reported and analyzed. Punitive approaches deter error-reporting and endanger patients by allowing latent failures to continue. The fear of criminal charges undermines an organization's attempts to create a culture of safety and improve dangerous systems. Criminal prosecutions have a potentially chilling effect on error reporting and analysis and accelerate the shortage of health care providers. A review of several cases demonstrates the political nature of these indictments and the destructive impact they have on patient safety. Suggestions are made for TAANA's involvement in the issue. Study type: EO/C
Liang BA. Layperson and physician perceptions of the malpractice system: implications for patient safety. Soc Sci Med. 2003 Jul;57(1):147-53. ¹⁹²	Research purpose: This exploratory study attempts to determine whether a bias could exist between clinical assessments and legal assessments. Method: Physicians and layperson jury pool members were asked to review 10 jury verdict case scenarios. Respondents were asked first to assess whether the defendant physician provided clinically appropriate care; they were then asked to predict what the jury in the case actually decided. Sample size: 138 physicians and 154 laypersons Risk adjustment/ confounders controlled for: None Confidence interval: p=0.05 Findings: Laypersons showed significantly better agreement with actual jury verdicts on clinical assessment and success in jury verdict prediction than physicians. Both physicians and laypersons switched the favoured party from clinical assessment to verdict prediction, with a vast majority of these changes being made from defendant to plaintiff. These results were consistent overall and when parsing assessments by case

	verdicts. Thus, laypersons and physicians may perceive a similar bias toward plaintiffs in the malpractice system. If these results can be generalised, the malpractice system may be inducing behaviour that has a negative impact on patient safety. Study type: D
Abbott RL, Weber P, Kelley B. Medical professional liability insurance and its relation to medical error and healthcare risk management for the practicing physician. Am J Ophthalmol. 2005 Dec;140(6):1106- 11. ¹⁹³	Research purpose: To identify physician predictors in LASIK and photorefractive keratectomy (PRK) surgery that correlate with a higher risk for malpractice liability claims and lawsuits. Method: Retrospective, longitudinal, cohort study. Sample size: 100 consecutive Ophthalmic Mutual Insurance Company (OMIC) LASIK and PRK claims and lawsuits with demographic and practice pattern data for all active refractive surgeons insured by OMIC between 1996 to 2002 Risk adjustment/ confounders controlled for: Confidence interval: 95%, p = 0.0001 Findings: Logistic regression analysis demonstrated that the most important predictor of filing a claim was surgical volume, with those performing more surgery having a greater risk of incurring a claim (odds ratio $[OR] = 31.4$ for >1000 surgeries/year versus 0–20 surgeries/year, 95% confidence interval [CI] = 7.9–125, <i>P</i> = 0.0001). Having one or more prior claim was the only other predictor examined that remained statistically significant after controlling for patient volume (OR = 6.4, 95% CI = 2.5–16.4, <i>P</i> = 0.0001). Physician gender, advertising use, preoperative time spent with patient, and co-management seemed to be strong predictors in multivariate analyses when surgical volume was greater than 100 cases per year. The chances for incurring a malpractice claim or lawsuit for PRK or LASIK correlate significantly with higher surgical volume and a history of a claim or lawsuit. Additional risk factors that increase in importance with higher surgical volume include physician gender, advertising use, preoperative time spent with optometrists.
Kostopoulou O. From cognition to the system: developing a multilevel taxonomy of patient safety in general practice. Ergonomics. 2006 Apr 15-May 15;49(5- 6):486-502. ¹⁹⁴	Research purpose: To investigate the role of information gathering and clinical experience on the diagnosis and management of difficult diagnostic problems in family medicine Method: Observational study Sample size: Seven diagnostic scenario presented on a computer to 84 physicians: 21 residents in family medicine, 21 family physicians with 1 to 3 y in practice, and 42 family physicians with >or=10 y in practice Risk adjustment/ confounders controlled for: Stated. Confidence interval: As below. Findings: Rates of misdiagnosis were in accordance with the number of features of difficulty. Seventy-eight percent of incorrect diagnoses were followed by inappropriate management and 92% of correct diagnoses by appropriate management. Number of critical cues requested (cues diagnostic of any relevant differential diagnoses in a scenario) was a significant predictor of accuracy in 6 scenarios: 1 additional critical cue increased the odds of obtaining the correct diagnostic by between 1.3 (95% confidence interval [CI], 1.0-1.8) and 7.5 (95% CI, 3.2-17.7), depending on the scenario. No effect of experience was detected on either diagnostic accuracy or management. Residents requested significantly more cues than experienced family physicians did. Supporting the gathering of critical information has the potential to improve the diagnosis and management of difficult problems in family medicine.

Kostopoulou O, Oudhoff J, Nath R, Delaney BC, Munro CW, Harries C, et al. Predictors of diagnostic accuracy and safe management in difficult diagnostic problems in family medicine. Medical Decision Making. 2008;28(5):668-80. ⁹³	Research purpose: To classify events of actual or potential harm to primary care patients using a multilevel taxonomy of cognitive and system factors. Method: Observational study of patient safety events obtained via a confidential but not anonymous reporting system. Reports were followed up with interviews where necessary. Events were analysed for their causes and contributing factors using causal trees and were classified using the taxonomy. Main outcome measures were frequencies of clinical types of events reported, cognitive types of error, types of detection and contributing factors; and relationship between types of error, practice size, patient consequences and detection. Sample size: Five general medical practices in the West Midlands were selected to represent a range of sizes and types of patient population. All practice staff were invited to report patient safety events. Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: 78 reports were relevant to patient safety and analysable. They included 21 (27%) adverse events and 50 (64%) near misses. 16.7% (13/71) had serious patient consequences, including one death. 75.7% (59/78) had the potential for serious patient harm. Most reports referred to administrative errors (25.6%, 20/78). 60% (47/78) of the reports contained sufficient information to characterise cognition: "situation assessment
	and response selection" was involved in 45% (21/47) of these reports and was often linked to serious potential consequences. The most frequent contributing factor was work organisation, identified in 71 events. This included excessive task demands (47%, 37/71) and fragmentation (28%, 22/71). Even though most reported events were near misses, events with serious patient consequences were also reported. Failures in situation assessment and response selection, a cognitive activity that occurs in both clinical and administrative tasks, was related to serious potential harm. Study type: O
Peterson GM, Wu MSH, Bergin JK. Pharmacists' attitudes towards dispensing errors: Their causes and prevention. Journal of Clinical Pharmacy & Therapeutics. 1999;24:57-71. ⁵¹ .	Research purpose: To assess the attitudes of pharmacists towards the issue of dispensing errors. Method: A postal survey was undertaken among all Tasmanian-registered pharmacists residing in Australia. The anonymous questionnaire sought opinions on whether the risk of dispensing errors and the actual numbers of errors are increasing, the major factors contributing to the occurrence of dispensing errors, factors that can best minimize the risk of dispensing errors, the number of prescription items that one pharmacist can safely dispense in a day and whether Australia should have a regulatory maximum dispensing load, and an estimation of the number of recent errors at the pharmacist's workplace. Sample size: 209 pharmacists Risk adjustment/ confounders controlled for: None
	Confidence interval: N/A Findings: Most pharmacists (82%) believed that the risk of dispensing errors is increasing. The principal contributing factors nominated were: high prescription volumes, pharmacist fatigue, pharmacist overwork, interruptions to dispensing, and similar or confusing drug names. The main factors identified as being important in reducing the risk of dispensing errors were: having mechanisms for checking dispensing procedures, having a systematic dispensing workflow, checking the original prescription (duplicate) when dispensing repeats, improving the packaging and labelling of drug products, having drug names that are distinctive, counselling patients at the time of supply, keeping one's knowledge of drugs up-to-date, avoiding interruptions, reducing workloads on pharmacists, improving doctors' handwriting, and privacy when counselling patients. Most pharmacists (72%) stated that they were aware of dispensing errors that had left the pharmacy undetected, in their place of practice during the past 6 months. The median number of such dispensing errors that they were aware of was three. A median of 150 was nominated as the maximum number of prescription items that can be safely dispensed per 9-h day (i.e. 17 items per hour) by or in the presence of one pharmacists.

	Most pharmacists (58%) stated that there should be a regulatory guideline for the safe dispensing load in Australia.
	Dispensing errors are occurring in numbers well above reports to regulatory authorities or professional indemnity insurance companies, and seem to be accepted as part of practice. High prescription volumes, pharmacist fatigue and overwork appear to be important factors. The profession needs to be proactive and standards must be set appropriately high (i.e. zero error tolerance).
	Study type: D
Wilf-Miron R, Lewenhoff I, Benyamini Z, Aviram	Research purpose: The development of a medical risk management programme based on the aviation safety approach and its implementation in a large ambulatory healthcare organisation is described.
A. From aviation to medicine: applying concepts of aviation safety to risk management in ambulatory care. Qual Saf Health Care. 2003 Feb;12(1):35-9. ¹⁹⁵	Method: The following key safety principles were applied: (1). errors inevitably occur and usually derive from faulty system design, not from negligence; (2). accident prevention should be an ongoing process based on open and full reporting; (3). major accidents are only the "tip of the iceberg" of processes that indicate possibilities for organisational learning. Reporting physicians were granted immunity, which encouraged open reporting of errors. A telephone "hotline" served the medical staff for direct reporting and receipt of emotional support and medical guidance. Any adverse event which had learning potential was debriefed, while focusing on the human cause of error within a systemic context. Specific recommendations were formulated to rectify processes conducive to error when failures were identified.
	Sample size: More than 2000 encounters between 1996 and 2001
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: During the first 5 years of implementation, the aviation safety concept and tools were successfully adapted to ambulatory care, fostering a culture of greater concern for patient safety through risk management while providing support to the medical staff.
	Study type: D
Wilson RM, Harrison BT, Gibberd RW,	Research purpose: To examine the causes of adverse events (AEs) resulting from healthcare to assist in developing strategies to minimise preventable patient injury
Hamilton JD. An	Method: Review
causes of adverse	Sample size: 2353 AEs previously reported by the Quality in Australian Health Care Study (QAHCS)
Quality in Australian	Risk adjustment/ confounders controlled for: Not stated
Health Care Study.	Confidence interval: Not stated
Medical Journal of Australia. 1999;170:411-5. ¹⁹⁶	Findings: 34.6% of the causes of AEs were categorised as "a complication of, or the failure in, the technical performance of an indicated procedure or operation", 15.8% as "the failure to synthesise, decide and/or act on available information", 11.8% as "the failure to request or arrange an investigation, procedure or consultation", and 10.9% as "a lack of care and attention or failure to attend the patient". AEs in which the cause was cognitive failure were associated with higher preventability scores than those involving technical performance. The main prevention strategies identified were "new, better, or better implemented policies or protocols" (23.7% of strategies), "more or better formal quality monitoring or assurance processes" (21.2%), "better education and training" (19.2%), and "more consultation with other specialists or peers" (10.2%).
	prominent causes of AES or errors leading to AES can be characterised, and human error is a prominent cause. Our study emphasises the need for designing safer systems for care, which protect the patient from the inevitability of human error. These systems should provide new policies and protocols and technological support to aid the cognitive activities of clinicians.
	l Sludy lybe: K

Essex B, Ashworth M, Crichton N.	Research purpose: To develop a set of criteria for assessment of risk to patients and for investigating performance concerns in general practice.
Performance concerns in primary care: a Delphi consensus on risk and investigation. Quality in Primary Care. 2007;15(5):293- 300.94	Method: Two-round Delphi questionnaire. Panellists were medical and non-medical people with extensive experience of assessing, investigating and managing performance concerns in primary care. Panellists were presented with scenarios about performance concerns, together with one of five possible investigation options: a medical record review, prescribing system review, practice management assessment, GP suspension hearing or a death review. They then considered 95 scenarios, rating 69 according to risk and all 95 according to investigation options. In the second round, ratings were repeated after panellists had reviewed their own and group first-round responses. Consensus was defined in advance as 80% of responses in the upper third on a nine-point rating scale.
	Sample size: 25 (first round panellists) and 23 (second round panellists)
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Consensus on high risk was achieved for 36 of the 69 (52%) risk scenarios. Consensus on the proposed investigation was achieved in 33 of the 95 (35%) investigation scenarios. A series of high-risk performance concerns were identified and these were linked to appropriate methods of investigation. The management of performance concerns should be guided by explicit consensus criteria to improve the quality of decision making in managing poor performance in primary care. Patient safety may be compromised by inconsistent management of performance concerns.
	Study type: Q
Rickard GD. An outline of appropriate	Research purpose: Discusses risk management in the use of temporary dental nursing staff in practice
risk management in	Method: Case study and survey
the use of temporary	Sample size: 44 dental practitioners
practice. Br Dent J.	Risk adjustment/ confounders controlled for: None
2004 Dec	Confidence interval: N/A
11;197(11):674-9.95	Findings: Be it due to poor governance, audit or quality control the cost to the practitioner, practice, profession and patient can be high. To mitigate this risk a comprehensive risk management system will be needed in practice. Planning to prevent such risks requires understanding, analysing, managing and costing the risk. Success depends on robust systems for screening, contracting and training of staff within an educated team of safety orientated personnel supported by suitable frameworks for standards, resources, policies, protocols, processes and checks within a clearly identifiable chain of command.
	Study type: D
National Patient	Research purpose: Best practice guide for patient safety
Safety Agency. Seven Steps to Patient Safety in Primary Care.	Method: N/A
	Sample size: N/A
	Risk adjustment/ confounders controlled for: N/A
London: National	Confidence interval: N/A
Agency; 2006. ¹¹⁵	Findings: 7 steps (see review)
	Study type: EO/C

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Kirk S, Parker D, Claridge T, Esmail A, Marshall M. Patient safety culture in primary care: developing a	Research purpose: To develop and test a framework for making the concept of safety culture meaningful and accessible to managers and frontline staff, and facilitating discussion of ways to improve team/organisational safety culture
	Method: Comprehensive review of the literature and a postal survey of experts helped identify the key dimensions of safety culture in primary care, followed by semistructured interviews and focus group interview
theoretical framework	Sample size: Survey-30 clinicians and managers
for practical use.	33 interviews and 14 focus groups
Care. 2007	Risk adjustment/ confounders controlled for: Not stated.
Aug;16(4):313-20.175	Confidence interval: Not stated.
	Findings: Nine dimensions were identified through which safety culture is expressed in
	primary care organisations. Organisational descriptions were developed for how these dimensions might be characterised at five levels of organisational maturity. The resulting framework conceptualises patient safety culture as multidimensional and dynamic, and seems to have a high level of face validity and utility within primary care. It aids clinicians' and managers' understanding of the concept of safety culture and promotes discussion within teams about their safety culture maturity. The framework moves the agenda on from rhetoric about the importance of safety culture to a way of understanding why and how the shared values of staff working within a healthcare organisation may be
	operationalised to create a safe environment for patient care.
	Study type: O+Q
Kerfoot KM. From blaming to proactively	Research purpose: The article discusses the blaming issues among health professionals in the workplace
changing the future:	Method: Expert opinion
the leader's safety	Sample size: N/A
Econ. 2008 Jul-	Risk adjustment/ confounders controlled for: N/A
Aug;26(4):280-1.197	Confidence interval: N/A
	Findings: If people blame each other in a work group rather than ask how a situation can be solve in the future, the leader has not set the behavioral standards that will eliminate blame and create a culture of learning and proactive prevention of problems. Moreover, the importance of rejecting all types of blame is to promote patient care outcomes as well as loyalty of medical staff
	Study type: EO/C
Hatlie MJ, Sheridan SE. The medical liability crisis of 2003: must we squander	Research purpose: Discusses lessons learned about medical risk and the legal system, communication about risk among health care providers and across the interfaces of the legal, regulatory, and health care systems.
	Method: Expert opinion
the chance to put natients first? Health	Sample size: N/A
Aff (Millwood). 2003	Risk adjustment/ confounders controlled for: N/A
Jul-Aug;22(4):37- 40. ¹⁹⁸	Confidence interval: N/A
	Findings: Medical liability reform should be aligned with a patient-centered, systems- based approach to preventing injury.
	Tort reform can be a vehicle for breaking down systemic barriers. Proposed reforms include (1) requiring disclosure of medical errors and restricting the use of information disclosed as evidence of guilt; (2) outlawing confidentiality agreements when malpractice cases are settled; (3) abolishing the National Practitioner Data Bank; and (4) establishing a national patient safety authority.
	Study type: EU/C

Gluck PA. Patient safety in women's health care: a framework for progress. Best Pract Res Clin Obstet Gynaecol. 2007 Aug;21(4):525-36. ¹⁹⁹	Research purpose: Provides a framework for understanding categories of safety in women's health care Method: Synthesis of literature Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Patient safety research is hampered by lack of a clear taxonomy and difficulty in detecting errors. Preventable adverse events occur in medicine because of human fallibility, complexity, system deficiencies and vulnerabilities in defensive barriers. To make medicine safer there needs to be a culture change, beginning with the leadership. Latent systems deficiencies must be identified and corrected before they cause harm. Defensive barriers can be improved to intercept errors before patients are harmed. Strategies include: (1) providing leadership at all levels; (2) respecting human limits in equipment and process design; (3) functioning collaboratively in a team model with mutual respect; (4) creating a learning environment where errors can be analysed without fear of retribution; and (5) anticipating the unexpected with analysis of high-risk processes and well-designed contingency plans.
Scholefield H. Embedding quality improvement and patient safety at Liverpool Women's NHS Foundation Trust. Best Pract Res Clin Obstet Gynaecol. 2007 Aug;21(4):593-607. ²⁰⁰	Study type: R Research purpose: This chapter looks at structures and processes for improving quality and patient safety, using the stepwise approach described by the National Patient Safety Authority (NPSA). Method: Case Study Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Structures and processes for improving quality and patient safety encompasses building a safety culture, leading and supporting staff, integrating risk management activity, promoting reporting, involving and communicating with patients and the public, learning and sharing safety lessons, and implementing solutions to prevent harm. Examples from the Liverpool Women's NHS Foundation Trust are used to illustrate these steps, including how they were developed, what obstacles had to be overcome, ongoing challenges, and whether good risk management has translated into better, safer health care. Study type: Q
Lankshear A, Lowson K, Harden J, Lowson P, Saxby RC. Making patients safer: nurses' responses to patient safety alerts. J Adv Nurs. 2008 Sep;63(6):567-75. ¹¹⁶	Research purpose: This paper is a report of a study to determine whether action required by patient safety alerts was effectively taken. Method: A multi-method study using surveys, interviews with senior managers and front- line staff, collection of documentary evidence and equipment audit. The implementation of three safety alerts for nursing action is reported. Sample size: 20 acute, two mental health, four ambulance and 15 primary care provider organizations in the United Kingdom Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Most staff were aware of the dangers posed by gloves to staff with latex allergy, but only 20% were aware of the types of common equipment that posed a danger to sensitive patients. Almost 40% of nurses were unable to give a correct acidity value to allow nasogastric feeding to commence. One alert, on needle-free intravascular connectors, was distributed in only a few organizations as the term used was unfamiliar at all levels of the organization. Healthcare providers have succeeded in setting up successful systems to disseminate alerts to middle management level, but there is evidence that implementation of recommendations by nurses is sub-optimal.

Mikkelsen TH, Sokolowski I, Olesen F. General practitioners' attitudes toward reporting and learning from adverse events: results from a survey. Scandinavian Journal of Primary Health Care. 2006;24(1):27-32. ¹¹⁷	Research purpose: To investigate GPs' attitudes to and willingness to report and learn from adverse events and to study how a reporting system should function. Method: Survey Sample size: 1198 GPs Risk adjustment/ confounders controlled for: Not stated. Confidence interval: Not stated. Findings: GPs had a positive attitude towards discussing adverse events in the clinic with colleagues and staff and in their continuing medical education groups. The GPs had a positive attitude to reporting adverse events to a database if the system granted legal and administrative immunity to reporters. The majority preferred a reporting system located at a research institute. Study type: O
Williams SK, Osborn SS. The development of the National Reporting and Learning System in England and Wales, 2001-2005. Med J Aust. 2006 May 15;184(10 Suppl):S65-8. ¹¹⁸	Research purpose: Reports on a National Reporting system Method: Report Sample size: Between 2003 and 2005, 303 447 incidents were reported from a wide range of health care settings. Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: In 2001, the National Patient Safety Agency (NPSA) was created as part of a wider reform process to improve quality of care for patients in the National Health Services of England and Wales. The NPSA was charged with developing and implementing a national system for collecting and learning from reported patient safety incidents. As a result, a range of interventions have been developed to improve safety. A number of lessons have been distilled from the experience of England and Wales, including that: clinical risk management system characteristics should be aligned with those of the national reporting system; and safety culture and information dissemination must be addressed at the same time as any new reporting system is implemented. These lessons should be of use to other countries implementing similar patient safety strategies. Study type: D
Ashcroft DM, Morecroft C, Parker D, Noyce PR. Likelihood of reporting adverse events in community pharmacy: an experimental study. Qual Saf Health Care. 2006 Feb;15(1):48-52.119	Research purpose: To examine the likelihood of community pharmacists and support staff reporting patient safety incidents which occur in community pharmacies. Method: Survey Sample size: 223 community pharmacists and 52 members of support staff. Risk adjustment/ confounders controlled for: Not stated. Confidence interval: Not stated. Findings: 275 questionnaires were returned (79% response rate) from 223 community pharmacists and 52 members of support staff. There were significant main effects for both patient outcome (F(2,520) = 18.19, p<0.001) and behaviour type (F(2,520) = 93.98, p<0.001), indicating that pharmacists and support staff would take into account both the outcome of the behaviour and whether or not it follows a protocol when considering to report an incident within the pharmacy. Likewise, both pharmacists and support staff considered patient outcome (F(2,524) = 12.59, p<0.001) and behaviour type (F(2,524) = 34.82, p<0.001) when considering to report to the NPSA. Both locally and nationally, the likelihood of reporting any incident was low, and judgements on whether to report were more affected by the behaviour of the pharmacists and their support staff would be unlikely to report adverse incidents if they witnessed them occurring in a community pharmacy. They remain to be convinced that the advantages to them and their patients outweigh the consequences of blame.

Härmark L, van Grootheest AC. Pharmacovigilance: methods, recent developments and future perspectives. European Journal of Clinical Pharmacology. 2008;64(8):743-52. ²⁰¹	Research purpose: To review and discuss various aspects of pharmacovigilance, including new methodological developments. Method: Review Sample size: Not stated. Risk adjustment/ confounders controlled for: Not stated. Confidence interval: Not stated. Findings: Our knowledge of a drug's adverse reactions can be increased by various means, including spontaneous reporting, intensive monitoring and database studies. New processes, both at a regulatory and a scientific level, are being developed with the aim of strengthening pharmacovigilance. On a regulatory level, these include conditional approval and risk management plans; on a scientific level, transparency and increased patient involvement are two important elements. Study type: R
Mick JM, Wood GL, Massey RL. The Good Catch Pilot Program: increasing potential error reporting. Journal of Nursing Administration. 2007;37(11):499- 503. ¹²²	Research purpose: To report on a reporting program Method: With only 175 reports submitted into an available close call reporting system during 2.5 years, the Good Catch Program was implemented to promote 3 strategies: (1) changing terminology from "close call" to "good catch," (2) implementing an "end-of-shift safety report," and (3) executive leadership sponsored incentives. The authors discuss the program and its positive outcomes in increasing potential error reporting. Sample size: 5 impatient nursing units Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: The Good Catch Program resulted in 1468% increase in potential error reporting Study type: D
Elder NC, Graham D, Brandt E, Hickner J. Barriers and motivators for making error reports from family medicine offices: a report from the American Academy of Family Physicians National Research Network (AAFP NRN). J Am Board Fam Med. 2007 Mar- Apr;20(2):115-23. ¹²⁰	Research purpose: To identify barriers and motivators for error reporting by family physicians and their office staff based on the experiences of those participating in a testing process error reporting study. Method: Qualitative focus group study Sample size: 139 physicians, nurse practitioners, physician assistants, nurses, and staff who took part in 18 focus groups Risk adjustment/ confounders controlled for: Not stated. Confidence interval: Not stated. Findings: Interview questions asked about making reports, what prevents more reports from being made, and decisions about when to make reports. RESULTS: Four factors were seen as central to making error reports: the burden of effort to report, clarity regarding the information requested in an error report, the perceived benefit to the reporter, and properties of the error (eg, severity, responsibility). The most commonly mentioned barriers were related to the high burden of effort to report and lack of clarity regarding the requested information. The most commonly mentioned motivator was perceived benefit. Successful error reporting systems for physicians' offices will need to have low reporting burden, have great clarity regarding the information requested, provide direct benefit through feedback useful to reporters, and take into account error severity and personal responsibility. Study type: Q

Spigelman AD, Swan J. Review of the Australian Incident Monitoring System.	Research purpose: to assess the benefits and limitations of the Australian Incident Monitoring System (AIMS) as a programme to improve patient safety.
	Method: Survey - a 12-point questionnaire was sent to 12 current users of AIMS in November 2002
ANZ JOURNAL OF	Sample size: 12 users of AIMS
2005;75:657-61. ¹²¹	Risk adjustment/ confounders controlled for: None
	Confidence interval: N/A
	Findings: The Australian Incident Monitoring System is beneficial as a component of a clinical risk management strategy. Usefulness could be improved by increased participation by medical staff. The level of resources required should not be underestimated if the programme is to demonstrate improvements to patient outcomes. More recent versions of AIMS promise improved capabilities and will require similar evaluation.
	Study type: D
Braithwaite J, Westbrook MT, Mallock NA, Travaglia JF, ledema RA. Experiences of health professionals who conducted root cause analyses after undergoing a safety improvement programme. Qual Saf Health Care. 2006	Research purpose: To study a cohort of health professionals who conducted RCAs after completing the NSW Safety Improvement Program (SIP). Hypothesis: Participants in RCAs would: (1) differ in demographic profile from non-participants, (2) encounter problems conducting RCAs as a result of insufficient system support, (3) encounter more problems if they had conducted fewer RCAs and (4) have positive attitudes regarding RCA and safety. Design, setting and participants:
	Method: Anonymous questionnaire survey of health professionals, drawn from a larger sample, who attended 2-day SIP courses across New South Wales, Australia. Outcome measures: Demographic variables, experiences conducting RCAs, attitudes and safety skills acquired.
	Background: Research on root cause analysis (RCA), a pivotal component of many patient safety improvement programmes, is limited. Objective: Results:
Dec, 13(0).373-7.	Sample size: 252 health professionals
	Risk adjustment/ confounders controlled for: Demographic variables, location, experience
	Confidence interval: p<.05
	Findings: No demographic variables differentiated RCA participants from non- participants. The difficulties experienced while conducting RCAs were lack of time (75.0%), resources (45.0%) and feedback (38.3%), and difficulties with colleagues (44.5%), RCA teams (34.2%), other professions (26.9%) and management (16.7%). Respondents reported benefits from RCAs, including improved patient safety (87.9%) and communication about patient care (79.8%). SIP courses had given participants skills to conduct RCAs (92.8%) and improve their safety practices (79.6%). Benefits from the SIP were thought to justify the investment by New South Wales Health (74.6%) and committing staff resources (72.6%). Most (84.8%) of the participants wanted additional RCA training. RCA participants reported improved skills and commitment to safety, but greater support from the workplace and health system are necessary to maintain momentum.
	Sluay type: D

Wallace LM, Boxall M, Spurgeon P, Barwell F. Organizational interventions to promote risk management in primary care: the experience in Warwickshire, England. Health Serv Manage Res. 2007 May;20(2):84-93. ¹¹⁰	Research purpose: This paper examines how a health authority in England promoted interventions to improve RM in General Practice that included the practices' own initiatives, significant event audit (SEA) and the Medical Defence Union's workshops which included SEA Method: Practices were approached before the programmes and when they were finished, eight months later. The practice manager from each practice completed an audit of RM activities, from which a RM competence score was derived. Up to six staff per practice completed the Learning organization Culture Questionnaire (LCQ) at both times. Sample size: 75 practices Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A
	study, particularly through a widening breadth of staff involved and in formal recording systems. There was little evidence that these improvements were mediated by organizational culture. It is argued that future interventions should more closely target specific competences (e.g. recording systems for adverse events, root cause analysis to understand error generation) and enable staff to see tangible personal and organizational benefits for the extra effort involved. Study type: Q
Spath PL. Using failure mode and effects analysis to improve patient safety. Aorn J. 2003 Jul;78(1):16-37; quiz 41-4. ¹²⁵	Research purpose: Discusses risk assessment processes. The steps of the FMEA process are described and applied to a high-risk perioperative process. Method: Training materials Sample size: N/A Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A Findings: THE FMEA PROCESS promotes systematic thinking about the safety of patient care processes (ie, what could go wrong, what needs to be done to prevent failures.)
McKay J, Bowie P, Murray L, Lough M. Levels of agreement on the grading, analysis and	Research purpose: To examine levels of agreement among different groups of general practitioners (GPs) on the grading, analysis and reporting of selected significant event
	Method: Cross-sectional postal questionnaire survey of 162 GPs split into five professional groups in the west of Scotland.
significant events by	Sample size: 122 GPs
general practitioners:	Risk adjustment/ confounders controlled for: Not stated.
a cross-sectional	Confidence interval: Not stated.
Health Care. 2008 Oct;17(5):339-45. ¹²⁶	Findings: 122 GPs responded (77%). No difference was found in the grading severity of significant events by GP groups. Increased grading severity was linked to the willingness of GP groups to analyse and report that event (p <0.05). A preference to anonymously report all event scenarios to a national educational body was reported (p <0.05). The majority of respondents were not willing to involve patients in relevant event analyses (83-100%). The strong levels of agreement suggest that GPs can prioritise relevant significant events for formal analysis and reporting. Focused guidance should be developed to encourage their engagement with the patient safety agenda, optimise learning from safety-relevant events and increase reporting opportunities. Exploration is required of the reasons why GPs may prefer an educational body as a potential reporting source or may be unwilling to include patients in relevant event analyses.

Beasley JW, Escoto KH, Karsh B-T. Design elements for a primary care medical error reporting system. Wisconsin Medical Journal. 2004;103(1):56-9. ¹²⁷	Research purpose: To understand the needs of primary care professionals in implementing a medical error reporting system Method: A series of focus groups were held over a 9-month period Sample size: 8 family physicians and 6 clinical asistants Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: 87 themes emerged. Participants supported a reporting system but were concerned about punishment or sanctions. The system must be immune from prosecutions to be successful. Study type: Q
Leape LL. Reporting of adverse events. New England Journal of Medicine. 2002;347:1633-8. ¹²⁸	Research purpose: To review reporting systems in USA Method: Synthesis of literature and current practices Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Interest in developing new voluntary reporting systems is high. If reporting is safe and provides reporters with useful information from expert analysis, it can measurably improve safety. Most of the benefits can be obtained with specialty-based or systemwide reporting programs, which are much more feasible than a national system. Although some of these programs are being developed in spite of concern about the risk of disclosure, federal legislation to protect shared information from disclosure would enhance reporting in all systems and accelerate expansion. The future of mandatory reporting is less clear. Despite calls for increased accountability on the part of hospitals and the availability of the National Quality Forum's standardized list of serious reportable events, mandatory systems appear to lack a major constituency in most states and therefore fail to receive adequate financial support. Unless that changes, mandatory reporting systems are likely to remain relatively ineffective. Study type: EO/C
Weingart SN, Toth M, Sands DZ, Aronson MD, Davis RB, Phillips RS. Physicians' decisions to override computerized drug alerts in primary care. Archives of Internal Medicine. 2003;163:2625-31. ²⁰²	Research purpose: To investigate the prevalence and character of medication-related symptoms in primary care and their relationship to adverse drug events (ADEs) or about factors that affect patient-physician communication regarding medication symptoms. Method: Interviews were conducted with patients 2 weeks and 3 months after the index visit, reviewed patients' medical records, and surveyed physicians whose patients identified medication-related symptoms. Physician reviewers determined whether medication symptoms constituted true ADEs. Multivariable regression was used to examine factors associated with patients' decision to discuss symptoms with a physician and with physicians' decision to alter therapy. Sample size: 661 patients who received prescriptions from physicians at 4 adult primary care practices. Risk adjustment/ confounders controlled for: Confidence interval: p<.001, 95% CI Findings: A total of 179 patients identified 286 medication-related symptoms but discussed only 196 (69%) with their physicians. Physicians changed therapy in response to 76% of reported symptoms. Patients' failure to discuss 90 medication symptoms resulted in 19 (21%) ameliorable and 2 (2%) preventable ADEs. In multivariable analyses, patients who took more medications (odds ratio [OR] = 1.06; 95% confidence interval [CI] = 1.04-1.08; P<.001) and had multiple medication allergies (OR = 1.07; 95% CI = 1.03-1.11; P = .001) were more likely to discuss symptoms. Male physicians (OR = 1.20; 95% CI = 1.09-1.26; P = .002) and physicians at 2 practices were more likely to change therapy (OR = 1.24; 95% CI = 1.17-1.28; P<.001; and OR = 1.17; 95% CI = 1.08-1.24; 95% CI = 1.07-1.26; P = .001; and OR = 1.17; 95% CI = 1.08-1.24; 95% CI = 1.07-1.28; P<.001; and OR = 1.17; 95% CI = 1.08-1.24; 95% CI = 1.07-1.28; P<.001; and OR = 1.17; 95% CI = 1.08-1.24; 95% CI = 1.07-1.28; P<.001; and OR = 1.17; 95% CI = 1.08-1.24; 95% CI = 1.07-1.28; P<.001; and OR = 1.17; 95% CI = 1.08-1.24; 95% CI = 1.07-1.28; P<.001; and OR = 1.17; 95% CI = 1.08-1.24; P

	Primary care physicians may be able to reduce the duration and/or the severity of many ADEs by eliciting and addressing patients' medication symptoms.
	Study type: D
Gandhi TK, Weingart SN, Seger AC, Borus J, Burdick E, Poon EG, et al. Outpatient prescribing errors and the impact of computerized	Research purpose: This study aimed to determine the rates, types, severity, and preventability of adverse events related to drugs among outpatients and to identify preventive strategies.
	Method: A prospective cohort study, including a survey of patients and a chart review, at four adult primary care practices in Boston (two hospital-based and two community-based). Prescriptions were computerized at two of the practices and handwritten at the other two.
prescribing. Journal of General Internal Medicine	Sample size: 1202 outpatients who received at least one prescription during a four-week period.
2005;20:837-41.49	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Of the 661 patients who responded to the survey (response rate, 55 percent), 162 had adverse drug events (25 percent; 95 percent confidence interval, 20 to 29 percent), with a total of 181 events (27 per 100 patients). Twenty-four of the events (13 percent) were serious, 51 (28 percent) were ameliorable, and 20 (11 percent) were preventable. Of the 51 ameliorable events, 32 (63 percent) were attributed to the physician's failure to respond to medication-related symptoms and 19 (37 percent) to the patient's failure to inform the physician of the symptoms.
	The medication classes most frequently involved in adverse drug events were selective serotonin-reuptake inhibitors (10 percent), beta-blockers (9 percent), angiotensin-converting–enzyme inhibitors (8 percent), and nonsteroidal antiinflammatory agents (8 percent). On multivariate analysis, only the number of medications taken was significantly associated with adverse events.
	Adverse events related to drugs are common in primary care, and many are preventable or ameliorable. Monitoring for and acting on symptoms are important. Improving communication between outpatients and providers may help prevent adverse events related to drugs.
Grizzle AJ, Mahmood MH, Ko Y, Murphy	Research purpose: To investigate prescribers' rationales for overriding drug-drug interaction (DDI) alerts and to determine whether these reasons were helpful to pharmacists as a part of prescription order verification
Skrepnek GH, et al.	Method: An observational retrospective database analysis
Reasons provided by	Sample size: 291 890 overrides
overridina drua-drua	Risk adjustment/ confounders controlled for: Not stated.
interaction alerts.	Confidence interval: Not stated.
American Journal of Managed Care. 2007;13(10):573- 80. ¹²⁹	Findings: Of 291 890 overrides identified, 72% were for critical DDIs. Across the Veterans Affairs medical centers, only 20% of the override reasons for critical DDI alerts were rated as clinically useful for order verification. Despite a mandatory override reason for critical DDI alerts, 53% of the responses were "no reason provided." The top response categories for critical and significant DDI alerts were "no reason provided," "patient has been taking combination," and "patient being monitored."
	The authors concluded that when given the opportunity to provide a reason for overriding a DDI alert, prescribers rarely enter clinical justifications that are useful to order verification pharmacists. This brings into question how computerized physician order entry systems should be designed.
	Sudy type: O

Fernando B, Savelyich BS, Avery AJ, Sheikh A, Bainbridge M, Horsfield P, et al. Prescribing safety features of general practice computer systems: evaluation using simulated test cases. BMJ: British Medical Journal. 2004;328:1171-3. ¹⁰⁴	Research purpose: We undertook a laboratory based evaluation of safety features for prescribing of the four main computing systems used in UK primary care. Method: We used a two round Delphi approach to reach agreement on the most important safety features of general practice computer systems. ¹ This involved electronically circulating a list of 55 theoretically derived statements related to safety to 22 members of a selected multidisciplinary expert panel. Statements related to eight broad themes covering key areas in the medicines management process: prescriber alerts, reports and clinical audit, user interface, repeat prescribing, decision support, coding, monitoring, and links to laboratories. Over 90% of the panel judged 32 of these statements to be important, and these were then used to develop 18 scenarios, which were tested using dummy patient records on the four computing systems. The systems (labelled A, B, C, and D in order to preserve suppliers' anonymity) were independently evaluated at Primary Care Information Services (PRIMIS) laboratories by two members of the project team. Sample size: 4 computing systems Risk adjustment/ confounders controlled for: To minimise risk of bias, systems were tested with each of the scenarios in random order and data were recorded on to piloted data extraction sheets. Finally, to ensure that there were no technical set-up problems that were identified to the manufacturers and invited comment. Confidence interval: N/A Findings: None of the systems produced alerts for all of the 18 scenarios. In terms of prescription of drugs with similar names, none of the systems warned for all 10 drug pairs considered. The evaluators produced no discrepancies in assessing the safety of systems. Each of the four system suppliers agreed with our assessments.
Glassman PA, Belperio P, Simon B, Lanto A, Lee M. Exposure to Automated Drug Alerts Over Time: Effects On Clinicians' Knowledge And Perceptions. Medical Care. 2006;44(3):250-6. ¹³⁰	Research purpose: We tested whether interval exposure to an automated drug alert system that included approximately 2000 drug-drug interaction alerts increased recognition of selected interacting drug pairs. We also examined other perceptions about computerized order entry. Method: We administered cross-sectional surveys in 2000 and 2002 that included more than 260 eligible clinicians in each time period. Sample size: We studied clinicians practicing in ambulatory settings within a Southern California Veterans Affairs Healthcare System and who responded to both surveys (97 respondents). Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Clinicians correctly categorized similar percentages of the 7 interacting drug- drug pairs at baseline and follow-up (53% vs. 54%, P = 0.51) but improved their overall recognition of the 3 contraindicated drug-drug pairs (51% vs. 60%, P = 0.01). No significant changes from baseline to follow-up were found for the 8 interacting drug- condition pairs (60% vs. 62%, P = 0.43) or the 4 contraindicated drug-condition pairs (52% vs. 56%, P = 0.24). More providers preferred using order entry at follow-up than baseline (63% vs. 45%, P < 0.001). Signal-to-noise ratio remained the biggest reported problem at follow-up and baseline (54 vs. 57%, P = 0.75). In 2002, clinicians reported seeing a median of 5 drug alerts per week (representing approximately 12.5% of prescriptions entered), with a median 5% reportedly leading to an action.

Ko Y, Abarca J, Malana DC, Dara	Research purpose: To assess Veterans Affairs (VA) prescribers' and pharmacists'
Malone DC, Dare DC, Geraets D, Houranieh H, et al. Practitioners' Views on Computerized Drug–Drug Interaction Alerts in	suggestions for improving DDI alerts.
	Method: A mail survey of prescribers and pharmacists from VA medical centers across the United States. The questionnaire asked respondents about their sources of drug and DDI information, satisfaction with the combined inpatient and outpatient computerized prescriber order entry (CPOE) system, attitude toward DDI alerts, and suggestions for improving DDI alerts.
Journal of the	Sample size: 725 prescribers and 142 pharmacists from seven VA medical centers across the United States.
Informatics	Risk adjustment/ confounders controlled for: None
Association.	Confidence interval: N/A
2007;14:56-64.131	Findings: The overall response rate was 40% (prescribers: 36%; pharmacists: 59%). Both prescribers and pharmacists indicated that the CPOE system had a neutral to positive impact on their jobs. DDI alerts were not viewed as a waste of time and the majority (61%) of prescribers felt that DDI alerts had increased their potential to prescribe safely. However, only 30% of prescribers felt DDI alerts provided them with what they needed most of the time. Both prescribers and pharmacists agreed that DDI alerts should be accompanied by management alternatives (73% and 82%, respectively) and more detailed information (65% and 89%, respectively). When asked about suggestions for improving DDI alerts, prescribers most preferred including management options whereas pharmacists most preferred making it more difficult to override lethal interactions. Prescribers and pharmacists reported primarily relying on electronic references for general drug information (62% and 55%, respectively) and DDI information (51% and 79%, respectively). Respondents reported neutral to positive views regarding the effect of CPOE on their jobs. Their opinions suggest DDI alerts are useful but still require additional work to increase their clinical utility.
	Study type: D
Lapane KL, Waring ME, Schneider KL, Dube C, Quilliam BJ. A mixed method	Research purpose: To describe primary care prescribers' perspectives on electronic prescribing drug alerts at the point of prescribing. DESIGN: We used a mixed-method study, which included clinician surveys (web-based and paper) and focus groups with prescribers and staff.
study of the merits of	Method: Survey and focus groups.
e-prescribing drug	Sample size: 157 prescribers for survey
J Gen Intern Med.	276 prescribers and staff for focus group
2008 Apr;23(4):442-	Risk adjustment/ confounders controlled for: Not stated.
6. ¹⁰⁰	Confidence interval: Not stated.
	Findings: More than 40% of prescribers indicated they override drug-drug interactions most of the time or always (range by e-prescribing system, 25% to 50%). Participants indicated that the software and the interaction alerts were beneficial to patient safety and valued seeing drug-drug interactions for medications prescribed by others. However, they noted that alerts are too sensitive and often unnecessary. Participant suggestions included: (1) run drug alerts on an active medication list and (2) allow prescribers to set the threshold for severity of alerts. The study concluded that primary care prescribers recognize the patient safety value of drug prescribing alerts embedded within electronic prescribing software. Improvements to increase specificity and reduce alert overload are needed.

Avery AJ, Savelyich BS, Sheikh A, Morris CJ, Bowler I, Teasdale S. Improving general practice computer systems for patient safety: qualitative study of key stakeholders. Qual Saf Health Care. 2007 Feb;16(1):28- 33. ¹³²	Research purpose: To identify ways in which the use of general practice computer systems could be improved to enhance safety in primary care. Method: Qualitative study using semistructured interviews Sample size: Thirty one participants Risk adjustment/ confounders controlled for: Not stated. Confidence interval: Not stated. Findings: Participants identified deficiencies in current systems that pose serious threats to patient safety. To bring about improvements, providers need to supply clinicians with safe, accurate and accessible information for decision support; be aware of the importance of human ergonomics in the design of hazard alerts; consider the value of audit trails and develop mechanisms to allow for the accurate transfer of information between clinical computer systems. These improvements in computer systems will be most likely to occur if mandated through regulations. Individual practices are in need of improved education and training which focuses, in particular, on providing support with recording data accurately and using call, recall and reminders effectively. There are significant opportunities for improving the safety of general practice computer systems. Priorities include improving the knowledge base for clinical decision support, paying greater attention to human ergonomics in system design, improved staff training and the introduction of new regulations mandating system suppliers to satisfy essential safety requirements.
Hoffman JM, Proulx SM. Medication errors caused by confusion of drug names. Drug Safety. 2003;26(7):445-52. ¹³³	Study type: Q Research purpose: A discussion of the problem of medication errors caused by confusion of drug names, policy changes and other potential solutions. Method: Literature review Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: This problem can be alleviated through actions by regulatory agencies, pharmaceutical manufacturers, healthcare professionals, and patients. Study type: R
Durieux P, Trinquart L, Colombet I, Nies J, Walton RT, Rajeswaran A, et al. Computerized advice on drug dosage to improve prescribing practice. The Cochrane Database of Systematic Reviews. 2008(3). ¹³⁵	Research purpose: This is an updated version of an earlier Cochrane systematic review, by Walton et al, published in 2001. The aim was to assess whether computerised advice on drug dosage has beneficial effects on the process or outcome of health care. Method: <i>search strategy</i> : We searched the Cochrane Effective Practice and Organisation of Care Group specialized register (June 1996 to December 2006), MEDLINE (1966 to December 2006), EMBASE (1980 to December 2006), hand searched the journal Therapeutic Drug Monitoring (1979 to March 2007) and the Journal of the American Medical Informatics Association (1996 to March 2007) as well as reference lists from primary articles. <i>Selection criteria</i> : Randomized controlled trials, controlled trials, controlled before and after studies and interrupted time series analyses of computerized advice on drug dosage were included. The participants were health professionals responsible for patient care. The outcomes were: any objectively measured change in the behaviour of the health of patients resulting from computerized advice (such as adverse reactions to drugs). <i>Data collection and analysis</i> : Two reviewers independently extracted data and assessed study quality including a wide range of drugs in inpatient and outpatient settings. Sample size: Twenty-six comparisons (23 articles) were included (as compared to fifteen comparisons in the original review)

	Confidence interval: 05% where possible
	Findings: Interval. 43.78 where possible Findings: Interval. 43.78 where possible Findings: Interventions usually targeted doctors although some studies attempted to influence prescriptions by pharmacists and nurses. Although all studies used reliable outcome measures, their quality was generally low. Computerized advice for drug dosage gave significant benefits by:1.increasing the initial dose (standardised mean difference 1.12, 95% CI 0.33 to 1.92)2.increasing serum concentrations (standardised mean difference 1.12, 95% CI 0.43 to 1.82)3.reducing the time to therapeutic stabilisation (standardised mean difference -0.55, 95% CI -1.03 to -0.08)4.reducing the risk of toxic drug level (rate ratio 0.45, 95% CI 0.30 to 0.70)5.reducing the length of hospital stay (standardised mean difference -0.35, 95% CI -0.52 to -0.17). This review suggests that computerized advice for drug dosage has some benefits: it increased the initial dose of drug, increased serum drug concentrations and led to a more rapid therapeutic control. It also reduced the risk of toxic drug levels and the length of time spent in the hospital. However, it had no effect on adverse reactions. In addition, there was no evidence to suggest that some decision support technical features (such as its integration into a computer physician order entry system) or aspects of organization of care (such as the setting) could optimise the effect of computerised advice.
Tamblyn R, Huang A, Perreault R, Jacques A, Roy D, Hanley J, et al. The medical office of the 21st century (MOXXI): effectiveness of computerized decision-making support in reducing inappropriate prescribing in primary care. Canadian Medical Association Journal. 2003;169:549-56. ¹⁰²	Research purpose: Our objective was to determine whether inappropriate prescribing could be reduced when primary care physicians had computer-based access to information on all prescriptions dispensed and automated alerts for potential prescribing problems. Method: We randomly assigned 107 primary care physicians with at least 100 patients aged 66 years and older (total 12 560) to a group receiving computerized decision-making support (CDS) or a control group. Physicians in the CDS group had access to information on current and past prescriptions through a dedicated computer link to the provincial seniors' drug-insurance program. When any of 159 clinically relevant prescribing problems were identified by the CDS software, the physician received an alert that identified the nature of the problem, possible consequences and alternative therapy. The rate of initiation and discontinuation of potentially inappropriate prescriptions was assessed over a 13-month period. Sample size: 107 physicians Risk adjustment/ confounders controlled for: Yes Confidence interval: Yes Findings: In the 2 months before the study, 31.8% of the patients in the CDS group and 22.2% of these is the careful group had at least 1 contaction in the consequences controlled for: Yes
	33.3% of those in the control group had at least 1 potentially inappropriate prescription. During the study the number of new potentially inappropriate prescriptions per 1000 visits was significantly lower (18%) in the CDS group than in the control group (relative rate [RR] 0.82, 95% confidence interval [CI] 0.69–0.98), but differences between the groups in the rate of discontinuation of potentially inappropriate prescriptions were significant only for therapeutic duplication by the study physician and another physician (RR 1.66, 95% CI 0.99–2.79) and drug interactions caused by prescriptions written by the study physician (RR 2.15, 95% CI 0.98–4.70). Study type: RCT

Morris CJ, Savelyich BS, Avery AJ, Cantrill JA, Sheikh A. Patient safety features of clinical computer systems: questionnaire survey of GP views. Qual Saf Health Care. 2005 Jun;14(3):164- 8. ¹³⁶	Research purpose: To investigate general practitioners' (GPs') stated knowledge, use and training needs related to the patient safety features of computerised clinical systems in England. Method: Questionnaire survey. Sample size: 381 GPs from six English primary care trusts. Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: GPs' views on the importance of specified patient safety features on their computer system; their knowledge of the presence of specified safety features; previous training and perceived future training needs. RESULTS: Three hundred and eighty one GPs (64.0%) completed and returned the questionnaire. Although patient safety features were considered to be an important part of their computer system by the vast majority of GPs, many were unsure as to whether the system they were currently using possessed some of the specified features. Some respondents erroneously believed that their computers would warn them about potential contraindications or if an abnormal dose frequency had been prescribed. Only a minority had received formal training on the use of their system's patient safety features. Study type: D
De Smet PAGM, Dautzenberg M. Repeat prescribing: Scale, problems and quality management in ambulatory care patients. Drugs. 2004;64(16):1779- 800. ²⁰³	Research purpose: To review research about repeat prescribing Method: Systematic Review Sample size: 1993 – 2003 papers Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Studies evaluating the repeat prescribing process have shown that GPs and medical practices vary widely in their degree of administrative and clinical control of repeat prescriptions. Contrary to the opinion that GPs cannot change prescribing behaviour when the prescription is initiated by a medical specialist, GPs have their own responsibility for controlling the repeats of such prescriptions. Intervention studies suggest that a medication review by a pharmacist can help to reduce drug-related problems with repeat prescriptions, and the effectiveness of the intervention may be increased by combining the medication review with a consultation of the patient's medical records and a patient interview. In several studies, such an intervention was relatively inexpensive and, therefore, feasible. However, these conclusions should be viewed with appropriate caution because a number of caveats pertain. There is still no evidence that these types of intervention improve health-related quality of life or reduce healthcare cost, and so far only a few trials have produced any evidence of clinical improvement. As implicit and explication may offer a more thorough assessment but may also be more complex and time consuming. Further studies on the development and evaluation of repeat prescription management models are needed, preferably focussing on improving clinical, humanistic and economic outcomes. New studies should investigate the effects of: different types of interventions; different types of healthcare professionals. Future studies should also assess whether results are sustained, the optimal time interval between reviews of repeat prescriptions, and the possibilities offered by new computerised support technologies.

Guerreiro MP, Cantrill J, Pisco L, Martins AP. Considerations on preventable drug- related morbidity in primary care. Part II - Strategies to reduce the risk of preventable drug- related morbidity. Revista Portuguesa de Clinica Geral. 2005;21:447-59. ¹⁴⁶	Research purpose: To review the literature on strategies to reduce the risk of preventable drug-related morbidities in primary care. Method: We searched nine electronic data bases, bibliographies of papers, two authoritative internet sites and used personal contacts to identify literature on strategies to improve the safety and quality of medicines usage in primary care. Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: The combined search strategy yielded 96 potentially relevant references. Those which met our inclusion criteria were divided into reviews and original articles; if available the former were used in the present work. References were further grouped into four not mutually exclusive categories, according to the stage of the medication-use process they were directed at: prescribing, dispensing, administration/ compliance and monitoring stages. Five main strategies emerged to improve the safety and quality of the medication-use process in primary care: educational strategies for patients, computerisation and revision of professional roles. These strategies may be applicable to more than one stage of the medication-use process and comprise a large number of possible interventions, such as academic detailing and workshops, the use of memorandums and information technology to support medicine-taking, computerising patient data, employing informatics to support practitioners' decision-making and automated signalling of risk events.
Boston-Fleischhauer C. Enhancing healthcare process design with human factors engineering and reliability science, Part 2: Applying the knowledge to clinical documentation systems. The Journal of Nursing Administration. 2008;38(2):84-9. ²⁰⁴	Research purpose: The author presents human factors engineering and reliability science as important knowledge to enhance existing operational and clinical process design methods in healthcare. An examination of these theories, application approaches, and examples are presented. Method: Synthesis of literature Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Clinical documentation is presented as an ideal product and process for applying HFE and reliability science. As a member of the executive team who oversees major IT initiatives, the nurse executive has the unique opportunity to partner with IT, organizational development, and process improvement leaders to ensure that the presented concepts are thoroughly adopted. Use of HFE and reliability science in process design and implementation solidly positions the organization to achieve efficient, effective, safe, and reliable results. Study type: EO/C
Kaelber DC, Bates DW. Health information exchange and patient safety. J Biomed Inform. 2007 Dec;40(6 Suppl):S40- 5. ¹³⁷	Research purpose: An overview is presented of six different ways in which health information exchange (HIE) can improve patient safety-improved medication information processing, improved laboratory information processing, improved radiology information processing, improved communication among providers, improved communication between patients and providers, and improved public health information processing. Method: Synthesis of literature Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: One of the most promising advantages for HIE is improved patient safety. Up to 18% of the patient safety errors generally and as many as 70% of adverse drug events could be eliminated if the right information about the right patient is available at the right time. Health information exchange makes this possible. Within the area of improved

	medication information processing are discussed: drug-allergy information processing, drug-dose information processing, drug-drug information processing, drug-diagnosis information processing, and drug-gene information processing. HIE and decreased patient safety is also discussed as well as standards and completeness of information for HIE and patient safety. Study type: EO/C
Pham CB, Dickman RL. Minimizing adverse drug events in older patients. American Family Physician. 2007;76(12):1837- 44. ¹³⁸	Research purpose: A review of the literature minimise adverse drug events in older adults Method: Literature review Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Physicians need to find ways to streamline the medical regimen, such as periodically reviewing all medications in relation to the Beers criteria and avoiding new prescriptions to counteract adverse drug reactions. The incorporation of computerized alerts and a multidisciplinary approach can reduce adverse drug events. Study type: R
Franks AS, Ray SM, Wallace LS, Keenum AJ, Weiss BD. Do Medication Samples Jeopardize Patient Safety? (January). Ann Pharmacother. 2008 Dec 17. ⁴⁵	Research purpose: To evaluate readability and formatting characteristics of written consumer medication information (CMI) included with nonsolid (ie, topical cream/lotion, inhalation, transdermal) drug samples. Method: We collected a convenience sample of nonsolid dosage sample medications (N = 55) from several different private and university-affiliated primary care and specialty physician practices at a large academic medical center in the south-eastern US. We noted whether CMI was present and, if it was, we assessed it for instruction presentation, reading level, text size, format/layout, and comprehensibility. Sample size: (N = 55) Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Most (43 of 55) products included CMI, either as a separate leaflet or directly on the packaging. Reading level of CMI leaflets ranged from the 6th- to 14th-grade level, with just 4 (16.0%) written at the recommended 6th-grade level. Text font point size was 9.48 +/- 2.14 (mean +/- SD; range 5-12). Text printed directly on sample packaging averaged 6.61 point +/- 2.62 (4-11) font size. Ninety-two percent of CMI leaflets included a combination of text and pictures; only 11.1% of CMI printed directly on the packaging used pictorial aids. Study type: D
Flanagan P, MacKinnon NJ, Hanlon N, Robertson H. Identification of intervention strategies to reduce preventable drug morbidity in older adults. Geriatrics Today Journal of the Canadian Geriatrics Society. 2002;5:76- 80. ²⁰⁵	Research purpose: The purpose of this study was to determine the perceived efficacy of each of 8 strategies for reducing PDRM, as expressed by physicians. Method: Three panels of physicians (12 general practitioners [GPs], 6 geriatricians and 6 clinical pharmacologists) who had previously developed and validated clinical indicators of PDRM in older adults, received a follow-up mail survey to identify strategies to reduce PDRM. Each physician was asked to decide how best to reduce PDRM, by choosing from 8 strategies for each clinical indicator as many preventive intervention methods as they felt could be useful. Sample size: 24 Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Overall,monitoring was the most frequently chosen strategy per indicator. The GPs and clinical pharmacologists chose monitoring most frequently per indicator, while the geriatricians chose health-system management most frequently per indicator. For each PDRM indicator, an average of 3.95 intervention strategies were chosen.

	Study type: D
Bond C, Matheson C, Williams S, Donnan	Research purpose: To compare a community pharmacist-managed repeat prescribing system with established methods of managing repeat prescribing.
P. Repeat prescribing: a role for community pharmacists in controlling and monitoring repeat prescriptions. British Journal of General	Method: A randomised controlled intervention study involving general medical practices, patients, community pharmacists. Patients on repeat medication were given sufficient three-monthly scripts, endorsed for monthly dispensing, to last until their next clinical review consultation with their general practitioner (GP). The scripts were stored by a pharmacist of the patient's choice. Each monthly dispensing was authorised by the pharmacist, using a standard protocol. The cost of the drugs prescribed and dispensed was calculated. Data on patient outcomes were obtained from pharmacist-generated patient records and GP notes.
Practice. 2000:50(453):271-	Sample size: 19 general medical practices, 3074 patients, 62 community pharmacists
5. ¹⁴⁰	Risk adjustment/ confounders controlled for: Age, gender
	Confidence interval: regression used
	Findings: A total of 12.4% of patients had compliance problems, side-effects, adverse drug reactions, or drug interactions identified by the pharmacist. There were significantly more problems identified in total in the intervention group. The total number of consultations, deaths, and non-elective hospital admissions was the same in both groups. Sixty-six per cent of the study patients did not require their full quota of prescribed drugs, representing 18% of the total prescribed costs (estimated annual drug cost avoidance of 43 Pounds per patient). CONCLUSION: This system of managing repeat prescribing has been demonstrated to be logistically feasible, to identify clinical problems, and to make savings in the drugs bill.
	Study type: RCT
Royal S, Smeaton L, Avery AJ, Hurwitz B, Sheikh A. Interventions in primary care to reduce medication related adverse events and hospital admissions: systematic review and meta-analysis. Qual Saf Health Care. 2006 Feb;15(1):23-31.97	Research purpose: To identify and evaluate studies of interventions in primary care aimed at reducing medication related adverse events that result in morbidity, hospital admission, and/or mortality.
	unpublished data. Bibliographies of retrieved papers were searched and experts and first authors contacted in an attempt to locate additional studies. There were no restrictions on language of publication. All interventions applied in primary care settings which aimed to improve patient safety by reducing adverse events resulting from medication overuse or misuse were considered. Randomised controlled trials, controlled trials, controlled before and after studies, and interrupted time series studies were eligible for inclusion. Study quality assessment and data extraction were undertaken using the Cochrane Effective Practice and Organisation of Care data collection checklist and template. Meta- analysis was performed using a random effects model.
	Sample size: 38 studies
	Confidence interval: Ves
	Findings: 159 studies were initially identified, of which 38 satisfied our inclusion criteria. These were categorised as follows: 17 pharmacist-led interventions (of which 15 reported hospital admissions as an outcome); eight interventions led by other primary healthcare professionals that reported preventable drug related morbidity as an outcome; and 13 complex interventions that included a component of medication review aimed at reducing falls in older people (the outcome being falls). Meta-analysis found that pharmacist-led interventions are effective at reducing hospital admissions (OR 0.64 (95% CI 0.43 to 0.96)), but restricting analysis to the randomised controlled trials failed to demonstrate significant benefit (OR 0.92 (95% CI 0.81 to 1.05)). Pooling the results of studies in the other categories did not demonstrate any significant effect.

Krska J, Cromarty JA, Arris F, Jamieson D, Hansford D, Duffus PRS, et al. Pharmacist-led medication review in	Research purpose: To study the effect of medication review led by a pharmacist on resolution of pharmaceutical care issues, medicine costs, use of health and social services and health-related quality of life.
	Method: A randomized, controlled trial. Pharmacists reviewed the drug therapy of patients, using information obtained from the practice computer, medical records and patient interviews. All outcome measures were assessed at baseline and after 3 months.
patients over 65: a randomized, controlled trial in	Sample size: General medical practices in the Grampian region of Scotland. Subjects: 332 patients aged at least 65 years, with at least two chronic disease states who were taking at least four prescribed medicines regularly.
and Aging	Risk adjustment/ confounders controlled for: demographic factors
2001;30:205-11.98	Confidence interval: p<0.05
	Findings: All patients had at least two pharmaceutical care issues at baseline. Half of these were identified from the prescription record, the rest from notes and patient interview. Of all the issues, 21% were resolved by information found in notes and 8.5% by patient interview. General practitioners agreed with 96% of all care issues documented on the care plans in the intervention group. At the time of follow-up, 70% of the remaining care issues had been resolved in the intervention group, while only 14% had been resolved in the control group. There were no changes in medicine costs or health-related quality of life in either group. There were small increases in contacts with health-care professionals and slightly fewer hospital admissions among the intervention group than the control group. Pharmacist-led medication review has the capacity to identify and resolve pharmaceutical care issues and may have some impact on the use of other health services.
	Study type: RCT
Pearson S-A, Ross- Degnan D, Payson A,	Research purpose: To review the effectiveness of strategies to improve the quality and efficiency of medication use in managed care organizations (MCOs).
Soumerai SB.	Method: Systematic review of published intervention studies.
Changing medication	Sample size: 105 studies, 70 of which were reported since 1996.
A critical review of	Risk adjustment/ confounders controlled for: N/A
available evidence.	Confidence interval: N/A
American Journal of Managed Care. 2003;9:715-31. ¹⁴¹	Findings: Overall, 46% of the studies met the minimum criteria for methodologic adequacy (n = 48). Consistently effective interventions included dissemination of educational materials with drug samples, participatory clinical guideline development, group or one-to-one educational outreach, and enhanced patient-specific feedback. Disease management (primarily for depression and diabetes) showed promise in improving short-term outcomes. Dissemination of educational materials and aggregated feedback alone were ineffective. Interventions in staff-model health maintenance organizations were more effective than those conducted in group-model health maintenance organizations.
	High-quality studies of interventions to improve drug use in MCOs are increasing in frequency. There is evidence for the effectiveness of several strategies to change drug use, but little is known about longer-term clinical outcomes. Few well-designed, published studies have assessed the efficacy or safety of financial incentives for physicians, tiered copayments for patients, or formulariesdespite their widespread use.

Jamtvedt G, Young JM, Kristoffersen DT, A. OBM, Oxman AD. Audit and feedback: effects on professional practice and health care outcomes (Review). The Cochrane Database of Systematic Reviews. 2006. ¹⁴²	Research purpose: To assess the effects of audit and feedback on the practice of healthcare professionals and patient outcomes. Method: We searched the Cochrane Effective Practice and Organisation of Care Group's register and pending file up to January 2004 Sample size: 118 studies Risk adjustment/ confounders controlled for: NA Confidence interval: NA Findings: In the primary analysis 88 comparisons from 72 studies were included that compared any intervention in which audit and feedback is a component compared to no intervention. For dichotomous outcomes the adjusted risk difference of compliance with desired practice varied from - 0.16 (a 16 % absolute decrease in compliance) to 0.70 (a 70% increase in compliance) (median = 0.05, inter-quartile range = 0.03 to 0.11) and the adjusted risk ratio varied from 0.71 to 18.3 (median = 1.08, inter-quartile range = 0.99 to 1.30). For continuous outcomes the adjusted percent change relative to control varied from -0.10 (a 10 % absolute decrease in compliance) to 0.68 (a 68% increase in compliance) (median = 0.16, inter-quartile range = 0.05 to 0.37). Low baseline compliance with recommended practice and higher intensity of audit and feedback were associated with larger adjusted risk ratios (greater effectiveness) across studies. Study type: SR
Ernst E. Serious adverse effects of unconventional therapies for children and adolescents: a systematic review of recent evidence. Eur J Pediatr. 2003 Feb;162(2):72-80.48	Research purpose: The aim of this systematic review was to summarise the recent evidence about unconventional therapies which have become popular in paediatric and adolescent populations. Method: Computerised literature searches were carried out in five databases to identify all recent reports of adverse events associated with unconventional therapies in children. The reports were summarised in narrative and tabular form. The results show that numerous case reports and several case series have been published since 1990. Investigations of a more systematic nature are, however, rare. Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Most of the adverse events were associated with herbal medications. Inadequately regulated herbal medicines may contain toxic plant material, be contaminated with heavy metals, or be adulterated with synthetic drugs. The adverse events included bradycardia, brain damage, cardiogenic shock, diabetic coma, encephalopathy, heart rupture, intravascular haemolysis, liver failure, respiratory failure, toxic hepatitis and death. A high degree of uncertainty regarding a causal relationship between therapy and adverse event was frequently noted. The size of the problem and its importance relative to the well-documented risks of conventional treatments are presently unknown. Several unconventional therapies may constitute a risk to the health of children and adolescents. At present, it is impossible to provide reliable incidence figures. It seems important to be vigilant and investigate this area more systematically.

Ko Y, Malone DC, Skrepnek GH, Armstrong EP, Murphy JE, Abarca J, et al. Prescribers' knowledge of and sources of information for potential drug-drug interactions: a postal survey of US prescribers. Drug	Research purpose: The objectives of this study were to assess prescribers' ability to recognize potential clinically significant drug-drug interactions (DDIs) and to examine the sources of information they use to identify potential DDIs and prescribers' opinions on the usefulness of various DDI information sources. Method: A postal questionnaire was developed to assess prescriber knowledge of medications that may interact and prescribers' usual sources of DDI information. Recipients were asked to classify 14 drug pairs as 'contraindicated', 'may be used together but with monitoring' or 'no interaction'. A response option of 'not sure' was also provided. The questionnaires were sent to a national sample of 12 500 prescribers based on past history of prescribing drugs associated with known potential for DDI, who were identified using data from a pharmacy benefit manager covering over 50 million individuals.	
Saf. 2008;31(6):525-	Sample size: 950 prescribers	
J0. ¹⁴³	Risk adjustment/ confounders controlled for: N/A	
	Confidence interval: N/A	
	Findings: The percentage of prescribers who correctly classified specific drug pairs ranged from 18.2% for warfarin and cimetidine to 81.2% for paracetamol (acetaminophen) with codeine and amoxicillin, with 42.7% of all combinations classified correctly. The number of drug pairs correctly classified by the prescribers ranged from 0 to 13. For half of the drug pairs over one-third of the respondents answered 'not sure'; among those drug pairs, two were contraindicated. When asked what source was used to learn more about a potential DDI, a quarter of the prescribers reported using personal digital assistants and another quarter used printed material. The majority of the prescribers (68.4%) reported that they were usually informed by pharmacists about their patients' potential exposure to DDIs. Compared with the prescribers who used other sources, those who used computerized DDI alerts as their usual source of DDI information consistently gave a lower rating score to the five statements that assessed the usefulness of the information.	
	Study type: D	
Pollock M, Bazaldua OV, Dobbie AE. Appropriate prescribing of medications: an eight-step approach. American Family Physician. 2007;75(2):231-6. ¹⁴⁵	Research purpose: To explicate an 8 step approach to prescribing medication advocated by the World Health Organization Method: expert opinion. Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: N/A Study type: EO/C	
Dennison RD. A	Research purpose: Not provided	
medication safety	Method: expert opinion.	
reducation program to	Sample size: N/A	
harm caused by	Risk adjustment/ confounders controlled for: N/A	
medication errors.	Confidence interval: N/A	
Journal of Continuing Education in Nursing. 2007;38(4):176-84. ¹⁴⁷	Findings: Data need to be collected, analysed and disseminated so that couples can make informed choices. Legal barriers to artificial insemination should be eliminated, and replaced with standards and guidelines on patient information, informed consent, and risk-reducing procedures. A national, 24-h, pregnancy and HIV hotline needs to be established, so that HIV-infected people, their partners, and providers can easily access accurate, up-to-date information and referrals on HIV and pregnancy matters.	
 and safety curricula in nursing education: matching practice realities. Nurs Outlook. 2007 May- Jun;55(3):151-5.¹⁴⁸ Findings: Potential first steps for thought leaders in academia and practice as they commit to working together to achieve a new direction to transform quality and safety fo nursing are: 1 Articulate the KSAs that should be developed for the 6 core competencies during pre- licensure education and the transition to practice, and among staff nurses who move u clinical ladder from advanced beginner to expert. 2 Integrate quality and safety competencies into job descriptions and performance evaluations for nurses in health care settings and the clinical faculty who teach student in those settings. 3 Invite faculty to attend practice setting courses, conferences, grand rounds, and inservices on quality improvement and patient safety to help faculty remain abreast of new terms, practice developments, and key strategies. 4 Include clinical faculty who teach students on the unit email lists so that they receive practice updates about new quality and safety protocols. 5 Evaluate the efficacy of various teaching strategies for developing quality and safety competencies. 6 Share quality outcome data from care settings with faculty and students so students see that quality improvement is part of the daily work of nursing. 	rerwood G, F renkard K. Quality s	Research purpose: Describes features of nursing education curricula for quality and safety
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Interimity product Risk adjustment/ confounders controlled for: N/A Outlook. 2007 May- Jun;55(3):151-5. ¹⁴⁸ Confidence interval: N/A Findings: Potential first steps for thought leaders in academia and practice as they commit to working together to achieve a new direction to transform quality and safety f nursing are: 1 Articulate the KSAs that should be developed for the 6 core competencies during prelicensure education and the transition to practice, and among staff nurses who move u clinical ladder from advanced beginner to expert. 2 Integrate quality and safety competencies into job descriptions and performance evaluations for nurses in health care settings and the clinical faculty who teach student in those settings. 3 Invite faculty to attend practice setting courses, conferences, grand rounds, and inservices on quality improvement and patient safety to help faculty remain abreast of new terms, practice developments, and key strategies. 4 Include clinical faculty who teach students on the unit email lists so that they receive practice updates about new quality and safety protocols. 5 Evaluate the efficacy of various teaching strategies for developing quality and safety competencies. 6 Share quality outcome data from care settings with faculty and students so students see that quality improvement is part of the daily work of nursing.	nursing education:	Sample size: N/A
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	e S	6 Share quality outcome data from care settings with faculty and students so students see that quality improvement is part of the daily work of nursing.
7 Build opportunities for students to actively participate in process improvements.	7	7 Build opportunities for students to actively participate in process improvements.
8 Develop common goals and standards for good inter-professional communication practices on the units where students have clinical experiences.	3 7	8 Develop common goals and standards for good inter-professional communication practices on the units where students have clinical experiences.
9 Create opportunities for students to use information and communication technologies as part of their clinical training.	c c	9 Create opportunities for students to use information and communication technologies as part of their clinical training.
10 Share ideas for how to assess whether learners have acquired the knowledge, skills and attitudes related to quality and safety competencies.	1 2	10 Share ideas for how to assess whether learners have acquired the knowledge, skills, and attitudes related to quality and safety competencies.
Study type: EO/C	ç	Study type: EO/C
Wakefield A, AttreeResearch purpose: To examine to what extent patient safety is addressed within medical and nursing curricula.	akefield A, Attree F , Braidman I, r	Research purpose: To examine to what extent patient safety is addressed within medical and nursing curricula.
Carlisle C, Johnson Method: Literature review	arlisle C, Johnson	Method: Literature review
M, Cooke H. Patient safety: do pursing Sample size: N/A	, COOKE H. Patient	Sample size: N/A
and medical curricula Risk adjustment/ confounders controlled for: N/A	nd medical curricula	Risk adjustment/ confounders controlled for: N/A
address this theme? Confidence interval: N/A	Idress this theme? (Confidence interval: N/A
Nurse Educ Today. 2005 May;25(4):333- 40. ¹⁴⁹ Findings: In the United Kingdom patient safety issues feature prominently in the (Department of Health, 2000a. An organisation with a memory. The report of an expert group on learning from adverse events. The Stationery Office, London, Department of Health, 2000b. Handling complaints: monitoring the NHS complaints procedures (England, Financial year 1998-99). The Stationery Office, London.) policy documentatii but this is not reflected within the formal curricula guidelines issued by the NMC and GMC. Yet if healthcare educational curricula were to recognise the value of learning fro errors, such events could become part of a wider educational resource enabling both students and facilitators to prevent threats to patient safety. For this reason, the paper attempts to articulate why patient safety should be afforded greater prominence within medical and nursing curricula. It is argued that learning how to manage errors effective would enable trainee practitioners to improve patient care, reduce the burden on an	Jrse Educ Today. 105 May;25(4):333-). ¹⁴⁹ (((((((((((((((((((Findings: In the United Kingdom patient safety issues feature prominently in the (Department of Health, 2000a. An organisation with a memory. The report of an expert group on learning from adverse events. The Stationery Office, London, Department of Health, 2000b. Handling complaints: monitoring the NHS complaints procedures (England, Financial year 1998-99). The Stationery Office, London.) policy documentation but this is not reflected within the formal curricula guidelines issued by the NMC and GMC. Yet if healthcare educational curricula were to recognise the value of learning from errors, such events could become part of a wider educational resource enabling both students and facilitators to prevent threats to patient safety. For this reason, the paper attempts to articulate why patient safety should be afforded greater prominence within medical and nursing curricula. It is argued that learning how to manage errors effectively would enable trainee practitioners to improve patient care, reduce the burden on an

	practice.
	Study type: R
Mercurio A. The evolving role of	Research purpose: To discuss the role of health educators in improving patient safety
	Method: Expert opinion and literature synthesis
advancing patient	Sample size: N/A
safety: forging	Risk adjustment/ confounders controlled for: N/A
partnerships and leading change. Health Promot Pract. 2007 Apr;8(2):119- 27. ²⁰⁶	Confidence interval: N/A
	Findings: Health educators possess a skill set and an ethical framework that effectively equip them to advance patient and family-centered care and contribute in other significant ways to a safer health care system. Health educators in clinical settings are playing varied and significant roles in advancing patient safety. They are removing barriers to clear communication and forging partnerships between patients, their families, and staff. Health educators are leading patient safety culture change within their institutions and contributing to the shift from provider-centric to patient-centric systems. To expand their impact in improving patient safety, health educators in clinical settings are participating in public awareness campaigns. In seeking to enhance patient safety, health educators face a number of challenges. To successfully manage those, health educators must expand their knowledge, broaden connections, and engage patients and families in meaningful ways.
	Study type: EO/C
Royal College of	Research purpose: Describes a curriculum for training in Patient Safety
General Practitioners. Patient Safety	Method: N/A
Curriculum Statement	Sample size: N/A
3.2. 2007. ¹⁵⁰	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: N/A
	Study type: D
Walton MM, Shaw T, Barnet S, Ross J. Developing a national patient safety education framework for Australia. Qual Saf Health Care. 2006 Dec;15(6):437- 42. ¹⁵²	Research purpose: The primary objective of the study was to assess the frequency of missed results and resulting treatment delays encountered by primary care providers in VA clinics.
	Method: An anonymous on-line survey of primary care providers was conducted as part of the health systems ongoing quality improvement programs. We collected information from providers concerning their clinical effort (e.g., number of clinic sessions, number of patient visits per session), number of patients with missed abnormal test results, and the number and types of treatment delays providers encountered during the two week period prior to administration of our survey.
	Sample size: The survey was completed by 106 out of 198 providers (54 percent response rate).
	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Respondents saw and average of 86 patients per 2 week period. Providers encountered 64 patients with missed results during the two week period leading up to the study and 52 patients with treatment delays. The most common missed results included imaging studies (29 percent), clinical laboratory (22 percent), anatomic pathology (9 percent), and other (40 percent). The most common diagnostic delays were cancer (34 percent), endocrine problems (26 percent), cardiac problems (16 percent), and others (24 percent). Missed results leading to clinically important treatment delays are an important and likely under-appreciated source of diagnostic error.
	Study type: D

Bajramovic J, Emmerton L, Tett SE. Perceptions around concordancefocus groups and semi- structured interviews conducted with consumers, pharmacists and general practitioners. Health Expectations. 2004;7(3):221-34. ¹⁵¹ .	Research purpose: To explore, in the Australian context, beliefs and expectations of general practitioners (GPs), consumers and pharmacists in relation to concordance to allow further exploration of the implementation of principles of concordance in Australia. Method: Focus groups Sample size: Focus groups were held with seven consumers and nine pharmacists and, in-depth, semi-structured interviews were held with 10 GPs between February and May 2003, in Brisbane (Australia). Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Consumers expressed the need for more input from health professionals - being given more information on their treatments and conditions, more time spent in discussion, and establishing a system where harmonious relationships between health professionals could take place, which would result in a more consumer-friendly health care system. The main issues voiced by the pharmacists were about the idea of organizing the health care system in a way that would accommodate more quality information sharing between all partners. GPs' issues included better and unlimited information for increased verbal contact with other health care professionals. Suggestions were made about ways to achieve concordance by improved information- sharing and shared decision-making. Study type: Q
Derkx H, Rethans JJ, Maiburg B, Winkens R, Knottnerus A. New methodology for using incognito standardised patients for telephone consultation in primary care. Med Educ. 2009 Jan;43(1):82-8. ¹⁸¹	Research purpose: This study aimed to assess the feasibility and validity of using telephone incognito standardised patients (TISPs), the accuracy of their role-play and the rate of detection. Further objectives included exploring the experiences of TISPs and the difficulties encountered in self-recording calls. Method: TISPs were trained in role-play by presenting their problem to a general practitioner and a nurse. They were also trained in self-recording calls. Calls were made to out-of-hours centres (OOHCs) from home. Of the four or five calls made per evening, one call was assessed for accuracy of role play. Retrospectively, the OOHCs were asked whether they had detected any calls made by a TISP. The TISPs filled in a questionnaire concerning their training, the self-recording technique and their personal experiences. Sample size: Twelve TISPs were trained, calls were made to 17 different out-of-hours centres (OOHCs). Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: The TISPs made 375 calls over 84 evenings. The accuracy of role-play was close to 100%. A TISP was called back the same evening for additional information in 11 cases. Self-recording caused extra tension for some TISPs. All fictitious calls remained undetected. Conclusions Using the method described, TISPs can be valuable both for training and assessment of performance in telephone consultation carried out by doctors, trainees and other personnel involved in medical services.
Perry W, Crean RD. A retrospective review of the neuropsychological test performance of physicians referred for medical infractions Archives of Clinical Neuropsychology. 2005;20(2):161-70. ⁵³	Research purpose: To examine neuropsychological testing results from physicians referred for assessment by the California Medical Board (CMB) for various infractions. Method: The neuropsychological test performance of the physicians was compared to normative reference samples. Sample size: 148 physicians Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Overall, the physicians performed in the average range on most measures; however, they demonstrated relative deficits on tests of sequential processing, attention, logical analysis, eye-hand coordination, verbal and non-verbal learning. These findings

	reveal that this cohort of physicians is performing lower than expected on tests of intellectual and neuropsychological functioning. Applying a neuropsychological framework to the assessment of physicians may uncover potential cognitive factors that contribute to medical practice errors. Study type: R
Varonen H, Kortteisto T, Kaila M. What may help of hinder the implementation of comuterized decision support systems (CDSSs): a focus group study with physicians. Family Practice. 2008;25:162-7. ¹⁵³	Research purpose: To identify potential barriers and facilitators to implementing computerized decision support systems (CDSSs) in health care as perceived by clinicians. Method: A qualitative focus group study with primary and secondary health care settings in six areas of Finland. The main outcome measures physicians' expectations, preconceived barriers and facilitators were explicitly identified by the participants during the interviews. Sample size: A total of 39 interviewed physicians, of whom 22 practised in primary care and 17 in secondary care. Risk adjustment/ confounders controlled for: Confidence interval: Findings: Identified barriers were: earlier experience of dysfunctional computer systems in health care, potential harm to doctor-patient relationship, obscured responsibilities, threats to clinician's autonomy and potential extra workload due to excessive reminders. Identified facilitators were self-control of frequency and contents of CDSS and noticeable help of CDSS in clinical practice. It was easy for the physicians to think of applications and clinical topics for CDSS that could help them to avoid mistakes and improve work processes. Physicians had relatively positive attitudes towards the idea of CDSS. They expected flexibility, individuality and reliability of the CDSS. The rather high level of computerized practices and wide use of electronic guidelines probably have paved the way for the CDSS in Finland.
Reiner BI, Siegel EL. Pay for performance (P4P) in medical imaging: The time has (finally) come. Journal of Digital Imaging. 2004;19(4):289-94. ¹⁵⁴	Research purpose: Argues for Pay for Performance (P4P) in Medical Imaging Method: Expert opinion Sample size: N/A Risk adjustment/ confounders controlled for: N/A Confidence interval: N/A Findings: Existing P4P programs have the potential to selectively reward "high performance" baseline physician groups (who merely maintain the status quo in order to receive bonus payments), with little overall gain in quality. P4P programs offer the potential benefit of "refocusing" the collective medical community's efforts on quality, with the long-term result being a higher standard of patient care. Although additional longitudinal research is required to validate these preliminary observations, the potentially derived benefit is substantial. The time is right for radiology activists and professional societies to heed the call and take a proactive role in leading the medical imaging community into a new era of quality-oriented, performance-based reimbursement. Study type: OP / EC

Sarkar U, Handley MA, Gupta R, Tang A, Murphy E, Seligman HK, et al. Use of an interactive, telephone-based self- management support program to identify adverse events among ambulatory diabetes patients. J Gen Intern Med. 2007 Apr;23(4):459-	Research purpose: The implementation of an automated telephone self-management support program for diabetes patients was used as an opportunity to monitor patient safety. Method: Identified were adverse and potential adverse events among a diverse group of diabetes patients who participated in an automated telephone health-IT self-management program via weekly interactions augmented by targeted nurse follow-up. adverse event (AE) was defined as an injury that results from either medical management or patient self-management, and a potential adverse event (PotAE) as an unsafe state likely to lead to an event if it persists without intervention. Differences between incident, or new, and prevalent, or ongoing, events were noted. A medical record review and present summary results for event characteristics including detection trigger, preventability, potential for amelioration, and private avareneess was conducted.
	Sample size: 111 nations
65. ¹⁵⁵	Risk adjustment/ confounders controlled for:
	Confidence interval
	Findings: Among the 111 patients, 111 AEs and 153 PotAEs were identifies. Eleven percent of completed calls detected an event. Events were most frequently detected through health IT-facilitated triggers (158, 59%), followed by nurse elicitation (80, 30%), and patient callback requests (28, 11%). More prevalent (68%) events were detencetd than incident (32%) events. The majority of events (93%) were categorized as preventable or ameliorable. Primary care providers were aware of only 13% of incident and 60% of prevalent events. Surveillance via a telephone-based, health IT-facilitated self-management support program can detect AEs and PotAEs. Events detected were frequently unknown to primary providers, and the majority were preventable or ameliorable, suggesting that this between-visit surveillance, with appropriate system-level intervention, can improve patient safety for chronic disease patients.
	Study type: Q
Davis R, Jacklin R, Sevdalis N, Vincent C. Patient involvement in patient safety: what factors influence patient participation and engagement? Health	Research purpose: To delineate factors that could affect the participation of the patient in quality and safety issues in their health care.
	Method: Literature review of patient involvement in health care, drawing from direct evidence (specifically from the safety context) and indirect evidence (extrapolated from treatment decision-making research and the wider patient involvement in health care literature); synthesis and conceptual framework developed, illustrating the known and putative factors that could affect the participation of the patient in safety issues in their health care.
2007:10:259-67. ¹⁵⁶	Sample size: N/A
2001,10.237-07.	Risk adjustment/ confounders controlled for: N/A
	Confidence interval: N/A
	Findings: Five categories of factors emerged that could affect patient involvement in safety: patient-related (e.g. patients_ demographic characteristics), illness-related (e.g. illness severity), healthcare professional-related (e.g. health care professionals_ knowledge and beliefs), health care setting-related (e.g. primary or secondary care), and task-related (e.g. whether the required patient safety behaviour challenges clinicians' clinical abilities).
	Study type: R

Little P, Dorward M, Warner G, Moore M, Stephens K, Senior J, et al. Randomised controlled trial of effect of leaflets to empower patients in consultations in primary care. BMJ: British Medical Journal. 2004;328:441-4.111	 Research purpose: To assess the impact of leaflets encouraging patients to raise concerns and to discuss symptoms or other health related issues in the consultation. Method: Randomised controlled trial. Setting Five general practices in three settings in the United Kingdom. Sample size: 636 consecutive patients, aged 16-80 years, randomised to receive a general leaflet, a depression leaflet, both, or neither. Risk adjustment/ confounders controlled for: Yes Confidence interval: Yes Findings: The general leaflet increased patient satisfaction and was more effective with shorter consultations (leaflet 0.64, 95% confidence interval 0.19 to 1.08; time 0.31, 0.0 to 0.06; interaction between both – 0.045, – 0.08 to –0.009), with similar results for subscales related to the different aspects of communication. Thus for a 10 minute consultation by 14%. The leaflet overall caused a small non-significant increase in consultation time (0.36 minutes, – 0.54 to 1.26). Although there was no change in prescribing or referral, a general leaflet increased the numbers of investigations (odds ratio 1.43, 1.00 to 2.05), which persisted when controlling for the major potential confounders of perceived medical need and patient preference (1.87, 1.10 to 3.19). Most of excess investigations were not thought strongly needed by the doctor or the patient. The depression leaflet had no significant effect on any outcome.
Weingart SN, Gandhi TJ, Seger AC, Seger DL, Borus J, Burdick E, et al. Patient- reported medication symptoms in primary care. Archives of Internal Medicine. 2005;165:234-40. ²⁰⁷	Research purpose: To investigate the prevalence and character of medication-related symptoms in primary care and their relationship to adverse drug events (ADEs) or about factors that affect patient-physician communication regarding medication symptoms. Method: Interviews were conducted with patients 2 weeks and 3 months after the index visit, reviewed patients' medical records, and surveyed physicians whose patients identified medication-related symptoms. Physician reviewers determined whether medication symptoms constituted true ADEs. Multivariable regression was used to examine factors associated with patients' decision to discuss symptoms with a physician and with physicians' decision to alter therapy. Sample size: 661 patients who received prescriptions from physicians at 4 adult primary care practices. Risk adjustment/ confounders controlled for: Confidence interval: p<.001, 95% CI Findings: A total of 179 patients identified 286 medication-related symptoms but discussed only 196 (69%) with their physicians. Physicians changed therapy in response to 76% of reported symptoms. Patients' failure to discuss 90 medication symptoms resulted in 19 (21%) ameliorable and 2 (2%) preventable ADEs. In multivariable analyses, patients who took more medications (odds ratio [OR] = 1.06; 95% confidence interval [CI] = 1.04-1.08; P<.001) and had multiple medication allergies (OR = 1.07; 95% CI = 1.30-1.11; P = .001) were more likely to discuss symptoms. Male physicians (OR = 1.20, 95% CI = 1.09-1.26; P = .002) and physicians at 2 practices were more likely to change therapy in QR = 1.24; 95% CI = 1.17-1.28; P<.001; and OR = 1.17; 95% CI = 1.08-1.24; P = .002). Primary care physicians may be able to reduce the duration and/or the severity of many ADEs by eliciting and addressing patients' medication symptoms. Male physicians (OR = 1.24; P = .002).

The Joanna Briggs Institute Royal Adelaide Hospital North Terrace, Adelaide South Australia 5000 telephone: +61 8 8303 4880 facsimile: +61 8 8303 4881 email: jbi@adelaide.edu.au



The Joanna Briggs Institute

www.joannabriggs.edu.au