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Evidence Check

# Patient safety in primary healthcare

An **Evidence Check** rapid review brokered by the Sax Institute for the Australian Commission on Safety and Quality in Health Care.
August 2015.

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**This report was prepared by:**
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# Patient safety in primary healthcare: a review of the literature

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# 1 Executive summary

The purpose of this document is to provide an overview of the scientific peer-reviewed and grey literature on the subject of patient safety in primary healthcare. The period of review spanned seven years, from January 2009 to May 2015. This follows a similar literature review previously commissioned on this topic by the Australian Commission on Safety and Quality in Healthcare (ACSQHC) which covered the period 1999 to 2009.

### Review questions

Two major questions were posed to be addressed by this review, being:

**Question 1: What is the evidence on the risks associated with patient safety in primary healthcare?**

**Question 2: What interventions have been shown to be effective in minimising risks to patient safety in primary healthcare?**

### Report structure

The report provides a detailed explanation of the search strategy that was used to conduct a systematic review of the peer-reviewed scientific literature to address these questions, and the strategy used to examine the grey literature (Section 3 and Section 4). The systematic review strategy is in keeping with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Section 5), which outlines an evidence-based set of items for transparent reporting in systematic reviews. The methods for assessing the quality and levels of evidence of the literature are also described (Section 6).

The results presented discuss the study designs and research methods used in the primary healthcare patient safety literature (Section 7), followed by a synthesis of the major findings from all of the literature combined. The major findings have been presented in three key areas: (i) a critical appraisal of the different methods used to determine risks to patient safety in primary healthcare, (ii) the nature of those risks (Section 8), and (iii) the interventions that have been proposed or found to reduce the risks (Section 9).

The appendices contain the full set of extracted data summaries from all of the included articles in the systematic review and the grey literature review for each question, along with their key findings, quality score and NHMRC level of evidence. The majority of papers from the systematic review addressed Question 1 (the risks associated with safety in primary healthcare), and these have been arranged in the appendices based on their different primary healthcare settings.

Also as the appendices are the tools used by the research team to conduct this review, showing the data extraction template and the quality scoring templates, a number of key primary healthcare patient safety tools that were described in the literature, and a full list of references for all of the articles used to synthesise the review. This contains the papers that were included in the systematic review of the published and grey

literature from 2009, as well as additional key papers that provide background information on the subjects discussed.

## Key findings of this review

### 1. Study designs and research methods used in primary healthcare safety literature

1.1 Studies included in the literature that addressed questions on the evidence of risk associated with patient safety in primary healthcare used designs that were descriptive where the aim was to describe risks, and analytic when the aim was to determine factors associated with risks.

1.2 Studies included in the literature that evaluated the effect of interventions to minimise risks to patient safety required experimental designs. These included randomised control trials and quasi-experimental study designs.

1.3 Studies that addressed questions on the evidence of risk associated with patient safety in primary healthcare used a range of qualitative methods (for example focus groups and semi-structured interviews) and cross-sectional methods (used in descriptive and analytic studies, and include questionnaires, collections from incident reporting systems, clinical record reviews, and reviews of malpractice databases).

### 2. Risks associated with patient safety in primary healthcare: definitions, strengths and weaknesses of methods, healthcare settings

2.1 The WHO International Classification for Patient Safety (ICPS) presents a comprehensive list of preferred terms and their definitions, a description for the level of harm associated with patient safety incidents, and a framework for classification systems that is applicable to primary healthcare.

2.2 A strong patient safety culture is a recognised pre-determinant of safer clinical practice. A number of tools to assess and educate clinicians about Patient Safety Culture were described in the literature. Examples include SCOPE-PC, The Safety Attitudes Questionnaire – Ambulatory Version (SAQ-AV), and the Frankfurt Patient Safety Climate Questionnaire for General Practices (FRaSiK).

2.3 The recent general practice patient safety literature has moved its focus regarding incident reporting systems. Researchers looked for ways to enhance incident reporting rather than describe the nature of patient safety incidents reported in these systems.

2.4 The development and validation of 'Trigger Tools' to detect patient safety incidents and harm in clinical record reviews was a common theme of a number of recent studies.

2.5 A range of research methods is the optimal way of investigating patient safety incidents in primary healthcare. Incident reporting and learning systems deliver rich detail and context about patient safety incidents and offer clinicians an opportunity to develop practice improvements; clinical record review has been suggested by researchers to be more suitable to determine prevalence and harm; and malpractice database reviews provide greater detail on incidents with serious clinical outcomes.

## 3. Factors associated with increased and decreased patient safety risks in primary healthcare

3.1 There were a range of factors reported to be associated with the risk of patient safety incidents occurring. Increased risk of patient harm was associated with patient factors including older age, more comorbidities, and more frequent emergency department visits based on large cross-sectional samples of patients from a UK general practice research database.

3.2 Reduced risk of patient harm was associated with being registered at a practice for a longer period based on large cross-sectional samples of patients from a UK general practice research database.

3.3 Reduced risk of having experienced an adverse event was associated with having longer clinical consultations, based on the results of a large cross-sectional patient survey.

3.4 Larger practice sizes of primary healthcare practices may be associated with a stronger patient safety culture based on practice assessments and physician questionnaires.

3.5 Accreditation of primary healthcare practices may be associated with a stronger patient safety culture based on surveys of accreditation providers.

3.6 Research in the recent literature describing patient safety incident characteristics has been conducted in a range of primary healthcare settings including midwifery, home care, dentistry, chiropractic and occupational therapy.

3.7 Most of the research evidence that has been published in the primary healthcare patient safety literature continues to be conducted in the general practice setting.

3.8 Diagnostic errors were commonly associated with the potential for moderate to severe harm outcomes in primary healthcare settings.

3.9 There is insufficient evidence to estimate the frequency of harm, adverse events and diagnostic error in the primary healthcare setting.

## 4. Evidence on interventions shown to be effective in minimising risks to patient safety in primary healthcare

4.1 There were 11 studies in the included peer-reviewed scientific literature that evaluated an intervention.

4.2 An intervention was tested that altered the reporting and analysis of incidents from a centralised to a localised system. A local incident reporting procedure increased the willingness to report into an incident reporting system and facilitated faster implementation of improvements.

4.3 Interventions that improve patient safety culture (the use of questionnaires and educational sessions for clinicians on patient safety issues such as the Frankfurt Patient Safety Matrix) were found to increase engagement with incident reporting systems, and enhance the quality of incident reports.

4.4 There is weak evidence that patient safety curricula and examinations for primary care clinicians in training enhance systems thinking and patient safety culture.

4.5 There is a paucity of evidence available to evaluate potential harm caused by computerised clinical decision support systems in the patient safety literature.

4.6 Primary care clinicians believe that electronic health records with clinical decision support capabilities improve the overall quality of care, reduce medication errors and improve follow-up of test results.

4.7 An automated text message appointment reminder was found to be an effective low cost intervention to increase post emergency department follow-up with primary healthcare and specialty clinicians in the community.

## 5. Tools and resources available to clinicians to assist them in minimising risks to patient safety in primary healthcare

5.1 'Never event' lists (that detail a range of patient safety incidents or situations that should never occur) have been developed by researchers in the UK and these may be useful in primary healthcare settings to help prevent serious patient safety incidents.

5.2 A primary healthcare collaboratives manual was developed in Australia and made freely available in 2014. This resource contains a comprehensive set of tools that may be applied to primary healthcare settings with the aim of minimising patient safety risk and enhancing patient safety culture in practices and was the most readily applicable to the Australian primary healthcare setting.

5.3 Toolkits of patient safety resources for primary care clinicians have been produced in recent years by a number of professional organisations and government agencies.

5.4 The NHS National Reporting and Learning System (NRLS) remains the only national incident reporting and analysis system found in the English language that is readily available for primary healthcare clinicians to use.

## A note on the relationship of these findings to the National Safety and Quality Health Service Standards (NSQHS)

The Australian Commission on Safety and Quality in Healthcare (ACSQHC) published the National Safety and Quality Health Service Standards (NSQHS), a set of ten national guidelines that aim to protect the public from harm and improve the quality of health service provision, in September 2012.

The first two standards: 1) Governance for Safety and Quality in Health Service Organisations, and 2) Partnering with Consumers, are overarching. The vast majority of the literature on patient safety in primary healthcare deals with aspects of the first standard. This standard addresses incident and complaints management, whereby patient safety incidents are recognised, reported and analysed, and this information is used to improve safety systems. In addition, the subject of governance and quality improvement systems, also key to this first standard, is an underlying driver for many of the studies that are conducted in patient safety in primary healthcare.

To a lesser extent, some of the other NSQHS are also specifically addressed by the body of literature that was examined, most notably in standards: 2) Partnering with Consumers, 4) Medication Safety, 5) Patient Identification and Procedure Matching, 6) Clinical Handover, and 10) Preventing Falls and Harms from Falls.

The literature that was specific to residential aged care facilities and specific to medication safety was not within the scope of this review, which is likely to have had an impact on the quality and volume of evidence that was found to be associated with a number of the standards, in particular 4) Medication Safety and 10) Preventing Falls and Harms from Falls. Additional work is therefore likely to be required to more clearly align a framework for patient safety improvement in Australian primary healthcare with the NSQHS.

## Conclusions

Patient safety research in primary healthcare is an area that has undergone considerable growth since the early 2000s, particularly during the time period that was examined in this review – approximately the past seven years of peer-reviewed scientific and grey literature.

The review provides an update on the evidence associated with risks to patient safety in primary healthcare, and the evaluation of interventions designed to reduce that risk. It also presents findings about the quality of studies, their design and research methods, and presents a range of tools and resources that can be used by primary care clinicians to enhance their patient safety culture and deliver safer care in their clinical practices.

The limitations of this work are related to the broad nature of the research questions. Primary healthcare risk (and the range of interventions that may be in use in its wide range of settings) covers a large range of issues and topics. Much research in primary healthcare patient safety is exploratory in nature, and interventions that improve safety are in developmental stages. Frequently they have not undergone evaluation using experimental study designs that offer a high level of evidence. In addition, areas such as medication safety systems and settings such as residential aged care facilities were not within the scope of this review, and so more investigation of these subjects may reveal further relevant evidence.

In order to develop a deeper understanding of patient safety incidents in primary healthcare, using a mixture of methods including incident reporting and learning systems, clinical record review and malpractice database reviews offers the best overall picture. There was relatively little evidence in the literature from non-general practice primary healthcare settings – most research is currently being conducted in general practice, and even here there remains much more work to be done in order to evaluate specific interventions that may reduce risks to patient safety.

There are a growing number of tools and toolkits (in particular designed for the general practice setting) that have become available from researchers, healthcare professional bodies and government agencies with a focus on patient safety. Their more rigorous evaluation is a key area where further research is required. However, their development in primary healthcare offers some evidence that patient safety culture is shifting in this setting, and their use offers hope that primary healthcare can be delivered more safely to patients in the future.

# 2 Introduction: a literature review on patient safety in primary healthcare

The investigation of risks to patient safety in healthcare is an area of research that is relatively recent, particularly in the primary healthcare setting. Awareness of the subject began a little over 25 years ago with landmark hospital based studies,[1] and gained much publicity as a result of the Institute of Medicine's report 'To Err is Human – Building a Safer Health System'.[2] This suggested that the vast majority of healthcare errors are the result of systems problems, not poor performance by clinicians. This finding was subsequently supported by research in the primary healthcare setting.[3-7] In 2004, WHO launched its World Alliance for Patient Safety and one of its major contributions to patient safety research was the International Classification for Patient Safety (ICPS), with its recommended definitions and conceptual framework published in 2009.[8] The focus on making care safer in the primary healthcare setting became a WHO priority in 2012, with the formation of its Safer Primary Care Expert Working Group.[9]

Primary healthcare patient safety research over the past seven years (the period of this review) has shown a growth in both the volume of publications in the scientific peer-reviewed literature, and in the development of resources and tools that are freely available from healthcare organisations and researchers for clinicians to assist them in delivering safer healthcare.

The aim of this review was to investigate the evidence published since 2009 that enhances our understanding of the risks to patient safety in primary healthcare, and which evaluates the effectiveness of interventions designed to minimise that risk. The time period leads on from a previous review that was published by the Australian Commission on Safety and Quality in Healthcare (ACSQHC) that had similar research questions.[10]

The review questions required the development of a search strategy that would be broad enough to capture a wide range of primary healthcare settings, and a range of terms that would encompass the concepts of risk to patient safety. A systematic review of the peer-reviewed scientific literature and a search of the grey literature was undertaken. Their results provided a large set of publications that were analysed, quality assessed and critically appraised.

Presented in the report is an executive summary that groups all of the key findings. A discussion of the search strategy and results of the searches is found in Section 3, Section 4, and Section 5. The quality appraisal methods and results are presented in Section 6 and a discussion of study designs and research methods used in the primary healthcare patient safety literature in Section 7. These are followed by the results sections that synthesise the major findings from the combined literature. The evidence that addresses the questions of risks associated with primary healthcare is presented in Section 8. Interventions that have been proposed or found to reduce those risks are discussed in Section 9.

The appendices include the full set of extracted data summaries from all of the included articles in the systematic review and the grey literature review for each question. The majority of these related to Question 1 (the risks associated with safety in primary healthcare), and these have been grouped according to their different primary healthcare settings. There is also a collection of tools that were used by the research team to conduct this review, including the data extraction template and the quality scoring templates. Finally, a number of key resources are presented as appendices that relate to the discussion within the results sections.

# 3 Summary of search strategy results

## 3.1 Questions relating to patient safety in primary healthcare that are addressed in this report

### Question 1: What is the evidence on the risks associated with patient safety in primary healthcare?

### Question 2: What interventions have been shown to be effective in minimising risks to patient safety in primary healthcare?

The questions that were posed for this review had a common theme – the risks associated with patient safety in primary healthcare. It was decided that the basis of the search strategy used would be fundamentally the same for both questions, as those papers which addressed Question 2 would be a subset of the group of papers found by a broader search strategy that addressed Question 1.

It was also felt that attempting to design a search strategy that narrowed the findings for Question 2 (that is, a strategy that started with the first broad set of criteria, and then additionally predefined the types of interventions that exist to be effective in minimising risks to safety in primary healthcare) would potentially limit the review findings. This is because it could miss novel interventions and tools that may have been described in the recent literature.

Therefore, during process of the full-text review data extraction to answer Question 1 those papers that specifically addressed Question 2 were also identified and underwent data extraction.

## 3.2 Search strategy for the systematic review of the literature

### 3.2.1 Terms and exclusions used in the search strategy

A search strategy was developed for the systematic review of the published literature based on the following terms (please note that the details of the search fields described here are specific to the Medline search strategy using OvidSP, and when applied to other databases these were appropriately adapted):

**Safety**

The term 'safety' was felt to be fundamental to the question, thus, the search strategy firstly examined 'safety' as a keyword within the search fields of abstract (ab), Subject heading word (hw), keyword heading word (kf) and title (ti).

**Risk**

The next set of terms related to a form of risk in the sense of a threat to patient safety. The terms included 'incident', 'error', 'harm', 'adverse event', 'hazard', and 'iatrogen*' and were searched as keywords within the search fields abstract (ab), Subject heading word (hw), keyword heading word (kf) and title (ti). The term 'risk' was not included due to the large number of irrelevant abstracts that this inclusion returned dealing with risk ratio or other concepts of risk (meaning chance of rather than threat to safety).

Each term in the group of risk synonyms was also searched based on relevant medical subject headings (MeSH), however explosion of MeSH terms was not undertaken unless the subheadings were appropriate to the research question. For example, the MeSH terms of Medication Errors, Diagnostic Errors and Medical Errors were all included as relevant to the keyword 'error'. These searches were all then combined using the Boolean operator 'OR'.

**Patients**
The terms 'patient', 'client', and 'consumer' were searched as keywords within the search fields of abstract (ab), Subject heading word (hw), keyword heading word (kf) and title (ti). The MeSH terms of Patients and Aged were also searched. These searches were then combined using the Boolean operator 'OR'.

**Primary healthcare**
The terms relating to primary healthcare were searched (as per the list of 'setting' terms below) using their MeSH terms. 'Primary care' was searched as both a MeSH term and as a keyword within the search fields abstract (ab), Subject heading word (hw), keyword heading word (kf) and title (ti). These searches were then combined using the Boolean operator 'OR'.

The searches resulting from the above groups (safety, risk, patients, and primary healthcare) were then combined using the Boolean operator 'AND'.

**Exclusions**
The search was narrowed by using the Boolean operator 'NOT' to exclude the terms 'hospital', 'intensive care units', and 'tertiary care', and by limiting the combined search results to the date range January 2009 to May 2015, and to articles available in the English language.

### 3.2.2 Detailed description of search terms

**Safety (as a key concept):**
Safety

**Risk terms:**
Incident; error; harm; adverse event; hazard; iatrogenic

**Patient terms:**
Patient; client; consumer; resident – resulted in Aged as MeSH term (and not searched as keyword as used for physician)

**Setting terms:**
General practice; family practice; primary care (MeSH and keyword); pharmacy; dentistry; nursing; midwifery; optometry; podiatry; speech therapy; physiotherapy; occupational therapy; chiropractor; home care; psychology; telehealth – resulted in telemedicine as MeSH term; community nursing – included in nursing MeSH term

**Exclusion terms:**
Hospital; intensive care units; tertiary care

**Search limits:**
2009–2015; English

### 3.3 Search stratefy for the grey literature

We searched the following grey literature databases and specific websites. These were of organisations with a known interest in primary healthcare patient safety, and those of professional colleges for primary healthcare clinicians:

1. WHO Patient Safety
2. The Health Foundation
3. The King's Fund
4. Institute for Healthcare Improvement
5. Agency for Healthcare Research and Quality
6. NHS England & Wales
7. NHS Scotland
8. Scottish Patient Safety Programme
9. Canadian Patient Safety Institute
10. Care Quality Commission
11. The Joint Commission
12. Health Quality and Safety Commission New Zealand
13. Royal Australian College of General Practitioners
14. Australian College of Rural and Remote Medicine
15. Royal College of General Practitioners
16. Greater Manchester Primary Care Patient Safety Translational Research Centre
17. National Institute for Health and Care Excellence
18. Royal New Zealand College of General Practitioners
19. The Commonwealth Fund.

In addition, we also searched the following databases of grey literature:

1. The National Library of Australia, see trove.nla.gov.au
2. System for Information on Grey Literature (2009 to current), see www.opengrey.eu
3. The Networked Digital Library of Theses and Dissertations, see www.ndltd.org
4. ProQuest Dissertations and Theses Database, see www.proquest.com/products-services/pqdt.html (or through University library)
5. The New York Academy of Medicine Grey Literature Report in Public Health database, see www.greylit.org.

Our search strategy for the grey literature mirrored the systematic review search of the peer-reviewed literature databases. Since the search options differ from that for published literature, a simplified search strategy using the keywords 'patient safety' and 'primary healthcare' was used. English language literature published after 1 January 2009 was reviewed, and reports, tools and interventions from settings as per those used for the systematic review were included.

# 4 Results of the systematic review of the literature

The results of the number of articles found from the included databases of peer-reviewed literature are described below:

**Medline** via OvidSP (n = 436) using the strategy described above.

**EBM Reviews** via OvidSP (Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment) (n = 58) using the strategy described above.

**Embase** (n = 306) using the keywords that were searched in the Medline search strategy within the search fields abstract and title (ab, ti), and the MeSH headings used in the Medline search strategy mapped to appropriate Embase Emtree terms.

**Cinahl** (n = 337) using the keywords that were searched in the Medline search strategy within the search field abstract and title (ab, ti), and the MeSH headings used in the Medline search strategy mapped to appropriate Cinahl headings.

After combining these results, the search of the peer-reviewed literature databases for the systematic review produced 758 papers (after duplicates were removed).

Initial reviews of the literature revealed a large body of work that was very specific to medication safety only. The purpose of this report was to look at patient safety measures in primary healthcare more generally rather than specific medication safety strategies or specific interventions, and therefore articles that addressed medication safety only were excluded for the purposes of this report.

## 4.1 Exclusion criteria used in the systematic review of the literature

An initial review of the 758 titles and abstracts that were found in the systematic review was conducted, with titles excluded using the following exclusion criteria:

1. Not the theme of patient safety in primary healthcare (n = 55)
2. Not in the primary healthcare setting (n = 91)
3. Relating to safety reviews of a specific treatment (n = 124)
4. Relating to safety reviews of a specific medication (n = 47)
5. Relating to the subject of medication safety only (n = 214)
6. Editorial, commentary or opinion pieces (n = 44).

This resulted in 183 articles which underwent full text review by two researchers (MM, LP). Exclusion criteria used for the full text review were the following:

1. Not the theme of patient safety in primary healthcare (n = 3)
2. Not in the primary healthcare setting (n = 10)
3. Relating to safety reviews of a specific treatment (n = 3)
4. Relating to safety reviews of a specific medication (n = 1)
5. Relating to the subject of medication safety only (n = 1)
6. Editorial, commentary or opinion pieces (n = 32)
7. Publications of study protocols or methods with no relevant findings (n = 5)
8. Conference abstracts (n = 12)
9. No data presented – single case studies and non-systematic reviews (n = 9)
10. Duplicate found in full-text (n = 2)
11. Reprint of pre 2009 article (n = 1)
12. Non-English full-text (n = 1).

Our inclusion and exclusion criteria for the grey literature were the same as those for the peer-reviewed literature in the systematic review. Included were studies and reports that addressed the nature of the risks to patient safety in primary healthcare settings (Question 1), and that addressed tools and interventions designed to reduce risks to patient safety in primary healthcare (Question 2). Excluded, were items that: were specific to medication safety only; described safety aspects of specific medications and treatments; or were set in ICU and hospitals, emergency departments, birthing suites and nursing homes. Single case studies and expert opinion pieces were also excluded.

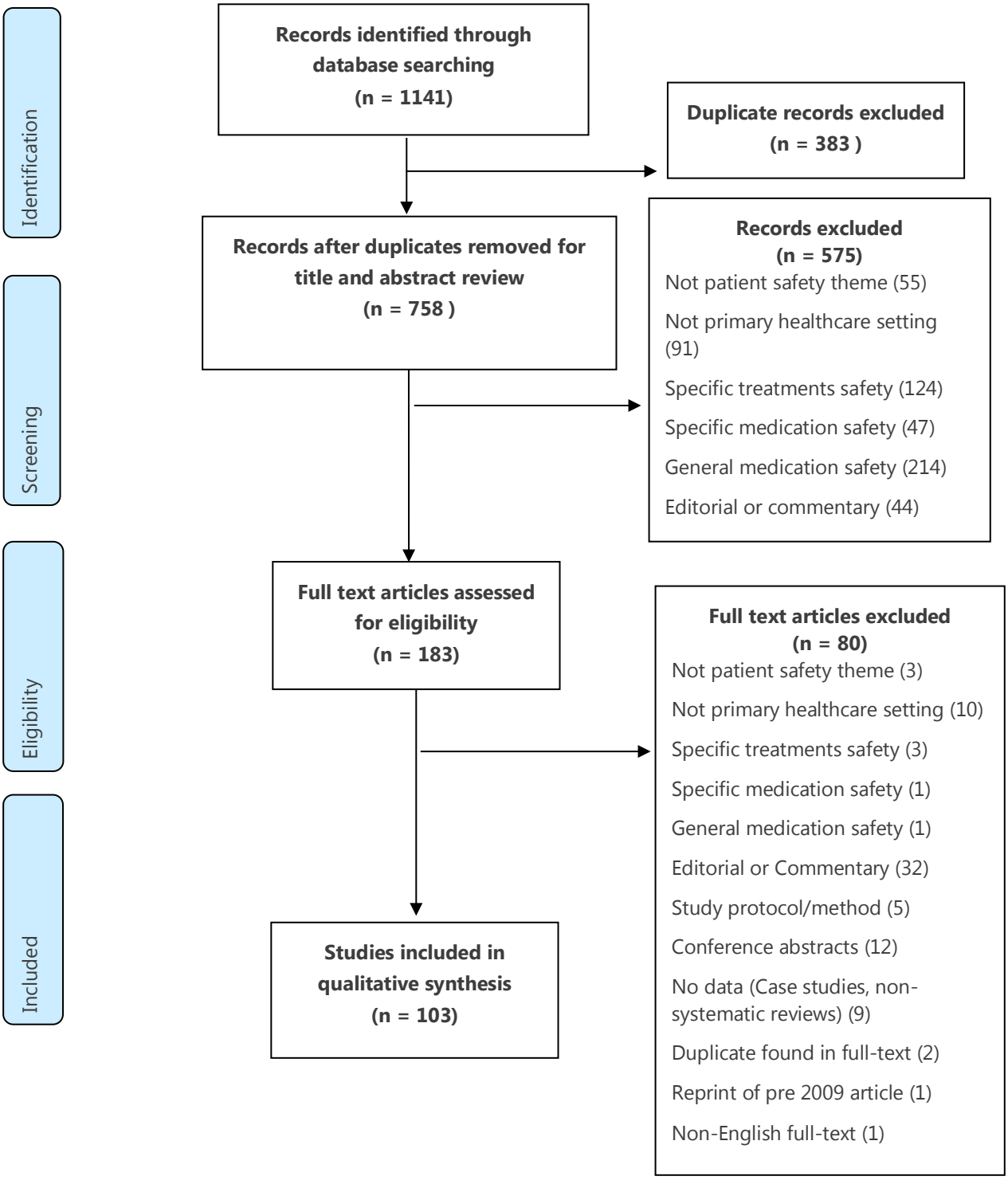
### 4.2 Data extraction methods and results

The remaining 103 articles underwent data extraction (conducted by two researchers MM, LP), quality scoring and assessment for the NHMRC level of evidence. In addition the articles were assessed for their relevance to the ACQSHC national standards.

Section 5 shows the PRISMA flow diagram[11] which details the results of the systematic review process. The data extraction and quality scoring tools used to assess the literature found by the systematic review are presented in Appendix 5 and Appendix 6. The quality scoring tool for the systematic literature reviews is included as Appendix 7. A further discussion of the quality scoring method and findings is presented in Section 6.

The results of the extracted data from the peer-reviewed literature for Questions 1 and 2 is presented according to primary healthcare setting and intervention type in Appendix 1 and Appendix 2. The results of the grey literature findings for Questions 1 and 2 is presented in Appendix 3 and Appendix 4. The synthesis and further interpretation of this extracted data is the subject of the results sections of this report, commencing in Section 6.

# 5 Prisma flow diagram: patient safety in primary healthcare



# 6 Assessing the quality of the included literature

## 6.1 Quality scoring methods

### 6.1.1 Quality assessment process

Each publication included in the systematic review of the literature was assessed for scientific quality using a quality scoring tool. A primary reviewer assessed study quality using the appropriate tool outlined below. Where there was uncertainty regarding quality assessment of a study it was assessed by a second reviewer and then discussed until consensus was reached.

### 6.1.2 Quality assessment tools

A different instrument was used depending on the type of study. These are described below.

#### 6.1.2.1 Quantitative studies

Quality of quantitative studies was assessed using the Effective Public Health Practice Project (EPHPP) tool. The EPHPP tool is recommended by the Cochrane Collaboration as the preferred quality assessment tool for assessing public health studies[12] and is a generic tool designed to evaluate quality across a range of quantitative study designs. This tool was selected for the current review given the validity of the tools across a breadth of study designs.[13] According to the EPHPP guidelines,[14] quality is assessed across six components: selection bias; design; confounders; blinding; data collection methods; and withdrawals and dropouts.[15] Studies are assessed as strong, moderate or weak in each domain using predefined criteria. A final quality assessment is assigned based on the overall component ratings. Studies are considered strong if they have no weak ratings in any of the six domains, moderate if they have one weak rating in any domain, and weak if they have two or more weak ratings across the six domains.

#### 6.1.2.2 Delphi and other consensus methods

Since the aim of Delphi and other consensus methods is to achieve consensus between groups of experts, the quality components used in the EPHPP tool focus on generalisability of results and are not relevant for use in these studies despite them being considered a quantitative research method. No quality assessment tools specifically for studies using Delphi or other consensus methods were found and thus study quality was not assessed for studies using these methods.

#### 6.1.2.3 Systematic reviews

The AMSTAR quality assessment tool has been developed and validated for assessing the methodological quality of systematic reviews.[16-18] The tool consists of 11 items. Each quality item is scored as yes, no, can't answer, or not applicable. A final score out of 11 is calculated by scoring each yes as a 1 and all other answers as a 0. The higher the final score, the higher the methodological quality of the review.

#### 6.1.2.4 Qualitative studies and other non-assessed study types

Since there is no validated tool for assessing the quality of qualitative studies, mixed methods studies and non-systematic reviews, no quality assessment of these study types was conducted.

## 6.2 Quality scoring results

The results of the quality assessment process largely reflected the nature of the included studies – a large number used cross-sectional methodologies. The overall results of the quality scoring is described below. The Appendix 1 and Appendix 2 tables with the full data extraction from included studies indicates the quality score for each study that was assessed.

### 6.2.1 Study quality findings

Study quality was assessed for all studies with quantitative study designs and systematic reviews. Overall there were 103 included studies, and the proportion of studies by design type is shown below in Figure 1. In total, study quality was assessed for 71% of the 103 studies included in the review. Of these, 69 were quantitative study designs and assessed using the EEPHPP tool, and five were systematic reviews assessed using the AMSTAR tool (Appendix 7).

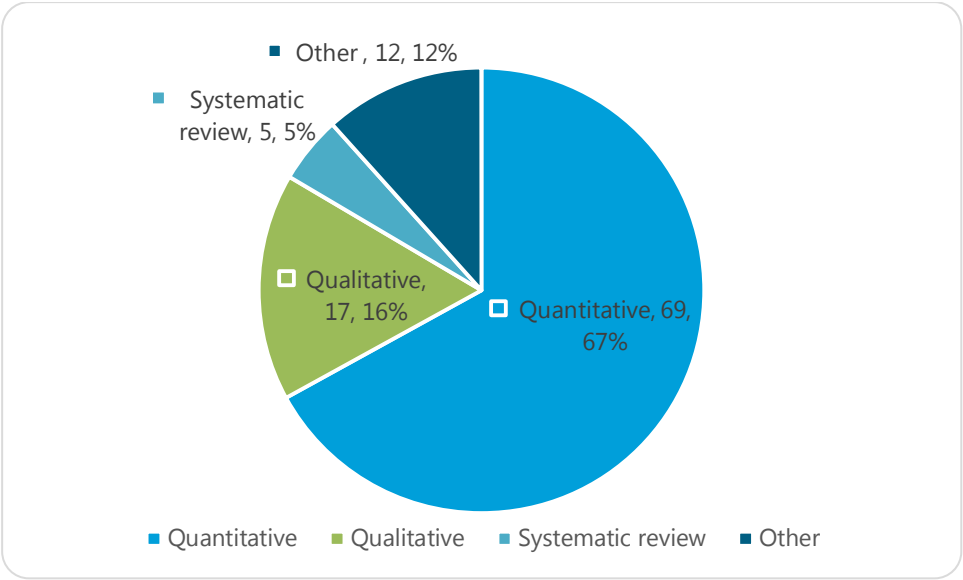



Figure 1: Percentage of studies included in the review by study design type

For the 29 studies where the quality was not assessed, 17 were qualitative designs, four were narrative or other non-systematic reviews, and four were mixed method designs. In addition, study quality was not assessed for two pharmaco-economic modelling studies and for one study using a Monte Carlo Simulation methodology.

#### 6.2.1.1 Quantitative studies

The quality rating for the majority of quantitative studies included in the review was weak (Figure 2). This reflects the large number of studies using cross-sectional methodologies. Three studies received a strong rating. All three studies rated as strong were randomised clinical trials. However none were double-blinded. One randomised controlled trial approached this – Hoffman et al. conducted a

randomised controlled trial using rater blinding to measure outcomes, though the subjects were aware of their exposure group.[19]

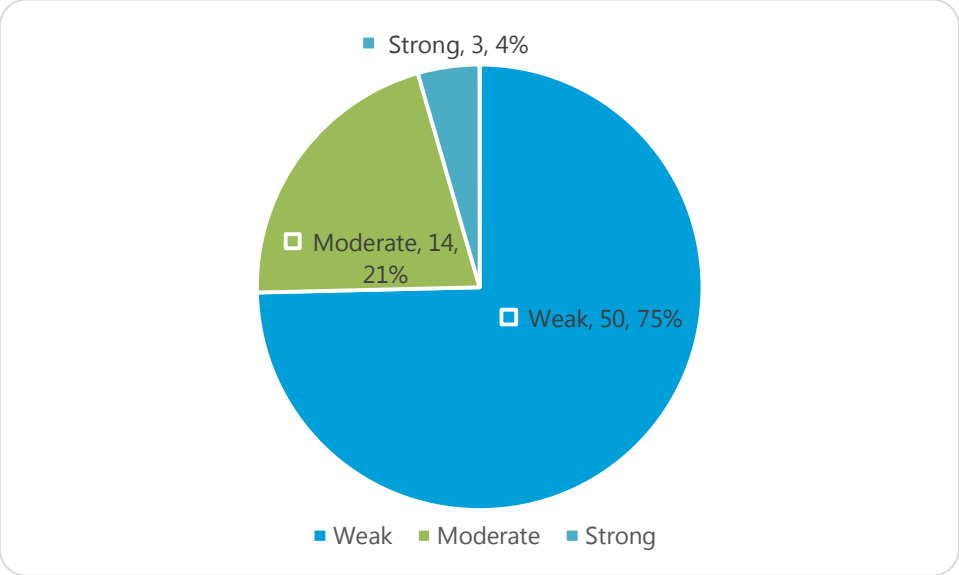



Figure 2: Methodological quality for quantitative studies

#### 6.2.1.2 Systematic reviews

The AMSTAR quality rating for the five systematic reviews ranged from 3/11 to 7/11 (mean rating 5/11, standard deviation 1.58). No studies reported registering a study protocol prospectively, no studies provided lists of included and excluded studies, and none reported conflict of interest statements for both the systematic review authors and the included study authors as per the AMSTAR tool.

# 7 Study designs and research methods used in primary healthcare safety

This section describes the range of methods being used in the current literature identified in the review. An overview of the different study designs found as well as a more detailed discussion of the common designs used in the literature is included. The aim of this section is to describe the various designs to show how patient safety research is being conducted in the current literature to address different types of questions. The results of the various studies (or what was actually found) are discussed in subsequent sections.

## 7.1 Overview of study designs found in the primary healthcare patient safety literature

In order to determine the study design type, we looked at three main issues, adapted from the schema and design questions used by the Oxford University Centre for Evidence Based Medicine (Figure 3).[20]

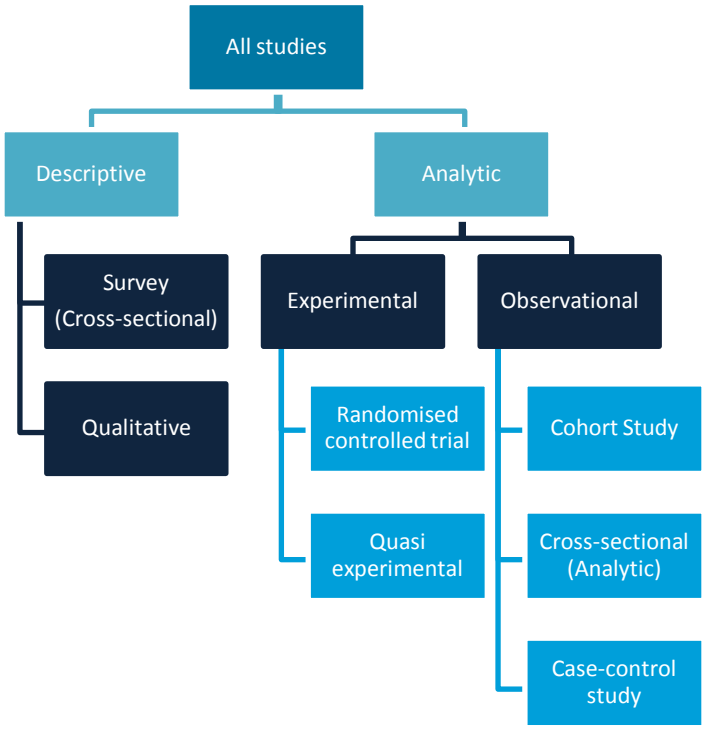



**Figure 3: Study design classification. Adapted from Oxford University Centre for Evidence Based Medicine**

### Question 1: What was the aim of the study?

If the aim of the research was to simply describe a population (P) or outcome (O), then it was a descriptive study. These were often surveys or qualitative studies, for example using focus groups or semi-structured interviews. A study that describes the nature of errors found using an incident reporting system is an example of a descriptive cross-sectional survey – it is collecting information about patient safety risks using a survey tool.

If the aim was to quantify the relationship between factors (population, intervention, comparison or control, and outcome (PICO) questions), then it was an analytic study. For example, studies that measured practice or clinician characteristics and then determined their association with patient safety culture, or studies that looked for a change in the number of incidents reported after an educational intervention was introduced, would be forms of analytic studies.

> **Key finding 1.1**: Studies included in the literature that addressed questions on the evidence of risk associated with patient safety in primary healthcare (Question 1) used designs that were **descriptive** where the aim was to describe risks, and **analytic** when the aim was to determine factors associated with risks.

### Question 2: Was the intervention or exposure allocated?

Allocation to intervention or control groups is a characteristic of experimental research. If the allocation was random then the design is considered a randomised controlled clinical trial. If allocation to intervention or control group was done in a non-random manner then the design is considered to be quasi-experimental. Pre-post studies are an example of a quasi-experimental study design.

Very few patient safety studies in the literature used a randomised controlled trial design. Examples of a randomised controlled trial in the literature were Arora et al., who examined the effect of a text reminder for primary care follow-up visits post ED attendances,[21] and Verbakel et al., who looked at the effects of patient safety culture questionnaires and educational interventions on incident reporting rates.

If exposure to the intervention was not randomly allocated then the design is considered quasi-experimental. Quasi-experimental studies include a wide range of non-randomised intervention testing designs.[22] Much of the patient safety research included in the review used quasi-experimental designs.

> **Key finding 1.2**: Studies included in the literature that evaluated the effect of interventions to minimise risks to patient safety required **experimental designs**. These included **randomised control trials** and **quasi-experimental study designs**.

If the intervention or exposure was not allocated, then it is an observational analytic study, and the majority of studies found in the literature review that were analytic in nature fell into this group.

For the observational studies, further categorisation then depends upon the timing of the measurement of outcome. The third question to pose is therefore:

### Question 3: When were the outcomes determined?

If it was some time after the exposure or intervention, then this is a cohort study (prospective study). If it was at the same time as the exposure or intervention, this is a cross-sectional study or survey, and if it was before the exposure was determined, this was a case-control study (retrospective study based on recall of the exposure). Another study type in this group is a case series, which makes observations on a series of individuals, usually all receiving the same intervention, before and after an intervention but with no control group.

The literature included in our review that fell into the observational analytic category was largely cross-sectional analytic, and there was also one case-control study example.[23] An example of a cross-sectional analytic study was Elder et al., looking at the safe management of test results and the association with factors such as safety culture, teamwork and communication.[24] An example of an observational analytic study using a before and after design was by Marstellar et al., who measured the effect of a quality improvement intervention on a series of safety issues in small practices.[25]

## 7.2 Overview of commonly used research methods in the primary healthcare patient safety literature

### 7.2.1 Qualitative methods

Qualitative methods are often better at determining questions about 'why' something is so, rather than measuring effects or determining the features of a system. There were a number of studies that used either pure qualitative methods (such as focus groups or interviews with individual subjects using open ended questions, as used in semi-structured interviews) or mixed methods, which usually implies that a qualitative approach has been combined with an analytic method of some kind. Their results often provide a rich context for better understanding complex systems such as a primary healthcare clinical environment.

Examples of qualitative studies in the included literature can be found with Hernan et al., where patient and carer perspectives on safety in rural primary healthcare were explored,[26] and Elnour et al., who asked Australian General Practice Accreditation Limited (AGPAL) surveyors about their perceptions of the effect of accreditation on patient safety in Australian general practices.[27] Mixed methods were also useful in the development of tools such as patient safety culture surveys and checklists for patient safety, for example by Bowie et al. in their development of a general practice patient safety checklist,[28] and by de Wet et al. in their development of a never event checklist.[29] Elder et al. applied mixed methods to their analysis of test results management using cross-sectional surveys combined with qualitative interviews and observations.[24]

### 7.2.2 Cross-sectional surveys – questionnaires

Used in both descriptive and analytic studies, surveys were very commonly used in the included literature. There were numerous examples where a survey was used to describe risks to patient safety, and it was often used to measure patient safety culture and attitudes, or specific safety practices such as test result management.[30-45] Delphi surveys were also used; designed to capture the opinion of a group of experts usually in a series of rounds where consensus is built on a subject.[9,28,29,46,47] The use of a cross-sectional survey was also found in some studies measuring the effect of interventions. For example, in Verbakel et al's study looking at the effect of patient safety culture questionnaires on incident reporting and safety culture, a patient safety survey was actually used as the intervention and an outcome measurement tool: in one of the groups the exposure was to a patient safety culture survey; another group was exposed to a survey and an educational program; and a third had no intervention. Following this, patient safety culture was again

measured in all three groups using a further survey (so then becoming the outcome measurement tool used to compare the interventions).[48]

### 7.2.3 Prospective incident reporting systems

Prospective incident reporting was a method described in a number of studies in the included literature.[48-54] It is found in numerous study designs (the collection of information about a patient safety incident at one point in time is in itself a form of cross-sectional survey). It is a method often used in descriptive studies to provide rich evidence on the types of risks to patient safety encountered in primary healthcare. Many general practice studies in the pre 2009 literature used incident reporting systems to collect information about the characteristics of patient safety incidents, and in fact it was the most common method found in 45% of studies in a recent systematic review that examined methods for detecting patient safety incidents in primary healthcare.[55]

It may be however, that having somewhat saturated the subject of the nature of patient safety incidents found by incident reporting systems in general practice settings, there was less literature on this topic found in our search of post 2009 publications apart from a large Canadian study.[49] Incident reporting for this purpose was more often found in recent literature from other primary healthcare settings (such as dentistry, midwifery and home care), where understanding the nature of patient safety incidents is at an earlier stage of development.[52,53,56]

Where incident reporting as a method was still described in general practice literature, it was often in studies conducted in countries where primary healthcare incident reporting systems are now well established (such as Denmark and the Netherlands), and the act of simply reporting incidents was the outcome measure of interest (rather than the content of the reports) and used to compare different interventions being tested.[48,50]

### 7.2.4 Retrospective records review

Retrospective records review, of either patient clinical records, databases of malpractice or insurance claims, was quite a frequently used method of obtaining information about risks to patient safety in the current primary healthcare literature.[51,53,54,56-71]

This method was used in studies that aimed to describe the types of adverse events occurring in primary healthcare, and was suggested as being the most suitable method to detect diagnostic error[59] and to detect harm from patient safety incidents.[62]

The development of trigger tools to detect patient safety incidents was a major theme of discussion in the included literature that used retrospective record review methods. These tools were central to quality improvements in the use of the retrospective record review method in the recent primary healthcare patient safety literature. These are further discussed in Section 8.

### 7.2.5 Systematic and non-systematic reviews of the literature

There were a small number of systematic and narrative reviews of literature found in the search of peer-reviewed articles.[55,72-78] They covered a range of topics: some dealt with the general subject of patient safety in primary healthcare,[55,73,74] while others looked at specific topics within patient safety in primary healthcare. For example, Callen et al. examined test result follow-up,[76] Huibers et al. looked at telephone triage in out-

of-hours care,[77] and safety aspects of computerised decision support and patients' online access to their medical records were examined by Mold et al. and Souza et al.[72,78]

**Key finding 1.3**: Studies that addressed questions on the evidence of risk associated with patient safety in primary healthcare used a range of **qualitative methods** (for example focus groups and semi-structured interviews) and **cross-sectional methods** (used in descriptive and analytic studies, and include questionnaires, collections from incident reporting systems, clinical record reviews, and reviews of malpractice databases).

# 8 Evidence on the risks to patient safety in primary healthcare

This section examines the findings from the included literature that relates to the question "What is the evidence found on the risks associated with patient safety in primary healthcare?". The summaries of the included studies that addressed this question are presented in the tables of Appendices A1.1 to A1.8, arranged by primary healthcare setting, and a summary of the grey literature findings can be found in the table of Appendix A3.1.

The synthesis of findings in this section combines the results of the peer-reviewed and grey literature. It covers a wide range of topics because the range of included primary healthcare settings was very broad, as was the question of what actually constitutes evidence relating to risks. There are many subjects within the discussion of risks to patient safety in the primary healthcare literature, and these cover a number of characteristics such as type; frequency; costs; association with patient, practice and practitioner features (such as the patient safety culture of the environment); and association with harm. In addition, there are a number of tools and methods designed to measure patient safety risk in primary healthcare.

One of the most important developments in the recent literature on risks to patient safety in primary healthcare is greater uniformity in the use of language and definitions. This section therefore commences with a discussion of definitions. It then discusses the recent evidence relating to patient safety culture, a key determinant of the occurrence and awareness of risks to patient safety. Following this are the findings relating to the recent evidence on tools being used to detect and reduce patient safety incidents, followed by a discussion of recent evidence relating to the characteristics of patient safety incidents in primary healthcare. It is beyond the scope of this report to revisit the pre 2009 literature findings that relate to the nature of patient safety incidents in primary healthcare. However some key literature that was outside the scope of the search parameters or published prior to 2009 is mentioned where it may be relevant as a baseline for further discussion.

## 8.1 A note on definitions

Using a commonly accepted language and definitions for terms is vital in order to make meaningful comparisons between studies. One of the most significant advances on this front in the post 2009 patient safety literature is the Conceptual Framework for the International Classification for Patient Safety (ICPS), published by the World Health Organization World Alliance for Patient Safety and included in the grey literature findings.[8,79] This has clarified the definition of several terms including patient safety incident; harm; medical error; adverse event; and near miss. The conceptual framework and classification for patient safety is applicable across the full spectrum of health care, including primary healthcare.[80]

The ICPS framework does not provide a complete classification but provides researchers with a method of organising patient safety data and information so that it can be aggregated for analysis. It consists of ten high level concepts: incident type; patient outcomes; patient characteristics; incident characteristics; contributing factors/hazards; organisational outcomes; detection; mitigating factors; ameliorating actions; and actions taken to reduce risk. It also contains a comprehensive set of definitions of key concepts and preferred terms, which has helped to create greater uniformity in the research literature. In addition, the ICPS has produced definitions of harm – also an important resource for researchers to use in order to standardise research findings on this subject. The Definitions of Key Concepts are included in this report as Appendix 8 and the Definitions of Harm are included as Appendix 9.

**Key finding 2.1:** The **WHO International Classification for Patient Safety** presents a comprehensive list of preferred terms and their definitions, a description for the level of harm associated with patient safety incidents, and a framework for classification systems that is applicable to primary healthcare.

## 8.2 Patient safety culture in primary healthcare

A major focus in current primary healthcare research is the influence of patient safety culture on the provision of safe primary healthcare. A large number of studies were found in the included systematic literature review that related to this topic.[19,23,27-32,35,38-41,43-46,48,75,81-85] It is not a new concept, with the importance of a strong patient safety culture as a precondition for patient safety having been recognised in some of the foundation pieces in the patient safety literature.[2,86-89] Patient safety culture has its origins in organisational culture, and refers to the shared values, attitudes, norms, beliefs practices, policies and behaviours about safety issues in daily practice.[88]

Various tools that measure safety culture were found in the recent literature. An example is SCOPE, (its title is a Dutch acronym for 'systematic enquiry on patient safety'), a patient safety culture survey that has been adapted from general practice to other primary healthcare settings in the Netherlands. It is described by Zwart for use by general practitioners[90] and adapted to a range of other settings by Verbakel with the broader title of SCOPE-PC.[30] The strength of this survey is that it serves all primary healthcare professions with one generic questionnaire. SCOPE-PC consists of seven key areas: open communication and learning from error; handover and teamwork; adequate procedures and working conditions; patient safety management; support and fellowship; intention to report events; and organisational learning. It has a series of simple statements within each of these areas that the respondent can rate using a five point Likert scale ranging from 'strongly disagree' to 'strongly agree', or 'never' to 'always'.[30,31] The full questionnaire has been included in this report as Appendix 10.

Another example of a well-tested patient safety culture or 'climate' measurement tool from the recent literature is the Frankfurt Patient Safety Climate Questionnaire. Based on a self assessment of safety culture, the Frankfurt Patient Safety Matrix (FraTrix) aims to enable healthcare teams to improve safety culture in their organisations.[19] Hoffman et al. conducted a descriptive analysis of items and climate factors, as well as performing a regression analysis, to identify potential predictors of the safety climate in family practice. They surveyed doctors and healthcare assistants and found a number of factors that affected the safety climate results. Whether or not the entire team had taken part in the survey had a positive influence on most

factors. Doctors had more positive perceptions of four of seven factors addressed to both professions, and male participants and doctors showed the most willingness to admit they had made an error.[39]

The Safety Attitudes Questionnaire also featured in two studies as a tool to assess patient safety culture in primary healthcare.[38,43,44] Both studies used the Ambulatory Version of this questionnaire, and in the US, Holden et al. found that older primary healthcare clinicians scored more highly than those younger than 32.[38] Bondevik et al., also conducting the same questionnaire in Norway, concurred: older health professionals scored higher than younger, male GPs scored higher than female GPs, and health professionals in general practices scored higher than those in out-of-hours clinics on several patient safety factors.[43,44]

**Key finding 2.2:** A strong patient safety culture is a recognised pre-determinant of safer clinical practice. A number of **tools to assess and educate clinicians about Patient safety Culture** were described in the literature. Examples include SCOPE-PC, The Safety Attitudes Questionnaire - Ambulatory Version (SAQ-AV), and the Frankfurt Patient Safety Climate Questionnaire for General Practices (FRaSiK).

## 8.3 Critical appraisal of methods used to detect risks to patient safety

There are a range of methods commonly used by researchers to detect risks to patient safety. A discussion of these with respect to their general role in the study design is presented in Section 7. This section addresses the findings from current research about the benefits and limitations of their use to detect patient safety incidents and other risks to patient safety in primary healthcare.

### 8.3.1 Use and utility of Incident reporting systems

Incident reporting systems have been used since the mid 1990s in the detection of patient safety incidents in primary healthcare settings, with an Australian study in general practice by Bhasale et al. being one of the earliest known examples of their use.[3] In the pre 2009 primary healthcare patient safety literature a growing number of incident reporting systems around the world were described and informed the development of classifications of patient safety incidents in primary healthcare settings.[4-7,91-94] The literature included in this review found relatively few studies which reported descriptive results of patient safety incident characteristics from incident reporting systems, and these were mainly from non-general practice settings. These results are discussed in Section 8.4. Where incident reporting systems did feature in the recent literature, it was generally in the context of how they might be used more effectively rather than an analysis of the reports that were received by them, and this section discusses these findings further.

Some evidence was presented in the literature on requirements for developing incident reporting systems in addition to the conceptual framework for the International Classification of Patient Safety published by WHO (discussed in Section 8.1).[8] O'Beirne et al. conducted an extensive literature review to inform the establishment of a Canadian primary healthcare incident reporting system. They concluded that for a reporting and learning system to be successful there needs to be strong leadership, voluntary reporting, legal protection and feedback to reporters.[95] They reported further on the results of the Medical Safety in Community Practice safety learning system (MSCP). They found that reporting was higher when practices first joined, and then decreased. The top four types of incidents reported were documentation (41.4%), medication (29.7%), clinical administration (18.7%) and clinical process (17.5%). The overall frequency of reporting was quite low, with an average of 1.4 reports received from practices per month, supporting the

theory that voluntary reporting may not be the best method to identify the occurrence of patient safety incidents in the general practice setting.[49]

In countries where incident reporting systems are well established in primary healthcare, such as the Netherlands, researchers turned their attention from collecting incidents in order to describe the types of incidents occurring and reporting frequencies, to looking at factors which have an impact on the use and utility of the reporting systems. Zwart et al. found that most reported incidents in primary healthcare concern non-clinical incidents with no or limited impact on the patient. They found that primary care providers rarely reported serious clinical incidents and found little evidence that the clinicians actively engaged with recommendations following the investigation of serious incidents.[96] This finding is not necessarily generalisable to other countries however as it was a relatively small qualitative study. Other studies where incidents are examined within the same patient cohort have found that generally clinicians reported less serious incidents (in terms of patient harm) using incident reporting systems than were found using retrospective record review [53]. This is further discussed in Section 8.3.2 and Section 8.3.5.

In Denmark, where incident reporting in primary healthcare is also well established, Kousgaard explored the reasons for not reporting patient safety incidents in general practice using qualitative interviews with GPs. While most respondents were initially positive towards the idea of reporting and learning from patient safety incidents, they actually reported very few incidents. The major reasons for the low reporting rates were found to be a perceived lack of practical usefulness, issues of time and effort in a busy clinic with competing priorities, and considerations of appropriateness in relation to other professionals. The researchers suggested that future studies should investigate how various ways of organising incident reporting at the regional level influence local activities of reporting and learning in general practice. [97] This next step of evaluating the effect of changing the structure of the incident reporting and feedback system was undertaken in the Netherlands by Zwart et al., and their findings are discussed in Section 9.[50]

Incident reporting was explored in other settings outside of general practice; the included literature found studies in pathology laboratories, midwifery and dentistry.[52,53,98] In the Netherlands, an allied health study established an incident reporting system, however no reports were received and the incident analysis depended upon retrospective record review.[51] It was suggested that the risk of harm in the allied health practices was likely to have been very low. However, other associations with successful incident reporting such as a patient safety culture may have contributed. Further discussion of factors that may increase engagement with incident reporting systems are discussed in Section 9.

**Key finding 2.3:** The recent general practice patient safety literature has moved its focus regarding incident reporting systems. Researchers looked for **ways to enhance incident reporting** rather than describe the nature of patient safety incidents reported in these systems.

### 8.3.2 Clinical record review and the use of Trigger tools

Retrospective review of medical records offers a different perspective on the nature of risks to patient safety in primary healthcare in comparison to the information gathered through incident reporting systems. It has been suggested as the most effective method for estimating the prevalence of different error types in primary healthcare.[64]

There was a focus in the included literature on studies that developed or validated 'trigger tools' for use in retrospective record review to detect patient safety incidents in primary healthcare.[61,63,66,68] The trigger tool is a method that has been developed in recent years in the secondary healthcare setting, and has now been applied to primary healthcare in a number of studies.[61,99-101] It involves the focused review of a random sample of patient records using a series of triggers that alert reviewers to potential errors and previously undetected adverse events. Reviewing clinical records using trigger tools is the method that has been used by landmark secondary care studies to detect patient safety incidents, adverse events and harm, and has greatly shaped our understanding of patient safety in that setting. The Institute for Healthcare Improvement (IHI) has promoted trigger tool use in secondary care to detect adverse events for harm detection, and specific trigger tools are now in routine use in many hospitals. However, it must be recognised that the reliability of trigger tools depends on factors such as the quality of the records, the training of the reviewers, the volume of records that are examined, and patient factors such as their 'frailty'.[62]

Trigger tool development in primary healthcare was reported in Scotland in 2009 by de Wet et al. They suggested that although it seemed to be the most reliable method for harm detection, the feasibility of its routine application was open to question. Trigger tool development was informed by previous research and content validated by expert opinion. The tool was applied by trained reviewers who worked in pairs to conduct focused audits of 100 randomly selected electronic patient records. The researchers undertook a review of 500 records which revealed 2251 consultations and 730 triggers, and an adverse event was found in 47 records (9.4%).[61] Recent research from this same group has described their attempts to teach GP trainees a trigger review method to detect patient safety incidents, and it was found to be of value to the participants as a patient safety tool and of potential value in GP patient safety curriculum delivery.[66]

The use of trigger tools was also described by Singh et al. who applied the technique to a study investigating diagnostic errors in the USA,[68] and by Eggleton and Dovey, who applied the method to a large practice in New Zealand.[63] Both of these studies are described in Appendix 1.1, and a further discussion of diagnostic error and harm associated with primary healthcare patient safety incidents can be found in sections 8.5.1 and 8.5.2.

**Key finding 2.4:** The development and validation of **Trigger Tools** to detect patient safety incidents and harm in clinical record reviews was a common theme of a number of recent studies.

### 8.3.3 Malpractice claims and complaints database review

Retrospective review of malpractice claims and complaints databases was also reported in several studies in the recent literature.[57,58,102,103] There is evidence suggesting that there are serious patient safety incidents in primary healthcare not detected by methods such as incident reporting and large scale medical record review that can be detected through the interrogation of malpractice databases.[58]

Amalberti et al. used the method to develop a novel patient safety incident classification system, further discussed in Section 8.3.4.[57] Because all of the cases in such a collection are likely to have resulted in an unwanted outcome for a patient they are a rich source of information about patient safety incidents. Depending upon the particular legal system operating in the country where they exist however, they will vary in terms of the types of cases that they contain.

In the Netherlands Gaal et al. analysed disciplinary law verdicts concerning family physicians submitted to the Dutch disciplinary law system to identify domains of high risk of harm for patients in family practice. This system offers patients the opportunity to file complaints against physicians outside a legal malpractice system, without possibility of financial compensation in the case of verdicts in which the physician was found to be at fault. Their analysis looked at 250 random disciplinary law verdicts on Dutch family physicians submitted to disciplinary tribunals and published between 2008 and 2010. They focused on clinical domains represented in the verdicts with serious permanent damage or death. There were 74 complaints with a serious health outcome. Diagnostic error was the most frequent underlying cause in 44.6% of cases.[58]

Another study, by Schiff et al., using a malpractice claims database from Massachusetts over a five year period also found diagnostic error was a major contributor to claims; allegations were related to diagnosis in 397 (72.1%) of 551 primary healthcare cases.[102]

New Zealand provides an example of how primary healthcare organisational structure influences the nature of error and harm reported in the literature where, by comparison, diagnostic errors did not feature prominently. Legislative reforms in 2005 established a no-fault scheme, where an Accident Compensation Authority awards financial compensation to patients with successful claims, but no longer has a duty to report findings of medical error to the registration authorities. This encourages providers to supply information about injury and assist patients in lodging claims for compensation without fear of disciplinary reprisal, consistent with a no-blame culture of openness and learning. It resulted in a much larger number of claims being lodged and accepted, enlarging the treatment injury claims database.[103]

In a study by Wallis and Dovey, four years of malpractice claims in New Zealand were reviewed. This uncommon no-fault perspective may represent a mix of patient safety incidents that more closely reflects the real underlying frequencies compared with other systems that have the pressures of a tort system affecting the numbers of claims lodged and accepted. The researchers found that most claims were assessed as minor (83%), 12% major, 4% serious and 1% sentinel. Medication caused most injuries (38%) and most serious and sentinel injuries (60%). Dental treatment caused 16% of injuries; injections and vaccinations combined caused 10%; and venepuncture, cryotherapy and ear syringing combined caused 13.5% of injuries, mostly minor. Delay in diagnosis caused few injuries overall (2%), but a disproportionate number of serious and sentinel injuries (16%) and deaths (50%). Spinal/neck manipulation caused 2% of serious and sentinel injuries.[103]

### 8.3.4 Development of new patient safety incident classifications

The literature review found a small number of new concepts in classifying and defining incident type, including a new taxonomy based on time related problems, and a method for detecting ‘contextual’ errors, which have previously not featured in the primary healthcare literature.

Using a malpractice database, Amalberti et al. reviewed 1046 malpractice claims from a French liability insurer to determine whether a medical injury had occurred. When it had, they determined if it was due to one or more time related problems. The researchers suggested that the role of time management in safe and efficient medicine is important but poorly incorporated into the taxonomies of error in primary healthcare. They presented a framework integrating five time scales termed 'tempos' requiring parallel processing by GPs: the disease's tempo (unexpected rapid evolutions, slow reaction to treatment); the office's tempo (day-to-day agenda and interruptions); the patient's tempo (time to express symptoms, compliance, emotion); the system's tempo (time for appointments, exams, and feedback); and the time to

access knowledge. The authors proposed that "the art of medicine is to control all of these tempos in parallel and simultaneously". They found that access to timely disease management factors, and access of GPs to required knowledge in a timely way, were both major contributors to the cases that were found in the malpractice claims database.[57]

'Contextual error' was another concept that emerged in the recent primary healthcare literature. Weiner et al. described a contextual error as one that occurs when a physician overlooks elements of a patient's environment or behaviour that are essential to planning appropriate care. In contrast to biomedical errors, which are not patient specific, contextual errors represent a failure to individualise care. The researchers used a technique of sending unannounced standardised patients (USPs) into attending physicians in a range of US primary healthcare clinics who presented a variant of four different scenarios to the doctors. In all scenarios, patients presented both a contextual and a biomedical red flag. Primary outcomes were the proportion of visits in which physicians probed for contextual and biomedical factors in response to hints or red flags and the proportion of visits that resulted in error free treatment plans. It was found that physicians probed fewer contextual red flags (51%) than biomedical red flags (63%). They provided error free care in 73% of the uncomplicated encounters, 38% of the biomedically complicated encounters, 22% of the contextually complicated encounters, and 9% of the combined biomedically and contextually complicated encounters.[104]

A further study by the same team also proposed using the standardised patient method combined with a retrospective record review to determine the costs to the health system of diagnostic error. The researchers used the notes of the participant physicians in the earlier study to work out which errors could have been determined by medical record review alone rather than the use of the USPs. They determined that errors in care resulted in predicted costs of approximately $174,000 across 399 visits, of which only $8745 was discernible from a review of the medical records alone (without knowledge of the correct diagnoses). Important information about patient context was often entirely missing from medical records.[105]

### 8.3.5 Comparison of different methods to detect patient safety incidents

It is widely accepted that all methods for the measurement of risks to patient safety may involve potential bias.[64,106,107] The use of a mixture of methods simultaneously in a single system provides the broadest perspective for understanding the nature of risk and patient harm in primary healthcare. Retrospective studies of patient records likely offer the best means to assess patient safety incident prevalence, while incident reporting by clinicians may be more appropriate to obtain an in-depth understanding of incidents.[64] Malpractice database and patient complaint reviews focus on the most serious risks to patient safety in terms of potential harm, and there is evidence that this is the most appropriate method to look at patient safety incidents associated with the most serious health outcomes.[58] Gaal et al. noted in their root cause analysis of incidents found using retrospective record review that mostly human and organisational factors played a role in the occurrence of patient safety incidents in primary healthcare, and that in-depth interviews with clinicians would strengthen the ability to better understand the detected incidents.[64]

A study in Swedish public dentistry by Jonnson et al. provided a rare opportunity to directly compare the results of an incident reporting system, a retrospective record review and a malpractice claims database of the same cohort of patients in a single system. The study material consisted of all adverse events reported in 2010 and 2011. These included 273 events reported by dental personnel, 53 events reported by patients to the insurance company and 53 events reported by patients to the patient committee. In addition, the records describing the dental personnel's reports from 2011 were studied to investigate if the event had

been documented and the patient informed. In 29% of the reported events there was no documentation of the adverse event in the records. This study provides evidence that, in order to obtain a full picture of the range of patient safety incidents that are occurring in a system there is a benefit to using different detection methods, including prospective incident reporting (from clinicians and patients), clinical record review, and reviewing insurance claims and malpractice databases.[53]

Further evidence that different methods used simultaneously will produce a different set of results was shown by a study that used a precursor to the Threats to Australian Patient Safety (TAPS) taxonomy[93,94] to design their incident reporting tool, and also collected incidents from the same doctors using retrospective chart audit. It was an explorative study with around 8000 patients registered in the audited practices, and there was a five month reporting period. There was no overlap of the incidents detected by the two methods, and harm occurred in 50% of events detected. The researchers commented that both methods had weaknesses in terms of detecting incidents and harm: GPs were sometimes unaware of patient safety incidents and would therefore not report, and clinical records do not provide all relevant contextual information on an event.[54]

These findings are consistent with a 2008 study in a general practice setting where five methods of error detection were compared and there was no overlap found in results.[106] It is also consistent with larger scale studies that have been conducted in hospital settings. For example, a recent study in the Netherlands examined to what extent the hospital reporting systems covered the adverse events identified by patient record review. They linked four reporting systems to the database of reviewed records: 1) informal complaints by patients/relative, 2) formal complaints by patients/relatives, 3) medico-legal claims by patients/relatives, and 4) incident reports by healthcare professionals. 5375 patient records were examined, and 498 adverse events were identified. Only 18 of the 498 (3.6%) adverse events identified by record review were found in one or more of the four reporting systems. It was determined that the hospital incident reporting system could not be relied upon to detect the same adverse events that were identified by retrospective record review.[108]

**Key finding 2.5:** A **range of research methods is the optimal way of investigating patient safety incidents** in primary healthcare. **Incident reporting and learning systems** deliver rich detail and context about patient safety incidents and offer clinicians an opportunity to develop practice improvements, **clinical record review** has been suggested by researchers to be more suitable to determine prevalence and harm, and **malpractice database reviews** provide greater detail on incidents with serious clinical outcomes.

### 8.4 Factors associated with reduced risk of patient safety incidents

A number of factors were suggested in the reviewed literature to be associated with reduced patient safety incidents. This section discusses the results of studies with observational analytic designs that often used cross-sectional methods to examine various patient, clinician and practice characteristics and determine which features were associated with safer care. It does not discuss interventions or exposures that were tested for their effect on safety in primary healthcare – those studies are discussed in Section 9.

#### 8.4.1 Patient factors including age, co-morbidities and being known to a practice

In a study by Tsang et al., increased risk to patient safety was associated with being an older patient, having more visits to the practice, chronic diseases and emergency admissions, and reduced risk was associated with being registered for longer at a general practice. The study aimed to determine the incidence of recorded iatrogenic harm in general practice and to identify risk factors for these adverse events. The researchers took a cross-sectional sample of 74,763 patients at 457 English general practices between 1 January 1999 and 31 December 2008, obtained from the General Practice Research Database. The incidence was 6.0 adverse events per 1000 person-years (95% CI: 5.74–6.27), equivalent to eight adverse events per 10,000 consultations (n = 2,540,877). After adjustment, patients aged 65–84 years (risk ratio [RR] = 5.62; 95% CI: 4.58–6.91; P < 0.001), with the most consultations (RR = 2.14; 95% CI: 1.60–2.86; P < 0.001), five or more emergency admissions (RR = 2.08; 95% CI: 1.66–2.60; P < 0.001), or the most diseases according to expanded diagnosis clusters (RR = 8.46; 95% CI: 5.68–12.6; P < 0.001) were at greater risk of adverse events. Patients registered at their practice for the longest periods of time were less at risk of an adverse event.[70]

**Key finding 3.1:** There were a range of factors associated with the risk of patient safety incidents occurring. **Increased risk of patient harm** was associated with patient factors including **older age, more comorbidities, and more frequent emergency department visits ,** based on large cross-sectional samples of patients from a UK general practice research database**.**

**Key finding 3.2: Reduced risk** of patient harm was associated with **being registered at a practice for longer** based on large cross-sectional samples of patients from a UK general practice research database**.**

#### 8.4.2 Length of time spent in consultations

Evidence was presented in the peer-reviewed literature that spending more time in consultations was associated with lower rates of adverse events from reviews of malpractice records in the Tempos study by Amalberti et al., and from a large study of interviews with patients conducted by Mira et al. in Spain.[57,109] Mira interviewed 15,282 patients from 21 primary healthcare centres in Spain, and found that consultation time (OR = 0.5; 95% CI: 0.4–0.5), doctor rotation at the health centre (OR = 2.04; 95% CI: 1.85–2.25) and information on treatment precautions (OR = 0.47; 95% CI: 0.43–0.53) predicted a higher risk of adverse reactions to treatment. The researchers suggested that planning at health centres should involve the monitoring of mean consultation time and doctor rotation as indirect indicators of safety.[109]

**Key finding 3.3: Reduced risk** of having experienced an adverse event was associated with **having more time spent in clinical consultations**, based on the results of a large cross-sectional patient survey.

### 8.4.3 Size of primary healthcare practices

There was evidence in the peer-reviewed literature that larger primary healthcare practices may be safer. Gaal et al. conducted a study that that found this association, though no causal link was proven. The researchers undertook secondary analysis of data from 271 primary healthcare practices, collected in 10 European countries. The data was collected by a practice visitor and physician questionnaires. The researchers constructed 10 measures of patient safety covering 45 items as outcomes, and six measures of practice characteristics as possible predictors for patient safety. They found that eight of the 10 patient safety measures yielded higher scores in larger practices (practices with more than two GPs). Medication safety, practice building safety, and incident reporting items showed the strongest associations with practice size. Measures on hygiene, medical record keeping, quality improvement, professional competence and organised patient feedback items had higher scores in larger practices.[84]

**Key finding 3.4: Larger practice sizes** of primary healthcare practices may be associated with a stronger patient safety culture based on practice assessments and physician questionnaires.

### 8.4.4 Accreditation of primary healthcare practices

Accreditation of general practices and other primary healthcare clinical settings is an activity that is undertaken in many countries with the intention of improving patient safety, and although there is evidence in acute settings that it has this effect,[110-112] there has been little work on this subject in primary healthcare. A recent Australian qualitative study interviewing general practice accreditors conducted by Elnour et al. provided some limited evidence that accreditation also has a positive effect on patient safety and quality in Australian general practices. The researchers conducted semi-structured telephone interviews with a purposive national sample of 10 Australian General Practice Accreditation Limited (AGPAL) surveyors during 2012. All participants agreed that accreditation had improved general practices' performance in quality and safety. Participants noted specific areas that need further attention, including sufficient evidence for clinical risk management, which half the participants estimated occurs in about 5%–10% of Australian general practices. Tangible evidence of patient safety activities included having a significant incidents register, providing documentation of near misses, slips, lapses or mistakes, and engaging in regular clinical meetings to discuss incidents and how to avoid them in the future. Participants agreed that the accreditation process could be improved through the inclusion of tighter clinical safety indicators and the requirement of verifiable evidence of a working clinical risk management system.[27]

**Key finding 3.5: Accreditation** of primary healthcare practices may be associated with a stronger patient safety culture based on surveys of accreditation providers.

## 8.5 Recent evidence on the type and characteristics of patient safety incidents

The literature on patient safety in primary healthcare from pre-2009 offers a large number of descriptive pieces about the nature of risks to patient safety, largely from incident reporting systems, and many of these also suggested classifications or taxonomies of error for general practice and primary healthcare. 'Incident type' is the preferred term in the International Classification for Patient Safety (shown in Appendix 8), meaning a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features. 'Incident characteristics' describe selected attributes of an incident, and would also

encompass features such as ameliorating actions, mitigating factors, harm level, and preventability. Developed from a large incident reporting study conducted in Australian general practice, the TAPS version of the International Taxonomy of Medical Error in primary healthcare was identified in a systematic review in 2014 as the most reproducible and internationally recognised codification to describe incident type in primary healthcare.[113 4,93,94,114]

Most of the accepted knowledge on the nature of patient safety incidents in primary healthcare is based on general practice research. The characteristics of patient safety incidents detected in non-general practice settings arose in the included literature in home care and community nursing,[56,60,85] midwifery,[52] occupational therapy,[115] and dentistry.[53,116] Their findings were descriptive and varied, and details of the results of these studies can be found in the Appendix 1 tables which are categorised by primary healthcare setting. It is beyond the scope of this report to describe findings on the type and characteristics of patient safety incidents in general practice that largely emerged in the literature prior to 2009. However where new evidence was found in our review of the recent primary healthcare literature that added to the previous knowledge base in general practice or other settings, these are addressed in this section of the report, which includes a discussion of characteristics of incidents diagnostic error, harm and adverse events.

**Key finding 3.6:** Research in the recent literature describing patient safety incident characteristics has been conducted in a range of primary healthcare settings including midwifery, home care, dentistry, chiropractic and occupational therapy.

**Key finding 3.7:** Most of the research evidence that has been published in the primary healthcare patient safety literature about patient safety risk continues to be conducted in the general practice setting.

### 8.5.1 Diagnostic error in primary healthcare

The accepted definition of an error is a failure to carry out a planned action as intended, or the application of an incorrect plan.[8] Diagnostic errors (missed, delayed or wrong diagnoses[68]) in primary healthcare are commonly associated with serious harm[58], but difficult to define and measure. The measurement of diagnostic errors depends mainly on detailed retrospective review of patients' medical records, [59] while the richest descriptions are likely to be found in malpractice databases.[58] They are generally an understudied aspect of ambulatory patient safety.[68,117] A recent literature review on tools for primary healthcare patient safety suggested diagnostic error as a priority for future primary healthcare safety research.[73]

Singh et al. reviewed the medical records of patients with diagnostic errors detected at two sites that were identified through electronic health record based triggers. Triggers were based on patterns of patients' unexpected return visits after an initial primary healthcare index visit. The study focused on 190 unique instances of diagnostic errors detected in primary healthcare visits over a 12-month period, and they collected data on presenting symptoms at the index visit, types of diagnoses missed, process breakdowns, potential contributory factors, and potential for harm from errors. In 190 cases, a total of 68 unique diagnoses were missed. Most missed diagnoses were common conditions in primary healthcare, with pneumonia (6.7%), decompensated congestive heart failure (5.7%), acute renal failure (5.3%), cancer (primary) (5.3%), and urinary tract infection or pyelonephritis (4.8%) being most common. Most errors were

associated with potential for moderate to severe harm and were related to process breakdowns in the patient-practitioner clinical encounter.[68]

The reported prevalence of diagnostic error widely varies in the literature, and this largely relates to the method by which it was measured, as previously discussed. Incident reporting systems usually find a lower prevalence than retrospective record reviews, and malpractice databases are skewed towards these error types as they are more frequently associated with harm and serious outcomes.[58,117-119] In the reviewed literature, Khoo et al. measured diagnostic error using retrospective chart review in a study of 1753 medical records in Malaysia, and found that diagnostic errors were present in 3.6% (95% CI: 2.2–5.0) of medical records.[65]

**Key finding 3.8: Diagnostic errors were commonly associated with the potential for moderate to severe harm** outcomes in primary healthcare settings.

### 8.5.2 Adverse events and the risk of harm in primary healthcare

An 'adverse event' is defined as an incident which resulted in harm to a patient, and the WHO classification and definitions for patient harm is shown in Appendix 9.[8] A large number of papers were found in the recent peer-reviewed literature that addressed the subject of adverse events in a range of primary healthcare settings in addition to general practice,[54,61,63,70,71] including community care,[56,60,120] dentistry, [53] chiropractic,[75] midwifery,[121] tele-health,[77] paediatric primary care physicians,[122] mixed primary healthcare settings,[72-74] and surveys of patients who reported on their adverse event experience.[37,109]

#### 8.5.2.1 Frequency of adverse events and harm

A variety of estimates were found in the literature relating to the frequency of adverse events or patient harm associated with patient safety incidents. Adverse events have been estimated to follow 19% of patient discharges, and further estimated by Yao et al. in the included literature was that that one third are preventable by improved handover (i.e. 6.3% of all discharges). Their intervention study is further discussed in Section 9.[123] Wetzels et al. conducted a small study that combined both event reporting and record review, and found that few incidents resulted in a serious harm, but most had the potential for harm.[54] De Wet et al. used trigger tools to detect patient harm, and found an adverse event was found in 47 records (9.4%), indicating that harm occurred at a rate of one event per 48 consultations. [61] Trigger tool studies in primary healthcare have estimated harm rates ranging from 10%–18% of patients, with estimates of 30%–42% of these preventable.[61,99-101]

O'Beirne et al. presented the results of a large Canadian incident reporting study based in general practice, and the vast majority of reported incidents were judged to have "virtually certain evidence of preventability" (93%). Harm was associated with 50% of incidents, though only 1% of the incidents had a severe impact.[49] In a Scottish study by McKay et al. using a voluntary educational model, GPs and doctors-in-training submitted Significant Event Analysis reports for feedback from trained peers. Approximately 25% of the reports described patient harm.[124]

A recent study published by de Wet et al. more closely investigated the application of clinical record review to quantifying harm. The researchers argued that measuring harm rates for specific patient populations and detecting significant changes in them over time are essential if patient safety in general practice is to be improved. They wanted to determine the quantum of records that would

need to be reviewed in order to accurately measure the harm rate, and then developed a formula to calculate the minimum values of clinical record review parameters required to achieve adequate precision and acceptable power when monitoring harm rates. They determined that approximately 2000 records (where baseline harm rates were assumed to be high), increasing to 20,000 records (where baseline harm rates were assumed lower), would need to be reviewed to ensure harm rate estimates with acceptable precision. [62]

**Key finding 3.9:** There is insufficient evidence to estimate the frequency of harm, adverse events and diagnostic error in the primary healthcare setting.

#### 8.5.2.2 Association of harm with incident types and health professionals

The reviewed literature also had some discussion about the association of harm with particular incident types. Diagnostic errors featured prominently, as discussed in Section 8.4.1. In a study by Gehring et al. where Swiss primary healthcare physicians and nurses were surveyed, a frequency-harm matrix was developed. It was suggested that triage by a nurse at initial contact, diagnostic errors, medication errors, failure to monitor patients after medical procedures, and test or intervention errors should be prioritised for action.[119]

In terms of patients' perceptions of who was to blame for an adverse event, the recent evidence suggests that doctors, specifically GPs, were the clear leader. In another large patient study that surveyed 19763 inhabitants of a municipality in northern Norway aged 30 years and older, it was found that around 10% of those surveyed had experienced adverse events. Of the respondents who had experienced adverse events personally, 62% placed the responsibility for the event on the general practitioner, 39% on the hospital doctor, and 19% on failing routines or cooperation. Only 7% of men and 14% of women who reported self-experienced events handed in a formal complaint. The public predominantly place the responsibility for medical adverse events on doctors, in particular GPs, and to a lesser degree on the system.[37]

# 9 Interventions and tools designed to reduce the risk to patient safety in primary healthcare

This section discusses the findings that address the question of "What interventions have been shown to be effective in minimising risks to patient safety in primary healthcare?".

It is important to note that to formally test an intervention requires a carefully considered study design where the effect of an exposure (the intervention) is able to be measured between two groups of subjects – exposed and not exposed. The ideal study design for proving that an exposure has had an effect is a double-blind randomised controlled trial, where the intervention is randomly assigned to two groups of subjects, and neither the subjects exposed to the intervention, nor the researchers measuring the outcome, is aware of which group of subjects was exposed. No studies with this design were described in the literature that was found in the search, although four studies approached this very closely using randomisation in a controlled trial.[19,21,48,125] One of these also used rater blinding to measure the outcome effect, however the subjects were aware of their exposure group therefore it wasn't a double-blinded design.[19] Double blinding is a very difficult design to apply to a primary healthcare patient safety intervention for reasons of expense and practicality. For example, clinicians who are undergoing a patient safety educational activity are usually aware that this is happening, and the researchers measuring the outcome effect are often also delivering the education. Non-blinded randomised controlled trials are still experimental in design, but have less strength of evidence due to the lack of blinding.

To address the question of interventions that have been shown to be effective in minimising risks to patient safety in primary healthcare, quasi-experimental designs and cross-sectional observational analytic studies were also often used. These studies delivered some evidence on the effect of safety interventions, although they provide weaker evidence about an association between an exposure and an outcome than true experimental studies – the level of evidence that they provide is considered to be of a lower strength.

Very few studies were identified in the peer-reviewed literature (11 in total) that provided evidence on a test of an intervention to reduce the risks to patient safety in primary healthcare, and none were found in the grey literature. The included studies are shown in the table of Appendix A2.1. They all aimed to test the effect of a patient safety intervention, and attempted to measure that effect by comparing an outcome measurement on the groups who were exposed or not exposed to that intervention. The outcome measurement tools vary (there were many different interpretations of how the risk could be measured), as do the intervention types. A discussion of their findings, grouped by intervention type, is presented in Section 9.1 of this section. Following this in Section 9.2 is a discussion of tools that have been designed with

the intention of reducing risks to patient safety in the peer-reviewed and grey literature, but are yet to be formally evaluated.

**Key finding 4.1:** There were 11 studies in the included peer-reviewed scientific literature that evaluated an intervention.

## 9.1 Interventions that reduce risks to patient safety in primary healthcare in the peer-reviewed literature

The eleven studies that were identified in the peer-reviewed literature that provided evidence on the effectiveness of interventions in primary healthcare to reduce risks to patient safety covered a range of intervention types and outcome measures. The use of practice based educational programs that increased knowledge and awareness of patient safety practices amongst primary healthcare clinicians featured prominently as interventions. Computerised clinical decision support software was also tested as an intervention, as were methods to improve clinical handover at transition of care points to and from primary healthcare settings. Incident reporting systems and scoring systems for the measurement of patient safety culture were commonly used outcome measurements as a proxy for safer practice in primary healthcare settings.

### 9.1.1 Interventions shown to increase incident reporting in primary healthcare

Incident reporting is a well established tool to collect information about patient safety incidents in hospital settings, however it is still relatively uncommon in primary healthcare. There are very few established large scale or national incident reporting systems that are used by primary healthcare clinicians; examples exist in the UK (the National Reporting and Learning System),[126] and in Denmark.[127] The presence of an incident reporting system in itself raises the awareness of patient safety issues amongst clinicians, and is therefore likely to affect patient safety behaviour. There has been previous discussion of these systems in this report in terms of their strengths and weaknesses. They are not useful for determining the prevalence of patient safety incidents, and less sensitive at detecting seriously harmful incidents. However, they provide very rich descriptions of patient safety risks and provide clinicians with an opportunity to feedback on threats to safety and potentially support health systems in delivering education and system improvements. The use of these systems in terms of a greater number of reports therefore doesn't indicate that the risk of patient safety incidents is higher, but more likely the opposite: more reports represent a raised patient safety awareness amongst clinicians using the system.

#### 9.1.1.1 Local versus central incident reporting and learning systems

The results of a quasi-experimental study by Zwart et al. suggested that local incident reporting procedures, involving the assessment of incidents and plans for system improvements by the local clinicians who make the reports, is a far more successful model to encourage incident reporting than a model where the analysis of incidents is centrally controlled. In 2005 a collaboration of nine separate out-of-hours services (OHS) in the central Netherlands initiated an incident reporting procedure in which every incident was evaluated by an advisory committee of the board of directors of the OHS collaboration. However, it was found that in the first two years of the system very few incidents were reported.

A local incident reporting procedure was instituted based on evidence that this might encourage more incident reporting and an earlier study by the researchers that had demonstrated its feasibility.[128] Three systems were then used for comparison. A local incident reporting procedure was implemented in OHS1, in which participants were encouraged to report all occurring incidents. A local committee with peers analysed the reported incidents fortnightly in order to initiate improvements if necessary. In OHS2 and OHS3 the existing centralised incident reporting procedure was continued, where incidents were reported to an advisory committee of the board of directors of the OHS collaboration and were assessed every two months. The main outcome measures were the number and nature of incidents reported. At baseline, participants each reported fewer than 10 incidents per year. In the follow-up period, the number of incidents reported in OHS1 increased 16-fold compared with the controls. The type of incidents reported did not alter. In the local incident reporting procedure, improvements were implemented in a shorter time frame, but reports in the centralised incident reporting procedure led to a more systematic addressing of general and recurring safety problems.

The research concluded that it is likely that a local incident reporting procedure increases the willingness to report and facilitates faster implementation of improvements. Locally initiated improvements also seemed to be more practical. However, the central procedure, by collating reports from many settings, seemed better at addressing generic and recurring safety issues. The study suggests that elements of both approaches should be combined to achieve optimal outcomes in an incident reporting and learning system.[50]

#### 9.1.1.2 Patient Safety Culture interventions increase engagement

Another recently published intervention study by Verbakel et al. that was in the included peer-reviewed literature also used numbers of incident reports as the outcome measure to assess the effect of two different patient safety culture interventions on patient safety culture.[48] A three-arm cluster randomised trial was conducted in a mixed method study examining the effect of: administering a patient safety culture questionnaire (intervention I), the questionnaire complemented with a practice-based workshop (intervention II) and no intervention (control) in 30 general practices in the Netherlands. The primary outcome was the number of reported incidents. This was measured with a questionnaire (SCOPE, see Section 8.2 which discusses this further) at baseline and a year after. The workshop was an adapted version of the Manchester Patient Safety Tool (MaPSaF),[129,130] which has also been adapted for use in other countries including Germany[40] and New Zealand.[131] There is further discussion of this tool as an educational intervention in Section 9.1.2. Mixed effects linear regression was used to analyse the culture questionnaires.

The number of reported incidents increased in both intervention groups, to 82 and 224 in intervention I and II respectively. Adjusted for baseline number of incidents, practice size and accreditation status, the study showed that practices that additionally participated in the workshop reported 42 times more incidents compared to the control group (95% confidence interval [CI]: 9.81–177.50). Practices that only completed the questionnaire reported five times more incidents (95% CI: 1.17–25.49). There were no statistically significant differences in staff perception of patient safety culture at follow-up between the three study groups.

**Key finding 4.2:** An intervention was tested that altered the reporting and analysis of incidents from a centralised to a localised system. **A local incident reporting procedure increases the willingness to report into an incident reporting system and facilitates faster implementation of improvements.**

This research supports the theory that educating staff and facilitating discussion about patient safety culture in their own practice leads to increased reporting of incidents, and the researchers suggest that policy makers should invest in a team based approach to patient safety education.[48] This finding is also supported by another included intervention study by Hoffman et al. which used a version of MaPSaF and noted that incident reporting (quantity and quality) improved in practices exposed to this intervention. [19] This is further discussed in Section 9.1.2.

### 9.1.2 Educational interventions that affect safety practices of primary healthcare clinicians

Education is perceived as the most important factor to improve patient safety in primary healthcare.[48,132] In addition to Verbakel et al. who used an educational intervention as part of their trial on incident reporting rates,[48] there were three further studies in the included literature that looked at the effect of educational interventions on patient safety culture or behaviours that were associated with safer primary healthcare practices.[19,23,25]

#### 9.1.2.1 The Frankfurt Patient Safety Matrix (FraTriix)

Another adaptation of the Manchester Patient Safety Framework (MaPSaF) was seen in a German study by Hoffman et al. that looked at the effect of this programme on a range of patient safety culture measures in general practices, including practice structure and processes (error management practices were the primary outcome measure), safety climate scores, and incident reporting rates and quality.[19] The MaPSaF was described in the literature in 2006. It uses an approach that combines group based self-assessment and interventions to improve organisational culture. It is built around a matrix of nine dimensions which can be assigned to five different levels of culture, and focuses mainly on the identification and assessment of patient safety incidents and on learning from them, along with other dimensions addressing patient safety aspects of the practice in areas such as teamwork and communication.[130,133]

Similar tools to MaPSaF had been previously evaluated and have shown promising results, but these studies had used pre-post test designs without randomly selected control groups, and the effects of MaPSaF itself had not been previously formally evaluated in a study with an experimental design.[19] The study by Hoffman et al. provided strong evidence based on its large scale and rigorous experimental design. It used an open randomised controlled parallel-group rater-blinded trial, which meant that the subjects were aware of their exposure status (they were undertaking patient safety culture team based educational activities), but the researchers who measured the outcomes were not aware of which group the subjects had been randomly assigned.[19]

The researchers translated, piloted and adapted the MaPSaF for the German setting, which they called the Frankfurt Patient Safety Matrix (FraTrix). They based their sample calculations on the size required to demonstrate an effect on their primary outcome measure of patient safety culture indicators (PSCI) that measured error management, as the management of patient safety incidents was felt to be a core aspect in patient safety and of FraTrix – three of the nine dimensions were based

on this. They recruited 65 practices of three of more GPs and randomly allocated them to control or intervention groups. The intervention group underwent three team sessions of between 60 and 90 minutes, led by a trained external facilitator, where they used the FraTrix and self-assessed their performance based on the nine dimensions. They then identified as a group the top three areas they wished to discuss and developed an action plan for improving patient safety practices at the end of each session. The outcome measurements were calculated at baseline and after 12 months, and were based upon patient safety culture indicators derived from the European Practice Assessment (EPA) Indicator system,[134] patient safety climate as assessed using the Frankfurt Patient Safety Climate Questionnaire for General Practices (FraSiK), which had also been previously developed and validated by the research team,[40] and patient safety incident reporting activity and quality – this was assessed using a method that was adapted from an instrument designed to assess significant event analysis in general practice.[135]

The results of this study suggested that FraTrix did not lead to measurable changes in error management (the primary outcome measurement) based upon structures, organisational processes and patient safety climate. The researchers felt that this could have been related to the time at which the outcomes were measured; further exposure may have yielded positive results, but more work was also required to develop appropriate and realistic outcome measures with sufficient sensitivity to study its potential effects. There was a very low drop out rate amongst participant practices, and FraTrix did positively affect the quality of incident reporting (a secondary outcome measure). At the end of the trial, more patient safety incidents had been reported at the intervention practices and were of a significantly better quality.[19]

**Key finding 4.3:** Interventions that **improve patient safety culture** (the use of questionnaires and educational sessions for clinicians on patient safety issues such as the Frankfurt Patient Safety Matrix) were found to **increase engagement with incident reporting systems**, and enhance the quality of incident reports.

#### 9.1.2.2 Brief educational Patient Safety updates for primary healthcare practices

In another educational intervention study by Marstellar et al., a pre-post study design was used to examine the effect of a quality improvement intervention provided by the Center for Practice Innovation (CPI) of the American College of Physicians (ACP) to 34 small internal medicine practices. The CPI intervention involved: two site visits; a practice assessment; self-selection of clinical, operational and financial focus areas for improvement; and ongoing 'directed guidance' of the practices in their efforts, including weekly 'practice tips' email alerts. The topics of these email alerts had quite a practical focus, providing brief educational messages on subjects such as: patient identification; vaccine information; sharps management; medication management issues such as storage and documentation; and practice tips on patient preventive care. Compliance with safety measures was reassessed in 30 practices after the intervention; a practice assessment form was completed by the CPI team, which included 21 safety measures. Many of the safety measures had high compliance rates at the first site visit. For other safety measures, fewer than half the practices followed the recommended procedures at the beginning of the study. The intervention was associated with statistically significant positive change for over 70% of the 21 safety issues. These positive effects were most profound in safety measures regarding how a practice managed sharps, hazardous materials, medications and vaccines.[25]

#### 9.1.2.3 Patient Safety curricula and examinations

Testing of a more formal educational intervention in junior doctors undertaking a family medicine residency programme in the USA was described by Singh et al., who compared the effect of a patient safety curriculum on the results of a specifically designed objective structured clinical examination (an OSCE) in three groups who had different exposures to the curriculum. The curriculum was developed by a multi-disciplinary group and initially delivered to 47 residents for two years. The OSCE was then designed and implemented, and the researchers compared the results of trainees who had been exposed to the curriculum to two other groups: an incoming group of 16 residents who were yet to undertake the safety curriculum educational module and a group of 10 residents at a neighbouring programme who had also not been exposed to the patient safety curriculum. The researchers also described the results of a pre-post study that was undertaken on third year (PGY3) residents that measured the effect of a 'systems approach' course that was also developed with the safety curriculum. They compared the results before and after exposure to this course using a written examination where the residents were required to undertake retrospective and prospective case analyses.

The OSCE used a standardised patient case, which showed that error detection and error disclosure skills were better among trained residents. The OSCE also used a chart-based case, where the trained residents showed better performance in identifying deficiencies in care and described more appropriate means of addressing them. The third year residents exposed to the systems approach course performed better at system analysis and identifying system based solutions after the course than before. The results of this study provided weak evidence on the positive effects of patient safety curricula on increased systems thinking and the culture of patient safety among residents, but more rigorous research and larger sample sizes are required to strengthen these findings.[23]

**Key finding 4.4:** There is weak evidence that patient safety curricula and examinations for primary care clinicians in training enhance systems thinking and patient safety culture.

### 9.1.3 Computerised clinical decision support systems effect on safety in primary healthcare

There were three studies in the included literature that discussed interventions to improve patient safety in primary healthcare using electronic health records with computerised clinical decision support systems (CCDSSs). These included a systematic review of randomised controlled trials that assessed these systems[72] and two intervention studies.[125,136] Of the latter, the study by Gurwitz et al. is discussed in Section 9.1.4, as its primary objective was to determine the effect of an electronic health record based intervention on improving patient safety around the transition of care between the hospital and primary healthcare settings.[125]

#### 9.1.3.1 Randomised Controlled Trials on the effect of Clinical Decision Support

A systematic review of the literature was published in 2011 by Souza et al., and updated a 2005 review by Garg et al[137] on the effects of CCDSSs on primary preventive care. The 2011 review examined the processes of care and patient outcomes that were based on the results of randomised controlled trials published up to January 2010. They added 17 more studies bringing the sample up to 41 studies in total. The researchers defined a positive effect (i.e. the CCDSS in the trial showed improvement) as having occurred if at least 50% of the relevant study outcomes were statistically significantly positive. The researchers commented that the quality of the studies had improved over

time, and their results suggested that cumulative and scientifically strong evidence supports the effectiveness of CCDSSs for the screening and management of dyslipidaemia in primary healthcare. There is mixed evidence for the effectiveness in screening for cancer and mental health conditions, multiple preventive care activities, vaccination, and other preventive care interventions. They found a paucity of evidence on CCDSS caused patient harm and cost-effectiveness in the reviewed randomised controlled trials.[72]

**Key finding 4.5:** There is a paucity of evidence available to evaluate potential harm caused by computerised clinical decision support systems in the patient safety literature.

#### 9.1.3.2 Effect of electronic health records on Patient Safety

A study conducted in the USA by El-Kareh et al. examined the changes in primary healthcare clinician attitudes towards a newly implemented electronic health record with clinical decision support features. The outcome measures specifically looked at aspects of quality of care, medication related errors, follow-up of test results and communication amongst clinicians.[136] The fully implemented system was virtually paperless, and supported electronic entry of clinical notes, diagnostic codes, procedure codes, and laboratory results, as well as computerised ordering of all medications, laboratory tests, procedures and referrals. The system also provided computerised clinical decision support such as electronic reminders for preventive care and chronic disease management.
The study design used a longitudinal survey to measure outcomes, and 86 primary healthcare clinicians participated. These clinicians were based in multidisciplinary care clinics where a new electronic health record was implemented in centres that were part of a large group called Atrius Health. The survey was based on an instrument that had been previously used by physicians to assess the impact of electronic health records on healthcare quality. It was conducted at months 1, 3, 6 and 12 with very high response rates for each of these points (92%, 95%, 90% and 82% respectively).

The results of this study found that the proportion of clinicians agreeing that the electronic health record improved the overall quality of care (63% to 86%; $P < 0.001$), reduced medication related errors (72% to 81%; $P = 0.03$), improved follow-up of test results (62% to 87%; $P < 0.001$), and improved communication among clinicians (72% to 93%; $P < 0.001$) increased from month 1 to month 12. It was also found that a decreasing proportion of clinicians agreed that the EHR reduced the quality of patient interactions (49% to 33%; $P = 0.001$), resulted in longer patient visits (68% to 51%; $P = 0.001$), and increased time spent on medical documentation (78% to 68%; $P = 0.006$) during the same time period. The significant improvements in perceptions related to test result follow-up were first detected at six months, while those related to overall quality, efficiency, and communication were first identified at 12 months. [136]

**Key finding 4.6:** Primary care clinicians believe that **electronic health records** with clinical decision support capabilities improve the overall **quality of care, reduce medication errors and improve follow up of test results**.

### 9.1.4 Interventions designed to improve patient safety during transitions in care

A number of intervention studies in the included literature examined the subject of threats to patient safety at transition of care points.[21,123,125,138] The complexities that occur at transitions of care are one of the major factors that contribute to them being associated with a higher risk of potential threats to patient safety. Such transitions include handovers amongst primary healthcare clinicians, or between primary healthcare and other settings in areas such as inpatient and emergency departments.

#### 9.1.4.1 Enhanced discharge planning and communication

Gurwitz et al. examined an electronic health record-based intervention that sent alerts to primary healthcare providers as older patients (>65 years) were discharged from hospital. [125] They had noted that in the USA, more than half of Medicare beneficiaries re-admitted to hospital within 30 days had had no outpatient contact with a physician. A randomised controlled trial was conducted in a large multispecialty group practice with 265 employees, 66 of whom were primary healthcare providers that care for older adults. The group practice cares for 24,000 senior plan members, and is associated with a primary hospital site that has some shared electronic health record capacity with the group practice. Older patients who were discharged from this hospital over a 12-month period were randomised to either the electronic health record based transitional care intervention or control group. The control group had discharge information communicated in the usual format, while the intervention group's primary healthcare provider was also notified about: new drugs added during the inpatient stay; warnings about drug-drug interactions; recommendations for dose changes; and laboratory monitoring of high-risk medications. An alert was also sent to their support staff to schedule a post-hospitalisation office visit. The outcome measures used were whether or not an outpatient office visit with a primary healthcare provider occurred after discharge, and whether re-hospitalisation occurred within 30 days after discharge.

The results of this study found no significant effect of the intervention on the outcomes measured. There were 1870 discharges in the intervention group, and of these, 27.7% had an office visit with a primary healthcare provider within seven days of discharge. Of the 1791 discharges in the control group, 28.3% had an office visit with a primary healthcare provider within seven days of discharge. In the intervention group, 18.8% experienced a re-hospitalisation within the 30-day period after discharge, compared with 19.9% in the control group. The hazard ratio for an office visit with a primary healthcare physician did not significantly differ between the intervention and control groups. The hazard ratio for re-hospitalisation in the 30-day period after hospital discharge in the intervention versus the control group was 0.94 (95% CI: 0.81–1.1). Although this intervention was not shown to have a significant effect, the researchers postulated new ideas for intervention testing, and suggested that assigning a re-hospitalisation risk score to inpatients prior to discharge, and targeting interventions that promote those individuals for timely follow-up with their primary healthcare physicians, may have a more targeted effect on re-hospitalisation rates.[125]

#### 9.1.4.2 Follow-up appointment reminder systems

Also based in the USA and examining an intervention designed to minimise the risk at the transition point between a hospital and primary healthcare setting was a study by Arora et al., that measured the effect of an automated text message reminder system for follow-up appointments with either a specialty or primary healthcare provider after patients were discharged from an emergency department. [21] The authors commented that attendance at these scheduled follow-up appointments has been found to improve patient outcomes, decrease ED bounce-backs, and reduce malpractice

risk. Reasons for patients missing follow-up visits are complex, but the most commonly cited reason is simply forgetting. This study also used a randomised controlled trial design, and 374 patients with text-capable mobile phones were enrolled. The study population had a large proportion of Spanish speaking patients, and messages were delivered in English or Spanish as per patient preference. The intervention group were sent follow-up automated, personalised text message appointment reminders including date, time, and clinic location at seven days, three days, and one day before their scheduled visits. Both per-protocol analyses and intention to treat (ITT) analyses were reported on the primary outcome measure of appointment adherence rate. ITT more accurately reflects real world conditions where errors such as number entry errors are bound to occur. The per-protocol analysis adds value by isolating the effect of the intervention by comparing patients who actually received it compared with those who did not.

The study results of the per-protocol analysis of the primary outcome, the overall appointment adherence rate, was 72.6% in the intervention group compared with 62.1% in the control group (difference between groups = 10.5%, 95% confidence interval [CI]: 0.3%–20.8%; P = 0.045; number needed to treat = 9.5). In the ITT analysis, the overall appointment attendance rate was 70.2% in the intervention group compared with 62.1% in the control group (difference between groups = 8.2%; 95% CI: -1.6%–17.7%; P = 0.100). In a secondary largely exploratory analysis, the intervention was found to have the most benefit in patients with the lowest baseline follow-up rate (English speakers with specialty care appointments). The researchers concluded that an automated text message appointment reminder was an effective low cost intervention to increase post-emergency department appointment adherence that was highly scalable.[21]

**Key finding 4.7:** An automated text-message appointment reminder was found to be an effective low cost intervention to increase post-emergency department follow up with primary healthcare and specialty clinicians in the community.

#### 9.1.4.3 Structured patient handover processes in primary healthcare

The third study in this group of interventions designed to reduce risks to patient safety at care transition points was a trial comparing two different interventions, however there was no control group [138] so this was not a randomised controlled trial. It was also quite specific to the care model operating in New York, and so results may not be generalisable to other primary healthcare locations. The interventions offered one of two different processes for a transfer of care handover between the outgoing resident and incoming intern at three ambulatory care practices at an academic medical centre in New York City, and were randomly assigned to 32 intern-resident pairs undertaking handover.

One intervention in the study was called a 'standard transfer', and these outgoing doctors were asked to create a document called a Ten Tasks List for patients who required ongoing care. This was a checklist of 10 items that the incoming intern should attend to in the first three months of the academic year. Doctors exposed to the other intervention, called the 'structured transfer', were also asked to make a Ten Tasks List for any patients who required it, however they were also provided with a directed list of their 'continuity patients', asked to additionally create a Sign-Out document (a list of patients from their continuity panel who they felt required sign-out from ongoing care at the clinic when treatment was completed), and they were encouraged to verbally sign out both forms to the intern replacing them. The primary outcomes measured were compliance with a Ten Tasks List of

care items that needed to be completed for the patients at a point of three months into the academic year. The junior doctors leaving and arriving were also surveyed, and results of their satisfaction with the handover process and its association with patient safety were also measured as secondary outcomes.

This study found that the clinical care tasks were more likely to be completed by interns in the structured group (73%, n = 49) versus the standard group (46%, n = 28) (adjusted OR = 3.21; 95% CI: 1.55–6.62; P = 0.002). However, there were no differences in survey results amongst the two different intervention arms. The researchers concluded that a structured outpatient sign out improved the odds of follow-up of important clinical care tasks after the year end resident clinic transition.[138]

#### 9.1.4.4 A cost-effectiveness method for evaluating a handover intervention

The final study in this group was a description by Yao et al. of a method to estimate the expected cost-effectiveness of a service intervention. They road tested their method using an intervention to improve patient handover of care between hospital and community, however the study was an ex ante evaluation (based on forecasts rather than actual results), and dealt with a handover process at its pre-implementation phase. They predicted that the intervention to improve handover would reduce the incidence of adverse events by 21% (i.e. from 6.3% to 4.7%) according to their elicitation exercise. Potentially preventable adverse events were postulated and classified by severity and duration. Utilities were assigned to each category of adverse event. The costs associated with each category of event were obtained from the literature. The unit cost of the intervention was 16.6 Euros, which would yield a Quality Adjusted Life Year (QALY) gain per discharge of 0.010. The resulting cost saving was 14.3 Euros per discharge. The limitations of this study make its findings difficult to generalise, however it offers a novel approach to assist in the ex ante health economic evaluations of health service interventions.[123]

### 9.2 Tools that aim to support primary healthcare clinicians in providing safer care

Support materials for primary healthcare clinicians that aim to assist them in the safer delivery of patient care were described in a number of studies that were included in the systematic literature review, and also in the grey literature. These patient safety tools are intended for use (or are being currently used) with the aim of reducing patient safety risk, but have not yet been tested as an intervention.

A narrative review by Spencer et al. aimed to identify tools that can be used by family practitioners as part of a patient safety toolkit to improve the safety of the care and services provided by their practices. They found 114 tools overall, mostly originating in the US (41%) and the UK (23%) within the last ten years. Very few were specific for primary healthcare, and many of the tools were yet to be used in quality improvement strategies and cycles such as plan-do-study-act (PDSA) so there was little evidence of their utility in improving as opposed to measuring and highlighting safety issues. Most were based on medication safety. They concluded that lack of focus on diagnostics, systems safety and results handling provide direction and priorities for future research.[73]

### 9.2.1 Never event tools

In the UK, Bell et al. describe their efforts to systematically develop a patient safety toolkit, though it is yet to be tested,[139] and de Wet et al. used similar consensus building methods to develop a tool called a 'never event' list.[29] This is a concept that has been implemented in many acute hospital settings to help prevent serious patient safety incidents. Benefits include increasing awareness of highly important patient safety risks among the healthcare workforce, promoting proactive implementation of preventive measures, and facilitating incident reporting. A total of 345 general practice team members suggested potential never events. Next, informed staff (n = 15) developed criteria for defining never events and applied the criteria to create a list of candidate never events. Finally, UK primary healthcare patient safety experts (n = 17) reviewed, refined, and validated a preliminary list via a modified Delphi group and by completing a content validity index exercise. The expert group endorsed a preliminary list of 10 items with a content validity index (CVI) score of >80%. This list is included in the report in Appendix 11. [29]

The search of grey literature also found a never event tool for general practice that was produced in 2014 by the Greater Manchester Primary Care Patient Safety Translational Research Centre. This organisation is funded by the National Institute for Health Research (NIHR) for five years from 1 August 2012 and is a partnership between The University of Manchester and Salford Royal NHS Foundation Trust, on behalf of NHS England.[140] The details of this tool are included in the Appendix A3.1 summary table.

**Key finding 5.1:** Never event lists have been developed by researchers in the UK and these may be useful in primary healthcare settings to help prevent serious patient safety incidents.

### 9.2.2 Primary healthcare collaboratives to improve patient safety

Another resource that was included in the search of the grey literature for tools to reduce the risks to safety in primary healthcare was developed by a South Australian group. It offers practical advice for GPs who are seeking guidance to reduce threats to patient safety in their clinical practice and was published online in 2014. It is described in the grey literature table of Appendix A4.1 and offers the most comprehensive toolkit of resources that was found in the search of grey literature that is applicable to the Australian primary healthcare context.

The Patient Safety Collaboratives Manual[141] provides resources and tools for Australian GPs to use to reduce risks for patients receiving care in their practices, and it is structured around four key concepts in safety: 1) engaging the team, 2) data quality, 3) finding harm, and 4) preventing harm.

The first section, engaging the team, suggests using a 2008 AHRQ patient safety culture survey annually (the Medical Office Survey of patient safety culture). The section Data quality, suggests improving medical records continuously in general practices through developing systems for creating and maintaining accurate patient health summaries; checking progress by monthly audit using a data checking tool; and uploading verified health summaries to the internet electronic health record (e-Health). The third section, finding harm, advises practices to run a trigger tool quarterly; randomly select at least 25 triggered patients for notes review to identify harms; and record harms in a prioritisation grid which is provided in the manual (an event log). Preventing harm guides practices to make systems changes within the general practice for improved patient safety through: firstly, identifying which events from the trigger tool and event log patients had experienced harm or risk of harm; secondly, prioritising which events to conduct significant event analysis; and thirdly, recording, sharing and undertaking actions to reduce harms. It is a resource that compiles a

number of well researched and useful patient safety tools in a single practical guide that has been specifically created for Australian GPs. It is yet to be formally evaluated, and has potential application to other primary healthcare clinicians outside of the general practice setting.[141]

**Key finding 5.2:** A primary healthcare Collaboratives Manual was developed in Australia and made freely available in 2014. This resource contains a comprehensive set of tools that may be applied to primary healthcare settings with the aim of minimising patient safety risk and enhancing patient safety culture in practices and was the most readily applicable to the Australian primary healthcare setting.

### 9.2.3 Other tools described in the grey literature designed to support safer primary healthcare

A range of proposed intervention tools were found in the search of the grey literature mainly developed by professional organisations, and suggested for use (mainly for GPs) to assist them in providing safer care.[126,140-143] There was no evidence found in the included peer-reviewed literature that evaluated these tools specifically, and this would be an aim of future research. Their descriptions are presented in table of Appendix A4.1. They cover incident reporting systems and toolkits of resources that primary healthcare clinicians can use to improve their practices.

**Key finding 5.3:** Toolkits of patient safety resources for primary care clinicians have been produced in recent years by a number of professional organisations and government agencies.

The National Reporting and Learning System (NRLS) of the NHS in the UK was the only national incident reporting system found in our search of the English language grey literature that is readily accessible to primary healthcare clinicians. It is a central database of patient safety incident reports that is accessible to all healthcare providers in the NHS and all patients. Since the NRLS was set up in 2003, over four million incident reports have been submitted. All information submitted is analysed to identify hazards, risks and opportunities to continuously improve the safety of patient care. Reports are confidential and online, and staff can log in to upload incident reports, view reports submitted by their organisation, and view feedback reports for their organisation.[126]

**Key finding 5.4:** The NHS National Reporting and Learning System remains the only national incident reporting and analysis system found in the English language that is readily available for primary healthcare clinicians to use.

# 10 Conclusion

The focus of the majority of research that addresses the question of risks to patient safety in primary healthcare in both the published and grey literature has moved in recent years. Earlier work attempted to determine and describe the range of different types of risks to patient safety in primary healthcare, and develop ways to classify these risks. Much of the research effort has now turned from simply describing the range of risk types, to investigating their relationship with patient safety culture and test more rigorous detection methods to find patient safety incidents in primary healthcare practices. However, most research is still quite specific to the general practice setting, and other primary healthcare settings are generally at an earlier phase in their exploration of the subject of patient safety.

The language and ability to draw comparisons between different health care models and different countries is becoming more uniform as researchers have heeded the calls for international consistency with definitions. However, again this is more specific to general practice than other settings, and there is still much room for improvement. Additionally, there is generally a lack of evidence outside of the primary healthcare settings in developed countries about risks to patient safety, where less research funding is available. The association of patient safety risk types with harm, using consistent definitions, is also a topic that has not been dealt with in any great detail by the majority of studies.

There is no one method that is solely appropriate to measure the range of risks to patient safety in primary healthcare, and a stronger patient safety culture is key to improving our knowledge in this field. The answer to the question 'What are the risks associated with patient safety in primary healthcare?' will differ depending on the lens through which it is asked – an incident reporting system, versus a retrospective record review using a trigger tool, versus a review of malpractice cases, versus a review of patient complaints – these will all reveal different (and equally important) answers. There is a complex interplay between the structure of the health system in which primary healthcare is operating and the ability of these different methods to be applied, but they all have value in answering this important question and all should be considered for use in a mature healthcare system which aims to make primary care safer.

The literature suggests that there is an association between a strong patient safety culture (including the availability of structured reporting and learning systems) and safer primary healthcare, however there are very few high quality studies that have been published to date that examine the role of specific interventions to minimise risks to patient safety in primary healthcare. A number of tools and proposed interventions are emerging, particularly in the grey literature from professional organisations and special interest groups, with a focus on patient safety in primary healthcare. Their more rigorous evaluation is a key area where further research is required in order to improve our understanding of how we can reduce risks to patient safety in primary healthcare.

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# 12 Appendices

## Appendix 1: Data extraction tables for findings of the systematic review relating to Question 1

Presented below are tables containing the papers from the systematic review of the scientific literature which underwent full-text review and inclusion in the group that addressed Question 1: What is the evidence on the risks associated with patient safety in primary healthcare? These are organised by primary healthcare setting?

### A1.1 Setting: general practice

| **General practice: studies with evidence on risks associated with patient safety in primary healthcare (N = 68 / 50 papers)** | |
|---|---|
| **Author/Year** | **Amalberti, R. and Brami, J. 2012[57]** |
| **Title** | *'Tempos' management in primary care: a key factor for classifying adverse events, and improving quality and safety* |
| **Aim** | To determine if a medical injury that had occurred in a series of malpractice claims was due to one or more of five time related problems, termed 'Tempos'. |
| **Design** | Descriptive (cross-sectional) |
| **Methods** | Two qualified physicians reviewed a sample of 1046 malpractice claims from one major French liability insurer to determine whether a 'medical injury' had occurred and, if so, whether it was due to one or more time related ('tempo') problems. The authors propose a framework integrating five time scales termed 'Tempos' requiring parallel processing by GPs: the disease's tempo (unexpected rapid evolutions, slow reaction to treatment); the office's tempo (day-to-day agenda and interruptions); the patient's tempo (time to express symptoms, compliance, emotion); the system's tempo (time for appointments, exams, and feedback); and the time taken to access knowledge. For each case, one tempo was recorded when it was the main source of the problem, or the two main tempos if two or more were felt to have contributed. |
| **Results** | 623 of the 1046 claims were included after exclusions for potential rather than actual claims, and problems unassociated with the GPs. The prevalence and characteristics of claims and related time management errors were measured. The percentages of contributing factors were as follows: disease tempo 37.9%; office tempo 13.2%; patient tempo 13.8%; out-of-office coordination tempo 22.6%; and GP's access to knowledge tempo 33.2%. Although not conceptualised in most error taxonomies, the disease and patient tempos are cornerstones in risk management in primary healthcare. Traditional taxonomies describe events from an analytical perspective of care at the system level and offer opportunities to improve organisation, process, and evidence-based medicine. The suggested classification describes events in terms of (unsafe) dynamic control of parallel constraints from the carer's perspective, namely the GP, and offers improvement on how to self-manage and coordinate different contradictory tempos and day-to-day activities. |
| **Key finding** | This paper addresses the lack of time management, presenting a framework integrating five time scales termed 'Tempos' requiring parallel processing by GPs: the |

| | | | |
|---|---|---|---|
| | disease's tempo (unexpected rapid evolutions, slow reaction to treatment); the office's tempo (day-to-day agenda and interruptions); the patient's tempo (time to express symptoms, compliance, emotion); the system's tempo (time for appointments, exams, and feedback); and the time to access to knowledge. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Bell, B. G. et al. 2014[139]** | | |
| **Title** | *Tools for measuring patient safety in primary care settings using the RAND/UCLA appropriateness method* | | |
| **Aim** | To produce a set of patient safety tools and indicators that could be used in general practice. | | |
| **Design** | Descriptive other (RAND/UCLA appropriateness) | | |
| **Methods** | A two round consensus process was undertaken following the RAND/UCLA process to evaluate a list of identified tools and to develop a taxonomy for classifying tools into dimensions of patient safety. A prior review identified 120 tools that were included in this study from these tools 205 statements were evaluated by the panel. | | |
| **Results** | The panel rated 101 statements as necessary for assessing the safety of general practice. Of these 73 covered structures or organisational issues, 22 addressed processes and six focused on outcomes. | | |
| **Key finding** | This paper reports the first attempt to systematically develop a patient safety toolkit for general practice, which has the potential to improve safety, cost effectiveness and patient experience, in any healthcare system. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Not applicable |
| **Author/Year** | **Bondevik, G. T. et al. 2014[44]** | | |
| **Title** | *The safety attitudes questionnaire – ambulatory version: psychometric properties of the Norwegian translated version for the primary care setting* | | |
| **Aim** | To validate a translation of The Safety Attitudes Questionnaire - Ambulatory Version (SAQ-AV) into Norwegian and to determine whether the factor structure in the translated version was the same as in the original questionnaire. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | The Safety Attitudes Questionnaire – Ambulatory Version was developed for measuring safety culture in the primary healthcare setting in Texas USA in 2006. As part of the Norwegian patient safety campaign "In Safe Hands" in 2011 by the Ministry of Health, the survey was translated and tested for validity in Norwegian primary healthcare. 510 clinicians (316 GPs and 194 nurses) in seven OOH Clinics and 17 general practices in Norway were invited to participate in an emailed survey in October 2012. | | |
| **Results** | 52% responded (266 people), including 139 nurses (72%) and 124 medical doctors (39%). The confirmatory factor analysis found that the following five factor model was shown to have acceptable goodness-of-fit values in the Norwegian primary healthcare setting: Teamwork climate; Safety climate; Job satisfaction; Working conditions; and Perceptions of management. Further research should investigate whether there is an association between patient safety culture in primary healthcare, as measured by the Safety Attitudes Questionnaire – Ambulatory Version, and occurrence of medical errors and negative patient outcome. | | |
| **Key finding** | The results of this study indicate that the Norwegian translated version of the Safety | | |

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| | Attitudes Questionnaire - Ambulatory Version, with the five confirmed factors, might be a useful tool for measuring several aspects of patient safety culture in the primary healthcare setting. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Bondevik, G. T. et al. 2014[43]** | | |
| **Title** | *Patient safety culture in Norwegian primary care: a study in out-of-hours casualty clinics and GP practices* | | |
| **Aim** | The Safety Attitudes Questionnaire – Ambulatory Version (SAQ-AV) was used to study whether patterns of safety attitudes amongst Norwegian primary healthcare clinicians were related to professional background, gender, age and clinical setting. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | The Safety Attitudes Questionnaire – Ambulatory Version was used to assess safety culture. 510 clinicians (316 GPs and 194 nurses) in seven OOH Clinics and 17 general practices in Norway were invited to participate in an emailed survey in October 2012. The demographic details of respondents were compared to safety attitude scores to determine the relationship. Statistical analysis included multiple linear regression and independent samples t-tests. | | |
| **Results** | The overall response rate was 52%; 72% of the nurses and 39% of the doctors answered the questionnaire. In the OOH clinics, nurses scored significantly higher than doctors on Safety climate and Job satisfaction. Older health care providers scored significantly higher than younger ones on Safety climate and Working conditions. In GP practices, male health professionals scored significantly higher than female on Teamwork climate, Safety climate, Perceptions of management and Working conditions. Health care providers in GP practices had significantly higher mean scores on the factors Safety climate and Working conditions, compared with those working in the OOH clinics. Overall, nurses scored higher than doctors, older health professionals scored higher than younger, male GPs scored higher than female GPs, and health professionals in GP practices scored higher than those in OOH clinics – on several patient safety factors. | | |
| **Key finding** | This study showed that nurses scored higher than doctors, older health professionals scored higher than younger, male GPs scored higher than female GPs, and health professionals in GP practices scored higher than those in out-of-hours clinics on several patient safety factors. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Bowie, P. et al. 2015[28]** | | |
| **Title** | *Participatory design of a preliminary safety checklist for general practice* | | |
| **Aim** | To identify workplace hazards that impact on safety, health and wellbeing of patients, visitors, GP team members and organisational performance, and to co-design a standardised checklist process for general practices which reflects system wide safety hazards and risks. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Members of three professional primary healthcare networks (GPs, nurses and practice managers) in Scotland were invited to participate by email. The total number of network members who were invited was not stated. Those indicating an interest in the study were asked to send the investigators safety related policies, protocols and procedures to inform the study purpose, scope and potential checklist development. | | |

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| | Two researchers jointly reviewed these and identified safety-critical checking processes of interest. A draft checklist was developed by a multi-professional expert group (seven members), and then tested in two 'consensus building workshops' with the study participants, where it was further refined. A content validity exercise was also undertaken to determine the acceptability of the final tool to the study participants. | | |
| **Results** | There were 18 study participants (10 practice managers, five nurses, three GPs) who worked in a range of rural and urban general practices. The safety checklist that was developed was comprised of six domains with a total 22 subcategories and 78 related items. The six domains are: Medicines management; Housekeeping; Information systems; Practice team; Patient access and identification; Health and Safety. As an example of levels two and three, a subcategory of medicines management is 'controlled drugs', and a related item within this would be 'monthly stock reconciliation undertaken'. The specific check items overlap with the Australian Standards for General Practice produced by the RACGP, but has more specific detail on some safety related items and is safety focused rather than being a general standards checklist. | | |
| **Key finding** | A prototype safety checklist was developed and validated consisting of six safety domains (for example, medicines management), 22 sub-categories (for example, emergency drug supplies) and 78 related items (for example, stock balancing, secure drug storage, and cold chain temperature recording). | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Bowie, P. et al. 2014[144]** | | |
| **Title** | *Laboratory test ordering and results management systems: a qualitative study of safety risks identified by administrators in general practice* | | |
| **Aim** | To explore the experiences and perceptions of frontline primary healthcare administrators directly involved in the systems-based management of laboratory test ordering and results handling, with a particular focus on identifying risks that may impact on patient safety and other relevant quality of care issues. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | 40 administrators (receptionists, healthcare assistants and phlebotomists) from general practices in three NHS territorial board areas in the west of Scotland were recruited to participate in a series of five focus group interviews on the subject of systems-based management of laboratory test ordering and results handling. The researchers used a brief topic guide, informed by issues previously raised in the literature. Participants were asked to view 'patient safety' pragmatically in terms of results handling incidents, or potential incidents, which they would not like to happen to themselves or relatives. The transcripts underwent qualitative content analysis to provide knowledge and understanding of the phenomenon under study. Data were systematically coded, categorised and themes identified. | | |
| **Results** | A total of 40 administrative staff were recruited. Four key themes emerged: (1) system variations and weaknesses (e.g. lack of a tracking process is a known risk that needs to be addressed); (2) doctor to administrator communication (e.g. unclear information can lead to emotional impacts and additional workload);[145] informing patients of test results (e.g. levels of anxiety and uncertainty are experienced by administrators influenced by experiences and test result outcome); and (4) patient follow-up and | | |

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| | confidentiality (e.g. maintaining confidentiality in a busy reception area can be challenging). The key findings were explained in terms of sociotechnical systems theory. This suggests that the success of any workplace system or technology is strongly interdependent on the social relational contexts of work organisation, rather than just on the systems or technology itself. The authors assert that there appears to be a clear alignment between many of the social and technical interactions and interdependencies of test results handling systems uncovered in this study (and the wider literature) that would benefit from a human factors approach. | | |
| **Key finding** | Four key themes emerged: 1) system variations and weaknesses (e.g. lack of a tracking process is a known risk that needs to be addressed); 2) doctor to administrator communication (e.g. unclear information can lead to emotional impacts and additional workload); 3) informing patients of test results (e.g. levels of anxiety and uncertainty are experienced by administrators influenced by experience and test result outcome); and (4) patient follow-up and confidentiality (e.g. maintaining confidentiality in a busy reception area can be challenging). | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Bowie, P. et al. 2012[46]** | | |
| **Title** | *Maximising harm reduction in early specialty training for general practice: validation of a safety checklist* | | |
| **Aim** | To prioritise the most safety-critical issues to be addressed in the first 12-weeks of specialty training in the general practice environment and validate a related checklist reminder. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | A six stage mixed methods approach was used to develop and content validate the safety checklist for educational supervisors. Initially three focus group sessions were held with GP educators, and a series of validation exercises were undertaken to develop the themes to be included in the checklist for educators and a self-assessment tool for the trainees. The relevance of potential checklist items was rated using a four-point scale content validity index to inform final inclusion. | | |
| **Results** | There were 123 GP educators and nine GP trainees involved in the series of methods to develop the checklist, although the method of recruitment of participants or their characteristics was not described. 14 themes (e.g. prescribing safely; dealing with medical emergency; implications of poor record keeping; and effective and safe communication) and 47 related items (e.g. how to safety-net face-to-face or over the telephone; knowledge of practice systems for results handling; and recognition of harm in children) were judged to be essential safety-critical educational issues to be covered. The mean content validity index ratio was 0.98. The checklist was developed and validated for educational supervisors to assist in the reliable delivery of safety-critical educational issues in the opening 12-week period of training, and aligned with national curriculum (RCGP) competencies. The tool can also be adapted for use as a self-assessment instrument by trainees to guide patient safety-related learning needs. Dissemination and implementation of the checklist and self-rating scale are proceeding on a national, voluntary basis with plans to evaluate its feasibility and educational impact. | | |
| **Key finding** | A checklist was developed and validated for educational supervisors to assist in the reliable delivery of safety-critical educational issues in the opening 12-week period of | | |

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| | GP training, and aligned with national curriculum competencies. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Burgess, C. et al. 2012**[146] | | |
| **Title** | *Patients' perceptions of error in long-term illness care: qualitative study* | | |
| **Aim** | To explore patients' perceptions of events that may represent errors in long-term illness care and evaluate potential associations with dimensions of quality in health care. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Participants were recruited from seven South London general practices. People were eligible if they had any one of seven long-term conditions: arthritis, coronary heart disease, stroke, hypercholesterolaemia, hypertension, diabetes mellitus or chronic obstructive pulmonary disease (COPD). Participants were purposively sampled according to these target conditions as well as age and sex to obtain a diverse range of participants for interview. Sampling was continued until semi-structured interviews revealed no new themes. The analysis aimed to identify patients' reports of errors in their care and to provide a preliminary mapping of these reports to dimensions of quality in primary healthcare. Definitions for 'error' and 'harm' were drawn from the conceptual framework for the International Classification for Patient Safety. In this framework, an error is a failure in the planning or execution of an action, including the failure to implement a correct action or the execution of an incorrect action. Harms may include impairment of physical or mental functioning that follow from exposure to health care. Errors may or may not cause harm; harms may occur in the absence of error. | | |
| **Results** | 33 patients were interviewed. Three main error types were determined, being errors of access (e.g. difficulties of gate-keeping leading to problems in gaining access to primary healthcare consultations, diagnostic tests and specialist care); errors of interpersonal care (e.g. patients' perceptions of not being taken seriously, and a perceived failure by professionals to respond adequately to reports of adverse drug reactions or accounts of painful symptoms); and errors of coordination and management continuity (e.g. difficulties of information transfer between primary and secondary care). Potential harms associated with errors of access included delayed diagnosis or delayed delivery of specialist care. Problems of gaining access to care and problems at transitions between levels of care may sometimes constitute errors, but they may also give rise to circumstances in which errors occur. Interpersonal and communication problems may also be associated with errors. There appears to be a close relationship between broader concepts of quality of care and the concept of patient safety. | | |
| **Key finding** | Problems of gaining access to care and problems at transitions between levels of care may sometimes constitute errors, but they may also give rise to circumstances in which errors occur. Interpersonal and communication problems may also be associated with errors. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |

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| **Author/Year** | **de Vries, C. et al. 2015[42]** | | |
| **Title** | *Results of a survey among GP practices on how they manage patient safety aspects related to point-of-care testing in every day practice* | | |
| **Aim** | To determine how patient safety aspects about three commonly used point of care tests (blood glucose, nitrites and haemoglobin) are managed in Dutch general practices. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | A random sample of 750 general practices was drawn from the 4090 practices in the Netherlands and electronically invited to participate in a survey using SurveyMonkey. The request to each practice was to have a person complete the survey who actually uses point of care (POC) tests. The survey was designed to capture information on training, the use of the tests, and pre- and post- testing processes that the practice followed that related to patient safety risks associated with POC testing. | | |
| **Results** | 111 practices (15%) of the random sample of 750 practices returned the questionnaire. The characteristics of the practices of returned questionnaires were statistically similar to those who did not. 60% of questionnaires were completed by GPs, and the rest by GP assistants or practice nurses. Training on the use of POC tests was given in 90% of practices. Results of the pre-analytic phase found issues with less attention (less than 65% for all three tests) to storage conditions, possible damage to the packaging and possible unclean and damaged test strips. Only 20% of users check whether the meter is calibrated or generally maintained. During testing, only about half of the respondents using blood glucose tests and only 38% of the respondents using haemoglobin tests took hygienic measures, such as washing their own hands before taking a blood sample. Less than 20% of the respondents indicated that they wore gloves. Washing/disinfecting the patient's finger before blood sampling was performed by less than half of the respondents. Most respondents manually entered results of POC tests rather than having a device that automatically downloaded into the electronic health record. The study found a number of risks for errors with POC tests in GP practices that may be reduced by proper training of personnel, introduction of standard operating procedures and measures for quality control and improved hygiene. | | |
| **Key findings** | A number of risks for errors with Point Of Care tests (POCT) in GP practices that may be reduced by proper training of personnel, introduction of standard operating procedures and measures for quality control and improved hygiene were identified. To encourage proper use of POCT in general practices, a national POCT guideline, dedicated to primary healthcare and in line with ISO standards, should be introduced. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **de Wet, C. et al. 2013[62]** | | |
| **Title** | *Can we quantify harm in general practice records? An assessment of precision and power using computer simulation* | | |
| **Aim** | To determine and quantify Clinical Record Review (CCR) parameters; to assess the precision and power of feasible CRR scenarios; and to quantify the minimum requirements for adequate precision and acceptable power in order to estimate harm rates in general practice. | | |
| **Design** | Monte Carlo simulation | | |

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| **Methods** | A range of parameter values were combined in 864 different clinical record review (CRR) scenarios, with 1000 random data sets generated for each, and harm rates were estimated and tested for change over time by fitting a generalised linear model with a Poisson response. 'Acceptable precision' of a harm rate was defined as an estimation error less than +/- 25%. A 'harm rate' quantifies the incidence of harm in defined populations at given points in time. They are expressed as a rate such as 'number of harm incidents per hundred patients per year'. Harm rate estimates at different points in time could be compared to detect increases or reductions. | | |
| **Results** | Clinical record review (CRR) is proposed as a more appropriate method for the detection of harm than incident reporting or analysing complaints data. A formula was created to calculate the minimum values of CRR required to achieve adequate precision and acceptable power when calculating harm rates. CRR scenarios with >100 detected harm incidents had harm rate estimates with acceptable precision. Harm reductions of 20% or >50% were detected with adequate power by those CRR scenarios with at least 100 and 500 harm incidents respectively. The number of detected harm incidents was dependent on the baseline harm rate multiplied by: the period of time reviewed in each record; number of records reviewed per practice; number of practices who reviewed records; and the number of times each record was reviewed. | | |
| **Key finding** | A formula was created to calculate the minimum values of CRR numbers required to achieve adequate precision and acceptable power when calculating harm rates. CRR scenarios with >100 detected harm incidents had harm rate estimates with acceptable precision. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **de Wet, C. and Bowie, P. 2009[61]** | | |
| **Title** | *The preliminary development and testing of a global trigger tool to detect error and patient harm in primary-care records* | | |
| **Aim** | To develop and test a global trigger tool to detect errors and adverse events in primary healthcare records | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Trigger tool development was informed by previous research and content validated by expert opinion. After evidence review, the IHI outpatient adverse event trigger tool was identified as the most relevant as a starting point for developing a primary healthcare equivalent. A 10 item trigger tool was agreed upon by using a modified Delphi technique with a group of 17 experienced GPs. The tool was applied by trained reviewers who worked in pairs to conduct focused audits of 100 randomly selected electronic patient records in each of five urban general practices in central Scotland. These practices all used the same electronic medical record database (used by 80% of Scottish general practices). The 12-month period for January to December 2007 was reviewed. Auditors answered four questions whenever a trigger was found: 1) Did the patient suffer actual harm or was there potential for harm? 2) Was harm caused by clinical management? 3) Was it preventable? 4. What was the severity of the adverse event? | | |
| **Results** | 500 records were reviewed for a 12-month period in 2007, comprising 2251 consultations in total with an average of 4.5 per patient. 730 triggers were identified in all records, and in 64 records there was an adverse events or potential adverse | | |

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| | event identified, of which 27 were judged to be preventable (42%). In 47 of these records this led to the identification of patient harm (9.4% of the total group of 500), and in the remaining 17 records, harm to the patient either did not occur or was prevented by intervention (3.4% of the total group of 500). The combined error and adverse event rate was one per 35 patient consultations, and the harm rate was one incident per 48 patient consultations. Most cases of harm were graded as category A–E (temporary harm to the patient requiring an intervention). The two events graded as G (permanent patient harm) were both related to procedures in secondary care. The majority of harm was detected in the older age groups despite this patient subgroup representing only a small percentage of all the records that were reviewed. The number of identified adverse events increased with age: 38 of 64 events (59%) of detected harm occurred in patients older than 60 years, and 23 of the 64 events (36%) occurred in patients older than 75 years. Medication and related activities such as prescribing accounted for most adverse events. Administrative issues included coding errors and errors resulting from correspondence with secondary care. Auditors took just over three minutes on average to review each record using the trigger tool. | | |
| **Key finding** | The developed trigger tool was successful in identifying undetected patient harm in primary healthcare records and may be the most reliable method for achieving this. However, the feasibility of its routine application is open to question. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **de Wet, C. et al. 2014[29]** | | |
| **Title** | *Developing a preliminary 'never event' list for general practice using consensus-building methods* | | |
| **Aim** | To develop a preliminary list of never events for general practice. | | |
| **Design** | Descriptive (Consensus method) | | |
| **Methods** | A total of 345 general practice team members suggested potential never events. Next, 'informed' staff (n = 15) developed criteria for defining never events and applied the criteria to create a list of candidate never events. Finally, UK primary healthcare patient safety 'experts' (n = 17) reviewed, refined, and validated a preliminary list via a modified Delphi group and by completing a content validity index exercise. The 'never event' criteria were all of the following: something known to cause severe harm or with that potential; preventable by the healthcare professional, team or practice; able to be clearly defined; able to be detected; and not the result of an unlawful act. | | |
| **Results** | There were 721 written suggestions received as potential never events. Thematic categorisation reduced this to 38. Five criteria specific to general practice were developed and applied to produce 11 candidate never events. The expert group endorsed a preliminary list of 10 items with a content validity index (CVI) score of >80%. The list included five items relating to medication errors (allergy previously noted; teratogen to a pregnant patient; aspirin to a child; unopposed oestrogen to a patient with intact uterus; and methotrexate daily rather than weekly); an item relating to not having adrenaline available; an item relating to needlestick injury caused by a previous failure to dispose of a needle in a sharps container; an item relating to failure to arrange a cancer referral; an item relating to investigation results not being reviewed; and an item relating to a failure to arrange emergency transport in an acute emergency admission. | | |

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| **Key finding** | A preliminary list of 10 'never event' items specific to general practice was produced by expert consensus opinion. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Eggleton, K. and Dovey, S. 2014[63]** | | |
| **Title** | *Using triggers in primary care patient records to flag increased adverse event risk and measure patient safety at clinic level* | | |
| **Aim** | To test the use of a preliminary trigger tool in a large provincial general practice in order to provide meaningful directions for improving safety. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Possible triggers were identified from reviewing the literature of triggers tested in primary healthcare and a focus group of two GPs, two pharmacists and one practice nurse decided. A 36 item trigger tool was used to review the records of 170 patients in a large provincial general practice (>12,000 enrolled patients). Sample size was based on an assumption that the background harm rate in primary healthcare was 5%, and in order to detect harm with 90% power. To be included in the review, patients had to be registered with the practice for 12-months and have at least one visit with a general practitioner in 2011. The trigger tool was applied by two teams of reviewers. One team consisted of a general practitioner and a community pharmacist and the other team was a general practitioner and a practice nurse. The teams separately reviewed each patient record for the presence of a trigger. If one was present, indication of harm relating to that trigger was then sought. Each record was then reviewed for the presence of any harm that was not related to the trigger. Harm was defined according to the Medication Error Index adopted by the National Coordinating Council for Medication Error Reporting and Prevention. Harm was classified according to the WHO National Coordinating Council for Medication Error Reporting. Following each session a reconciliation of findings between teams ensured consistency of interpretation of triggers and harm. If there was a difference between the two teams then a decision was made based on consensus. Harm events that were associated with each trigger were examined. A logistic regression analysis was conducted, adjusting for sex, ethnicity and age to estimate the odds of harm associated with each trigger and with the 36 triggers combined. Triggers with the lowest specificity were then excluded and a refined trigger tool derived and tested for its ability to identify harm, using a further age-sex-ethnicity-adjusted logistic regression analysis. | | |
| **Results** | The rate of harm per consultation was 0.07 (95% CI: 0.05–0.09) or seven occurrences of harm per 100 consultations. The rate of harm per 100 patient years was 41 (95% CI: 29–55). Of the 45 occurrences of harm: 34 (76%) were classified as Category E – temporary harm to the patient and required intervention; eight (18%) were classified as Category F – temporary harm to the patient and required initial or prolonged hospitalisation; two (4%) were classified as Category G – permanent patient harm; and one (2%) was classified as Category I – patient death. The odds ratio (OR) of harm occurring using 36 triggers was 0.78 (95% CI: 0.5–30) with a sensitivity of 0.98 and a specificity of 0.08. The refined primary healthcare trigger tool included only eight triggers: adverse drug reaction documented in the record, two consultations with a GP in the same practice in a week, cessation of medication, reduction in medication dose, six medications prescribed, attending the emergency department or an afterhours | | |

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| | provider within two weeks of having seen a GP, estimated glomerular filtration rate (eGFR) <35, and death. The odds ratio of harm occurring if one of the reduced set of triggers was present was 3.4 (95% CI: 1.7–7.1) when adjusted for age, sex and ethnicity. The sensitivity of this refined trigger tool was 0.81 and the specificity was 0.51. The correlation coefficient for the refined primary healthcare trigger tool was 0.4 between the two groups of reviewers. | | |
| **Key finding** | 27.1% of the study sample of 170 patients experienced at least one of the 36 triggers within the time their electronic records were held by the study general practice. All harms identified were medication related. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Elder, N. et al. 2009[24]** | | |
| **Title** | *Management of test results in family medicine offices* | | |
| **Aim** | To explore test results management systems in family medicine offices and to delineate the components of quality in results management. | | |
| **Design** | Mixed methods | | |
| **Methods** | The researchers used a multi-method protocol, we intensively studied four purposefully chosen family medicine offices using observations, interviews, and surveys. Data analysis consisted of iterative qualitative analysis, descriptive frequencies, and individual case studies, followed by a comparative case analysis. The researchers assessed the quality of results management at each practice by both the presence of and adherence to system wide practices for each results management step, as well as outcomes from chart reviews, patient surveys, and interview and observation notes. | | |
| **Results** | Variability was found between offices in how they performed the tasks for each of the specific steps of test results management. No office consistently had or adhered to office-wide results management practices, and only two offices had written protocols or procedures for any results management steps. Most patients surveyed acknowledged receiving their test results (87%–100%), although a far smaller proportion of patient charts documented patient notification (58% to 85%), clinician response to the result (47%–84%), and follow-up for abnormal results (28%–55%). Two major themes that emerged as factors of importance in assessing test results management quality were: 1) safety awareness – a leadership focus and communication that occurs around quality and safety, teamwork in the office, and the presence of appropriate policies and procedures; and 2) technological adoption – the presence of an electronic health record, digital connections between the office and testing facilities, use of technology to facilitate patient communication, and the presence of forcing functions (built-in safeguards and requirements). | | |
| **Key finding** | Safety awareness and technology adoption (use of an electronic health record and decision support) are key determinants of quality in test result management practices in primary healthcare offices. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Elnour, A. A. et al. 2014[27]** | | |
| **Title** | *Surveyors' perceptions of the impact of accreditation on patient safety in general practice* | | |
| **Aim** | To explore Australian General Practice Accreditation Limited (AGPAL) surveyors' perceptions of the impact of accreditation on patient safety and to elicit suggestions | | |

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| | for improving patient safety in Australian general practices. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | 10 surveyors of general practice accreditation standards participated in a semi-structured telephone interview. AGPAL invited surveyors from across Australia with varying levels of experience on behalf of the research team, however the sample size and response rate are not defined, nor the comparison of the participant's characteristics with the background population of AGPAL surveyors. The interview questions were around GPs' awareness of patient safety and the impact of accreditation on clinical risk management and patient safety culture. | | |
| **Results** | All participants agreed that accreditation has improved general practices' performance in quality and safety. Participants noted specific areas that need further attention, including sufficient evidence for clinical risk management, which half the participants estimated occurs in about 5%–10% of Australian general practices. Tangible evidence of patient safety activities included having a significant incidents register, providing documentation of near misses, slips, lapses or mistakes, and engaging in regular clinical meetings to discuss incidents and how to avoid them in the future. It was estimated that evidence of these types of activities could only be provided by approximately 5%–10% of general practices, and more experienced surveyors offered lower estimates on this figure generally. The majority of accreditors felt that practices who had engaged with the Australian Primary Care Collaboratives (APCC) Program showed a higher interest in patient safety and recall systems. Participants agreed that the accreditation process could be improved through the inclusion of tighter clinical safety indicators and the requirement of verifiable evidence of a working clinical risk management system. | | |
| **Key finding** | Accreditation has had a positive role in improving quality and safety in general practice. There is very little tangible evidence of clinical risk management activities in practices. The inclusion of tighter indicators that require verifiable evidence will be a step forward. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Gaal, S. et al. 2011**[58] | | |
| **Title** | *Complaints against family physicians submitted to disciplinary tribunals in the Netherlands: lessons for patient safety* | | |
| **Aim** | To describe and examine complaints against family physicians submitted to Dutch disciplinary tribunals with a view to improving patient safety and identifying domains of high risk of harm for patients in family practice. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | A retrospective analysis was conducted of the most recent 250 online anonymous summaries of the Dutch disciplinary law verdicts that contained the term 'family physician' and occurred in the general practice setting in the period up to October 2010. The Dutch system offers patients an avenue to seek disciplinary measures on a physician through a complaints process. This 'disciplinary law' is to guard and improve the quality of health care, to protect patients from incompetent and careless behaviours, and to enhance public trust in the medical profession. There is a parallel malpractice system available through the courts, however the disciplinary tribunal system differs in that the patient does not receive financial compensation if the physician is found to be at fault. The process takes one to two years, and involves | | |

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| | written and oral testimony from both parties. If the tribunal accepts the complaint, a written judgment is passed and an anonymous summary of the verdict is published online. Each week a verdict of interest is published in a medical journal with a commentary by the Dutch healthcare inspectorate. A descriptive analysis of the cases was conducted. Classification of complaint, diagnosis, health outcome and verdict were recorded. A detailed analysis including logistic regression models of the cases with serious harm outcomes was undertaken to determine the relationships between type of complaint, health outcome and a negligence verdict. | | |
| **Results** | Of the 250 complaints examined, the most common complaint type related to a wrong diagnosis in 60 cases (24%). Other types were 'insufficient medical care' (54, 21.6%); wrong treatment (23, 9.2%); a too late referral (18, 7.2%); an 'incorrect statement or declaration' (15, 6%); a violation of privacy (14, 5.6%); not attending a house call (14, 5.6%); a 'provision of insufficient information' (6, 2.4%); 'impolite behaviors' (5, 2%); 'inappropriate patient contact' (2, 0.8%) and billing for treatment (1, 0.4%); 'other reasons' (19, 7.6%); and in the other cases, it was not possible to identify the complaint type (19, 7.6%). There were 74 cases that resulted in a serious health outcome which included 49 deaths (19.6%) and 25 (10%) severe harms. In these cases, 'wrong diagnosis' was related to close to half of the cases (33, 44.6%). The wrong or late diagnosis-related cases mostly consisted of myocardial infarction and stroke (35.1%) and malignancies (33.7%). The family physician was disciplined in 88 of the 250 cases (35.2%). However in cases with serious health outcomes (including death), there was a disciplinary action in 50% of cases. Logistic regression analysis showed that a serious outcome was associated with a higher probability of disciplinary measures (B=0.703; P =.02) | | |
| **Key finding** | Malpractice record review is a method that detected a much higher proportion of patient safety incidents with serious health outcomes (including severe harm and death) compared to other methods such as incident reporting and large scale medical record review. The most commonly found type of complaint related to a wrong diagnosis, and these had a much higher association with a serious health outcome. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Gaal, S. et al. 2011[64]** | | |
| **Title** | *Prevalence and consequences of patient safety incidents in general practice in the Netherlands: a retrospective medical record review study* | | |
| **Aim** | This study aimed to assess patient safety in general practice, and to show areas where potential improvements could be implemented. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | A retrospective review of patient records in Dutch general practice was conducted. A random sample of 1000 patients from 20 general practices was obtained. The number of patient safety incidents that occurred in a one-year period, their perceived underlying causes, and impact on patients' health were recorded. | | |
| **Results** | 211 patient safety incidents were identified across a period of one year (95% CI: 185 until 241). A variety of types of incidents, perceived causes and consequences were found. A total of 58 patient safety incidents affected patients; seven were associated with hospital admission; none resulted in permanent disability or death. The authors suggest that about 60,000 hospital admissions per year (of 1.8 million in the Netherlands in 2007 for example) are partly related to patient safety incidents in the | | |

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| | Primary Care setting. | | |
| **Key finding** | Only a few of the identified safety incidents in Primary Care had major consequences, and incidents with serious consequences appear to have a lower prevalence in the general practice setting than the hospital setting. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Gaal, S. et al. 2010[84]** | | |
| **Title** | *Patient safety features are more present in larger primary care practices* | | |
| **Aim** | To explore whether specific characteristics of a general practice organisation were associated with aspects of patient safety management. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | The study was a secondary analysis of survey data from convenience samples of 30 practices in each of 10 European countries that participated in the European Practice Assessment (EPA) study. The data were collected by a practice visitor and physician questionnaires. The researchers constructed 10 measures of patient safety, covering 45 items as outcomes, and six measures of practice characteristics as possible predictors for patient safety. Only practices that provided data on practice size, rurality, and staff experiences (such as work load and working conditions) were included. Multiple regression analysis was conducted to determine whether practice characteristics (size, area of location, experienced physical working conditions, experienced team climate, experienced amount of responsibility given, and experienced working hours) were associated with the 10 constructed measures of patient safety. | | |
| **Results** | Eight of the 10 patient safety measures yielded higher scores in larger practices (practices with more than two GPs). Medication safety, practice building safety and incident reporting items showed the strongest associations with practice size. Also measures on hygiene, medical record keeping, quality improvement, professional competence and organised patient feedback items had higher scores in larger practices. Consistent with other research, a number of other aspects like experienced team climate or experienced workload did not have an impact on patient safety scores. Although larger general practice practices may have better safety management, no causal relationship could be established in this study. | | |
| **Key finding** | Larger practices (with more than two GPs) scored more highly across a range of patient safety measures. Medication safety, practice building safety and incident reporting items showed the strongest associations with practice size. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Gaal, S. et al. 2010[83]** | | |
| **Title** | *Patient safety in primary care has many aspects: an interview study in primary care doctors and nurses* | | |
| **Aim** | To explore the views of primary healthcare doctors and nurses on patient safety in daily general practice and to identify aspects of care that are linked to patient safety. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Qualitative interview study conducted with a purposeful sample of 30 GPs and 10 primary healthcare nurses. The sampling strategy aimed to guarantee a good spread regarding practice size, urbanisation, GPs' age, gender and experience. The concept of patient safety was explored in the first component of the interview. The second | | |

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| | component contained 16 semi-structured questions that explored the ideas of primary healthcare workers on a variety of topics concerning patient safety in primary healthcare (e.g. medication monitoring, telephonic accessibility, triage and incident reporting). The analysis used an iterative process to identify patient safety themes through an interpretive analysis. | | |
| **Results** | A total of 22 doctors and seven practice nurses were interviewed. A number of participants defined patient safety as "Do not harm the patient". The answers of the 16 semi-structured questions were ordered into three developed categories: organisation, professionalism and culture. The items named by the practice nurses did not systematically differ from the answers given by GPs. Before all interviews were conducted, data saturation occurred in the main themes. Medication was the item seen as most important in the relationship with patient safety, including its organisational aspects: repeat prescribing and computerised medication monitoring systems. Many GPs mentioned the frequent warnings of the computerised medication system, which often were not read carefully. Many primary care workers considered polypharmacy as an important risk factor, especially in the elderly. Theoretical definitions of patient safety in the literature were disconnected from the views of practicing doctors. | | |
| **Key finding** | A number of participants defined patient safety as "Do not harm the patient". Medication was the item seen most important in relationship with patient safety. Theoretical definitions of patient safety in the literature were disconnected from the views of practicing doctors. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Gaal, S. et al. 2010[41]** | | |
| **Title** | *Patient safety in primary care: a survey of general practitioners in the Netherlands* | | |
| **Aim** | To identify what risk and safety means in actual practice to GPs, and to gain better insight into what they consider unsafe practices and what they judge to be risk factors for patient safety in primary healthcare. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | All GPs from the Nijmegen University Network of GPs (132 GPs) were sent a web-based survey. The items were derived from aspects of patient safety issues identified in a prior interview study (Gaal, 2010). The questionnaire used 10 clinical cases and 15 potential risk factors to explore GPs' views on patient safety. For each of the clinical cases, the respondent was asked to judge the impact of the specific situation on patient safety along a five-point Likert scale which ranged from 'patient safety not at all at stake' to 'patient safety is greatly at stake'. Comments could also be provided. | | |
| **Results** | A total of 68 GPs responded (51.5% response rate). None of the clinical cases was uniformly judged as particularly safe or unsafe by the GPs. Cases judged to be unsafe by a majority of the GPs concerned either the maintenance of medical records or prescription and monitoring of medication. Cases which only a few GPs judged as unsafe concerned hygiene, the diagnostic process, prevention and communication. The risk factors most frequently judged to constitute a threat to patient safety were a poor doctor-patient relationship, insufficient continuing education on the part of the GP and a patient age over 75 years. Language barriers and polypharmacy also scored high. Deviation from evidence-based guidelines and patient privacy in the reception/ waiting room were not perceived as risk factors by most of the GPs. The views of GPs | | |

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| | on safety and risk in primary healthcare did not completely match those presented in published papers and policy documents. The GPs in this study judged not keeping detailed and up-to-date medical records, not heeding electronic warnings and doctor's responsibility as critical issues for patient safety. A poor doctor-patient relationship, failure to maintain one's medical knowledge and polypharmacy were scored highest as risk factors for patient safety. Guideline adherence, patient privacy and telephone waiting time scored low. | | |
| **Key finding** | Not keeping detailed and up-to-date medical records, not heeding electronic warnings and doctors responsibility were viewed by GPs as critical issues for patient safety. A poor doctor-patient relationship, failure to maintain one's medical knowledge and polypharmacy were regarded as the greatest risk factors for patient safety. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Gehring, K. 2013[82]** | | |
| **Title** | *Safety climate and its association with office type and team involvement in primary care* | | |
| **Aim** | To assess differences in safety climate perceptions between occupational groups and types of office organisation in primary healthcare. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Primary healthcare physicians and nurses working in outpatient offices were surveyed about safety climate. Explorative factor analysis was performed to determine the factorial structure. Differences in mean climate scores between staff groups and types of office were tested. Logistic regression analysis was conducted to determine predictors for a 'favourable' safety climate. | | |
| **Results** | 630 individuals returned the survey (response rate, 50%). Differences between occupational groups were observed in the means of the 'team-based error prevention'-scale (physician 4.0 vs. nurse 3.8, P < 0.001). Medical centres scored higher compared with single-handed offices and joint practices on the 'team-based error prevention'-scale (4.3 vs. 3.8 vs. 3.9, P < 0.001) but less favourable on the 'rules and risks'-scale (3.5 vs. 3.9 vs. 3.7, P < 0.001). Characteristics on the individual and office level predicted favourable 'team-based error prevention'-scores. Physicians (OR = 0.4; P = 0.01) and less experienced staff (OR = 0.52; P = 0.04) were less likely to provide favourable scores. Individuals working at medical centres were more likely to provide positive scores compared with single-handed offices (OR = 3.33; P = 0.001). The largest positive effect was associated with at least monthly team meetings (OR = 6.2, P < 0.001) and participation in quality circles (OR = 4.49, P < 0.001). | | |
| **Key finding** | Frequent quality circle participation and team meetings involving all team members are effective ways to strengthen safety climate in terms of team-based strategies and activities in error prevention. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Gehring, K. et al. 2012[119]** | | |
| **Title** | *Frequency of and harm associated with primary care safety incidents* | | |
| **Aim** | To assess frequency and severity of patient safety incidents in primary healthcare. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Physicians and nurses in primary healthcare offices were surveyed about the frequency and severity of 23 safety incidents. Differences between professional | | |

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| | groups and types of offices were analysed. Reported incidents were classified in a matrix. | | |
| **Results** | A total of 630 individuals (50.2% physicians, 49.8% nurses) participated. Among them, 30% of physicians (95% CI: 25%–35%) and 16.6% of nurses (95% CI: 12%–21%) reported that at least one of the incidents occurred daily or weekly in their offices (c2 16.1, P < 0.001). On average, each responder reported a total of 92 incidents during the preceding 12 months (mean of 117 events for physicians, mean of 66 events for nurses; P < 0.001). Documentation failure was reported most frequently. The highest fraction of last occurrences with severe injury or death was for diagnostic errors (4.1%). Unadjusted for caseload, staff working in medical centres reported higher frequencies of several incidents. The frequency-harm matrix suggests that triage by nurse at initial contact, diagnostic errors, medication errors, failure to monitor patients after medical procedures, and test or intervention errors should be prioritised for action. | | |
| **Key finding** | Many incidents occur regularly and are highly relevant for healthcare professionals' daily work. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Goldman, R. et al. 2010[147]** | | |
| **Title** | *Doctor's perceptions of laboratory monitoring in office practice* | | |
| **Aim** | To explore doctors attitudes towards and practice behaviors regarding problems with laboratory monitoring. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Six focus groups and one individual interview with 20 primary healthcare doctors and nine specialists from three Massachusetts communities. | | |
| **Results** | Participants viewed laboratory monitoring as a critical, time-consuming task integral to their practice of medicine. Most believed they commit few laboratory monitoring errors and were surprised at the error rates reported in the literature. They listed various barriers to monitoring, including not knowing which doctor was responsible for ensuring the completion of laboratory monitoring, uncertainty regarding the necessity of monitoring, lack of alerts/reminders and patient non-adherence with recommended monitoring. The primary facilitator of monitoring was ordering laboratory tests while the patient is in the office. Primary healthcare doctors felt more strongly than specialists that computerised alerts could improve laboratory monitoring. Participants wanted to individualise alerts for their practices and warned that alerts must not interrupt work flow or require too many clicks. | | |
| **Key finding** | Doctors in community practice recognised the potential of computerised alerts to enhance their monitoring protocols for some medications. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Hernan, A. L. et al. 2014[26]** | | |
| **Title** | *Patients' and carers' perceptions of safety in rural general practice* | | |
| **Aim** | To explore patients' and carers' experiences of rural general practice to identify their perceptions of safety of care. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Four focus group interviews were conducted with 26 rural patients and carers in south-west Victoria between September and December 2012. Frequent users of | | |

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| | general practice were recruited from local allied health self-management programs and a mothers' group. Focus groups were audio recorded, transcripts were independently analysed and interpreted using narrative methodologies. | | |
| **Results** | Participants who had experienced some level of harm were able to comment more extensively on safety aspects of care. Several key themes related to safety were identified from the analysis of all participant narratives. An assumed sense of safety in general practice was predominant, and was influenced by participants' level of risk awareness and trust in their general practitioner. Additional unique themes included feelings of vulnerability, desire for an explanation and apology, a forgiving view of mistakes, and preference for GP interpersonal skills over competence. | | |
| **Key finding** | This study revealed new insights into the factors that influence patients' and carers' perspectives of safety, and demonstrated the value of incorporating the patient voice into safety research. An assumed sense of safety due to a default position of trust, coupled with limited risk perception, directly contests the current literature on patient involvement in safety. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Hoffmann, B. et al. 2011[40]** | | |
| **Setting** | General practice | | |
| **Title** | *The Frankfurt patient safety climate questionnaire for general practices (FraSik); analysis of psychometric properties* | | |
| **Aim** | This study aims to evaluate psychometric properties of a newly developed safety climate questionnaire for use in German general practices. | | |
| **Design** | Descriptive (questionnaire development) | | |
| **Methods** | The existing Safety Attitudes Questionnaire, Ambulatory Version, was considerably modified and enhanced in order to be applicable in general practice. After pilot tests and its application in a random sample of 400 German practices, a first psychometric analysis led to modifications in several items. A further psychometric analysis was conducted with an additional sample of 60 practices and a response rate of 97.08%. Exploratory factor analysis with orthogonal varimax rotation was carried out and the internal consistency of the identified factors was calculated. | | |
| **Results** | Nine factors emerged, representing a wide range of dimensions associated with safety culture: teamwork climate; error management; safety of clinical processes; perception of causes of errors; job satisfaction; safety of office structure; receptiveness to healthcare assistants and patients; staff perception of management; and quality and safety of medical care. Internal consistency of factors is moderate to good. | | |
| **Key finding** | This study demonstrates the development of a patient safety climate instrument that contains features that might be specific to small-scale general practices. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Hoffmann, B. et al. 2013[39]** | | |
| **Title** | *Impact of individual and team features of patient safety climate: a survey in family practices* | | |
| **Aim** | To analyse the impact of the professional group, the professional experience of practice staff, and practice characteristics on perceptions of the safety climate. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Health care assistants and doctors in 1800 randomly selected family practices in | | |

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| | Germany were contacted and asked to complete a newly developed and validated Frankfurt Patient Safety Climate Questionnaire. A descriptive analyses of items and climate factors, as well as regression analysis, to identify potential predictors of the safety climate in family practice was conducted. | | |
| **Results** | The response rate from the participating practices was 36.1%. Safety climate was perceived to be generally positive with the exception of the factors of error management and perception of the causes of errors. We discovered that whether or not the entire team had taken part in the survey had a positive influence on most factors. Doctors had more positive perceptions of four of seven factors addressed to both professions. Male participants and doctors showed the most willingness to admit they had made an error. | | |
| **Key finding** | Though the safety climate in German family practices was positive overall, health care professionals' use of incident reporting and a system's approach to errors was fairly rare. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Hotvedt, R. and Førde, O. H. 2013[37]** | | |
| **Title** | *Doctors are to blame for perceived medical adverse events. A cross-sectional population study. The Tromsø study* | | |
| **Aim** | To investigate the occurrence of experienced medical adverse events in a large general population. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | 19,763 inhabitants of a municipality in northern Norway, age 30 years and older, were invited to fill in a questionnaire. The main outcome measures were life time prevalence of AEs experienced by respondents or their first degree relatives, perceived responsibility for and predictors of such events, as well as formal complaints as a reaction to the events. | | |
| **Results** | The response rate was 66%. Nine and 10% of the respondents reported self-experienced adverse events, and 15 and 19% (men and women, respectively) that their relatives had experienced AEs. Logistic regression models showed that the strongest predictors of reporting self-experienced adverse events were: having been persuaded to accept an unwanted examination or treatment, difficulties in getting a referral from primary to specialist health care, and inadequate communication with the doctor. Of the respondents who had experienced adverse events personally, 62% placed the responsibility for the event on the general practitioner, 39% on the hospital doctor, and 19% on failing routines or cooperation. Only 7% of men and 14% of women who reported self-experienced events handed in a formal complaint. | | |
| **Key finding** | Approximately 10% of the community population aged over 30 years surveyed reported experiencing an adverse event. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Huibers, L. et al. 2011[77]** | | |
| **Title** | *Safety of telephone triage in out-of-hours care: a systematic review* | | |
| **Aim** | To assess the research evidence on safety of telephone triage in out-of-hours primary healthcare. | | |
| **Design** | Systematic review | | |
| **Methods** | A systematic review was performed of published research on telephone triage in out- | | |

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| | of-hours care, searching in PubMed and EMBASE up to March 2010. Studies were included if they concerned out-of-hours medical care and focused on telephone triage in patients with a first request for help. Study inclusion and data extraction were performed by two researchers independently. Post-hoc two types of studies were distinguished: observational studies in contacts with real patients (unselected and highly urgent contacts), and prospective observational studies using high-risk simulated patients (with a highly urgent health problem). | | |
| **Results** | Thirteen observational studies showed that on average triage was safe in 97% (95% CI: 96.5%–97.4%) of all patients contacting out-of-hours care and in 89% (95% CI: 86.7%–90.2%) of patients with high urgency. Ten studies that used high-risk simulated patients showed that on average 46% (95% CI: 42.7%–49.8%) were safe. Adverse events described in the studies included mortality (n = 6 studies), hospitalisations (n = 5), attendance at emergency department (n = 1), and medical errors (n = 6). | | |
| **Key finding** | On average, 10% of telephone triage contacts in out-of-hours care were unsafe. | | |
| **NHMRC evidence** | No specific classification (the studies were not all RCTs) | **Quality score** | 3/11 (Systematic review) |
| **Author/Year** | **Khoo, E. M. et al. 2012[65]** | | |
| **Title** | *Medical errors in primary care clinics – a cross-sectional study* | | |
| **Aim** | The aim of the study is to determine the extent of diagnostic inaccuracies and management errors in public funded primary healthcare clinics. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | This was a cross-sectional study conducted in twelve public funded primary healthcare clinics in Malaysia. A total of 1753 medical records were randomly selected in 12 primary healthcare clinics in 2007 and were reviewed by trained family physicians for diagnostic, management and documentation errors, potential errors causing serious harm and likelihood of preventability of such errors. | | |
| **Results** | The majority of patient encounters (81%) were with medical assistants. Diagnostic errors were present in 3.6% (95% CI: 2.2–5.0) of medical records and management errors in 53.2% (95% CI: 46.3–60.2). For management errors, medication errors were present in 41.1% (95% CI: 35.8–46.4) of records, investigation errors in 21.7% (95% CI: 16.5–26.8) and decision making errors in 14.5% (95% CI: 10.8–18.2). A total of 39.9% (95% CI: 33.1–46.7) of these errors had the potential to cause serious harm. Problems of documentation including illegible handwriting were found in 98.0% (95% CI: 97.0–99.1) of records. Nearly all errors (93.5%) detected were considered preventable. | | |
| **Key finding** | Errors in primary healthcare were common and the likelihood of errors causing serious harm was high. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Kousgaard, M. B. 2012[97]** | | |
| **Title** | *Reasons for not reporting patient safety incidents in general practice: a qualitative study* | | |
| **Aim** | To explore the reasons for not reporting patient safety incidents in general practice. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Thirteen semi-structured interviews were conducted with 12 GPs from nine clinics. The main outcome measures were the experiences and reflections of the involved professionals with regard to system use and non-use. | | |

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| **Results** | While most respondents were initially positive towards the idea of reporting and learning from patient safety incidents, they actually reported very few incidents. The major reasons for the low reporting rates are found to be a perceived lack of practical usefulness, issues of time and effort in a busy clinic with competing priorities, and considerations of appropriateness in relation to other professionals. | | |
| **Key finding** | While most respondents were initially positive towards the idea of reporting and learning from patient safety incidents, they actually reported very few incidents. The major reasons for the low reporting rates are found to be a perceived lack of practical usefulness, issues of time and effort in a busy clinic with competing priorities, and considerations of appropriateness in relation to other professionals. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Manwell, L. B. et al. 2009[148]** | | |
| **Title** | *Physician perspectives on quality and error in the outpatient setting* | | |
| **Aim** | To elicit ideas on how workplace factors such as culture and policies or procedures affect errors and care quality. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Nine focus groups were conducted with 32 family physicians and general internists from five areas in the upper Midwest and New York City. | | |
| **Results** | The physicians described challenging settings with rapidly changing conditions. Patients are medically and psychosocially complex and often underinsured. Communication is complicated by multiple languages, time pressure, and inadequate information systems. Complex processes of care have missing elements including medication lists and test results. Physicians are pressed to be more productive, and key administrative decisions are made without their input. Targeted areas to improve safety and reduce error included teamwork, aligned leadership values, diversity, collegiality, and respect. | | |
| **Key finding** | Teamwork, respect, diversity, collegiality and working beyond the job description, having aligned values and leadership were all identified as workplace factors that have the potential to enhance care. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **McKay, J. et al. 2009[124]** | | |
| **Title** | *A review of significant events analysed in general practice: implications for the quality and safety of patient care* | | |
| **Aim** | To identify the range of safety issues analysed, learning needs raised and actions taken by GP teams. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Content analysis of 191 Significant Event Analysis (SEA) reports submitted by two GP groups in an 18 month period between 2005 and 2007. | | |
| **Results** | 191 SEA reports were reviewed. 48 described patient harm (25.1%). A further 109 reports (57.1%) outlined circumstances that had the potential to cause patient harm. Individual 'error' was cited as the most common reason for event occurrence (32.5%). Learning opportunities were identified in 182 reports (95.3%) but were often non-specific professional issues not shared with the wider practice team. 154 SEA reports (80.1%) described actions taken to improve practice systems or professional behaviour. However, non-medical staff were less likely to be involved in the changes | | |

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| | resulting from event analyses describing patient harm (P < 0.05). | | |
| **Key finding** | The two most common reasons cited for significant events were doctor error and communication issues. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **McKay, J. et al. 2013[66]** | | |
| **Title** | *Applying the trigger review method after a brief educational intervention: potential for teaching and improving safety in GP specialty training* | | |
| **Aim** | To determine the feasibility and impact of a Trigger Review Method (TRM) and a related training intervention in GP training. | | |
| **Design** | Quasi experimental | | |
| **Method** | 25 west of Scotland GP trainees attended a two-hour TRM workshop. Trainees then applied TRM to 25 clinical records and returned findings within four weeks. A follow-up feedback workshop was held. | | |
| **Results** | 21/25 trainees (84%) completed the task. 520 records yielded 80 undetected PSIs (15.4%). 36/80 were judged potentially preventable (45%) with 35/80 classified as causing moderate to severe harm (44%). Trainees described a range of potential learning and improvement plans. Training was positively received and appeared to be successful given these findings. TRM was valued as a safety improvement tool by most participants. | | |
| **Key findings** | Trigger review is of potential value in GP safety curriculum delivery. GP trainees valued the trigger review method as a safety improvement educational tool. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **McKinstry, B. et al. 2011[149]** | | |
| **Title** | *Comparison of the accuracy of patients' recall of the content of telephone and face-to-face consultations: an exploratory study* | | |
| **Aim** | To measure how accurately patients recall the content of face-to-face and telephone consultations and what factors may be associated with accurate recall. | | |
| **Design** | Observational (cross-sectional) | | |
| **Method** | The advice (diagnoses; management plan(s); and safety-netting arrangements) given in audio recorded face-to-face and telephone consultations was compared with the advice recalled by patients at interview approximately 13 days later. Ten GPs and 175 patients participated in the study. Patients also performed a memory test. Interactions were sought between accurate recall, consultation type, and factors postulated to influence recall. | | |
| **Results** | Patients (n = 144) recalled most important components of telephone and face-to-face consultations equally accurately or with only minor errors. Overall, patients presenting multiple problems (P < 0.001), with brain injury (P < 0.01) or low memory score (P < 0.01) had reduced recall. GPs rarely used strategies to improve recall; however, these were not associated with improved recall. | | |
| **Key finding** | Patients tended to remember important components of both face-to-face and telephone consultations. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |

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| **Author/Year** | **Mira, J. J. et al. 2010[109]** | | |
| **Title** | *Patient report on information given, consultation time and safety in primary care* | | |
| **Aim** | To analyse the frequency of adverse events to treatment reported by patients in relation to consultation time, attention from their usual doctor and information provided by their doctor about treatment. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | 15,282 patients from 21 primary healthcare centres participated in a telephone survey regarding adverse events. The main outcome measures were patients' report on frequency of unexpected or adverse reaction to a treatment; whether informed or not about possible complications of the treatment and precautions to take; consultation time; and whether or not patient is usually seen by the same doctor. | | |
| **Results** | 1557 (17.6%; CI: 95% 16.8%–18.4%) of the adults and 867 (13.7%; 95% CI: 12.8%–14.5%) of the children reported adverse or unexpected reactions to the treatment according to patients' reports. Consultation time (OR = 0.5; 95% CI: 0.4–0.5), doctor rotation at the health centre (OR = 2.04; 95% CI: 1.85–2.25) and information on treatment precautions (OR = 0.47; 95% CI: 0.43–0.53) determine the higher risk of adverse reactions to treatment. | | |
| **Key finding** | 17.6% of adults and 13.7% of children reported an adverse event. Shorter consultation time and frequent change of doctor were associated with an increased adverse event risk. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Mold, F. et al. 2015[78]** | | |
| **Title** | *Patients' online access to their electronic health records and linked online services: a systematic review in primary care* | | |
| **Aim** | To assess the impact of providing patients with access to their general practice electronic health records (EHR) and other EHR-linked online services on the provision, quality, and safety of health care. | | |
| **Design** | Systematic review | | |
| **Methods** | A systematic review was conducted that focused on all studies about online record access and transactional services in primary healthcare. Data sources included MEDLINE, Embase, CINAHL, Cochrane Library, EPOC, DARE, King's Fund, Nuffield Health, PsycINFO, OpenGrey (1999–2012). The literature was independently screened against detailed inclusion and exclusion criteria; independent dual data extraction was conducted, the risk of bias assessed, and a narrative synthesis of the evidence conducted. | | |
| **Results** | A total of 176 studies were identified, 17 of which were randomised controlled trials, cohort, or cluster studies. Patients reported improved satisfaction with online access and services compared with standard provision, improved self-care, and better communication and engagement with clinicians. Safety improvements were patient-led through identifying medication errors and facilitating more use of preventive services. Provision of online record access and services resulted in a moderate increase of email, no change on telephone contact, but there were variable effects on face-to-face contact. However, other tasks were necessary to sustain these services, which impacted on clinician time. There were no reports of harm or breaches in privacy. | | |

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| **Key finding** | Patient access to online health records and linked services had a positive impact on patient safety through identification of medication errors and increased use of preventative services. | | |
| **NHMRC evidence** | No specific classification (the studies were not all RCTs) | **Quality score** | 7/11 (Systematic review) |
| **Author/Year** | **O'Beirne, M. et al. 2013[150]** | | |
| **Title** | *The costs of developing, implementing and operating a safety learning system in community practice* | | |
| **Aim** | To determine the costs of the development, implementation, and operation of the community-based SLS. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Nineteen participating family physician clinics in Calgary, Alberta, were included (15 urban and four rural) consisting of 47 physicians, 53 office staff, 18 nurses, and six clinic managers. Costs of the SLS were determined by the ingredient method using micro-costing. The costs were divided into three stages: development, implementation, and operational. Development costs were processes required to create and initiate the SLS. Implementation costs were accrued as a result of establishing, running, and refining the SLS. Finally, operational costs were those related to maintaining the SLS. Costs were further broken down into fixed, marginal, and in kind; this approach will allow policy and decision makers to apply the appropriate costs to their own settings. | | |
| **Results** | The total development, implementation, and operational costs for the SLS in Canadian dollars were $77,011, $19,941, and $166,727, respectively, with a total cost of $263,679 over approximately a four-year period. During this time, 270 incident reports were submitted, and 54 improvement cycles were implemented. | | |
| **Key finding** | The total costs for the Safety Learning System in Canadian dollars were $77,011 (development), $19,941 (implementation), and $166,727 (operational) with a total cost of $263,679 over approximately a four-year period. During this time, 270 incident reports were submitted, and 54 improvement cycles were implemented. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **O'Beirne, M. et al. 2011[49]** | | |
| **Title** | *Safety incidents in family medicine* | | |
| **Aim** | To discuss the characteristics of incidents reported to the Medical Safety in Community Practice (MSCP) safety learning system. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Members of family physician offices in the Alberta Health Services – Calgary zone, confidentially reported patient safety incidents via web or fax from September 2007 to August 2010. The incident reporting form contained both open-ended and closed questions. Incidents were reviewed for their characteristics. | | |
| **Results** | A total of 19 family practices participated in MSCP. A total of 264 useable reports were collected. Reporting was higher when practices first joined and then decreased. There was an average of 1.4 reports per month. Physicians submitted the majority of reports. Physicians and nurses were more likely to report an incident than office staff. The vast majority of reported incidents were judged to have 'virtually certain evidence of preventability' (93%). Harm was associated with 50% of incidents. Only 1% of the | | |

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| | incidents had a severe impact. The top four types of incidents reported were documentation (41.4%), medication (29.7%), clinical administration (18.7%), and clinical process (17.5%). | | |
| **Key finding** | 264 incidents were collected from 19 family practices. The majority of reported incidents were judged to have 'virtually certain evidence of preventability' (93%). Harm was associated with 50% of incidents and 1% of the incidents had a severe impact. The top four types of incidents reported were documentation (41.4%), medication (29.7%), clinical administration (18.7%) and clinical process (17.5%). | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **O'Beirne, M. et al. 2010[95]** | | |
| **Title** | *Safety learning system development – incident reporting component for family practice* | | |
| **Aim** | To determine the required components for developing the reporting components of a safety learning system (SLS) for community-based family practice. | | |
| **Design** | Non-systematic review | | |
| **Methods** | Multiple databases were searched for all languages for all types of papers related to medical safety in community practice: Books@Ovid, BIOSIS Previews, CDSR, ACP Journal Club, DARE, CCTR, Ageline, AMED, CINAHL, EMBASE, HealthSTAR, Ovid MEDLINE In-Process, Other Non-Indexed Citations, Ovid MEDLINE, PsycINFO, HAPI and PsycBOOKS. A grey literature search was done in Google. | | |
| **Results** | A non-Systematic literature review was conducted. An online search identified 190 papers. English abstracts were read and the full papers (or chapters) were retrieved for 90, of which 18 were deemed appropriate. The grey literature search revealed 18 additional papers, and an additional 12 papers were identified from bibliographies of included papers. Common themes around the following areas were identified: system design, incident reporting form, taxonomy/classifications. | | |
| **Key finding** | For the reporting component of an SLS to be successful, there needs to be strong leadership, voluntary reporting, legal protection and feedback to reporters. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Palacios-Derflinger, L. et al. 2010[151]** | | |
| **Title** | *Dimensions of patient safety culture in family practice* | | |
| **Aim** | The objectives of this study were to explore the dimensions of patient safety culture that relate to family practice in Canada and to determine if differences and similarities exist between dimensions found in Canada and those found in previous studies undertaken in the United States and the United Kingdom. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Focus groups were held with staff from two clinics participating in the Medical Safety in Community Practice research. A third focus group was held with informed stakeholders (patient safety experts, family physicians, staff and patient advocates) from the Medical Safety in Community Practice research. Participants were asked about dimensions of patient safety they felt were important. | | |
| **Results** | A qualitative study was undertaken applying thematic analysis using focus groups with family practice offices and supplementary key stakeholders. Analysis of the data indicated that most of the dimensions from the United States and United Kingdom are appropriate in our Canadian context. Exceptions included owner/managing partner/leadership support for patient safety, job satisfaction and overall perceptions | | |

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| | of patient safety and quality. Two unique dimensions were identified in the Canadian context: disclosure and accepting responsibility for errors. | | |
| **Key finding** | Most of the dimensions from the United States and United Kingdom are appropriate in the Canadian context. Exceptions included owner/managing partner/leadership support for patient safety, job satisfaction and overall perceptions of patient safety and quality. Two unique dimensions were identified in the Canadian context: disclosure and accepting responsibility for errors. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Ruth, J. L. et al. 2011[122]** | | |
| **Title** | *Evaluating communication between pediatric primary care physicians and hospitalists* | | |
| **Aim** | To determine the preferences for and satisfaction with communication between pediatric primary healthcare physicians and hospitalists. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Primary healthcare and hospitalist members of the Pennsylvania American Association of Pediatrics (AAP) were invited to take part in an online survey. | | |
| **Results** | Overall, primary healthcare Physicians were less satisfied than hospitalists with communication ($P < 0.01$). The two provider types had differing opinions on responsibility for care after hospital discharge, with hospitalists more likely than PCPs to assign responsibility to the PCP for pending labs (65% vs. 49%; $P < 0.01$), adverse events (85% vs. 67%; $P < 0.01$), or status changes (85% vs. 69%; $P < 0.01$). | | |
| **Key finding** | Whereas satisfaction with and preferences for patient-related communication differed between hospitalists and PCPs, the incongruent views on the responsibility for care after patient discharge have major implications for safety particularly if poor communication occurs at discharge. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Schiff, G. D. et al. 2013** | | |
| **Title** | *Primary care closed claims experience of Massachusetts malpractice insurers* | | |
| **Aim** | To study patterns of primary healthcare malpractice types, causes, and outcomes as part of a Massachusetts ambulatory malpractice risk and safety improvement project. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Retrospective review of pooled closed claims data of two malpractice carriers covering most Massachusetts physicians during a five-year period (1 January 2005, through 31 December 2009). Data were harmonised between the two insurers using a standardised taxonomy. Primary healthcare practices in Massachusetts. All malpractice claims that involved primary healthcare practices insured by the two largest insurers in the state were screened. A total of 551 claims from primary healthcare practices were identified for the analysis. Outcome measures were numbers and types of claims, including whether claims involved primary healthcare physicians or practices; classification of alleged malpractice (e.g. misdiagnosis or medication error); patient diagnosis; breakdown in care process; and claim outcome (dismissed, settled, verdict for plaintiff, or verdict for defendant). | | |
| **Results** | Most primary healthcare claims filed related to alleged misdiagnosis. During a five-year period there were 7224 malpractice claims of which 551 (7.7%) were from primary healthcare practices. Allegations were related to diagnosis in 397 (72.1%), medications in 68 (12.3%), other medical treatment in 41 (7.4%), communication in 15 | | |

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| | (2.7%), patient rights in 11 (2.0%), and patient safety or security in eight (1.5%). Leading diagnoses were cancer (n = 190), heart diseases (n = 43), blood vessel diseases (n = 27), infections (n = 22), and stroke (n = 16). primary healthcare cases were significantly more likely to be settled (35.2% v.s. 20.5%) or result in a verdict for the plaintiff (1.6% vs. 0.9%) compared with non-general medical malpractice claims (P < 0.001). | | |
| **Key finding** | In a Massachusetts insurnace claims database, most primary healthcare claims filed are related to alleged misdiagnosis. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Schwappach, D. L. B. et al. 2012[152]** | | |
| **Title** | *Threats to patient safety in the primary care office: concerns of physicians and nurses* | | |
| **Aim** | To identify threats to patient safety in primary healthcare from the perspective of physicians and nurses. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | A cross-sectional survey was sent to 1260 physicians and nurses from four primary healthcare networks. Respondents were asked to name and rank the patient safety threats they were most concerned about. Content analysis was used to identify recurring themes and then a quantitative assessment of the coded data was conducted. | | |
| **Results** | Of 1260 invited individuals, 630 responded to the survey and 391 (31%) described 936 threats to patient safety. The coding system included 29 categories organised in five themes. Agreement of coders was good (kappa = 0.87; CI: 0.86–0.87). Safety of medication (8.8%), triage by nurses (7.2%) and drug interactions (6.8%) were the threats cited most frequently. Errors in diagnosis (OR = 0.21; CI: 0.09–0.47; P < 0.001), drug interactions (OR = 0.10; CI: 0.04–0.25; P < 0.001) and compliance of patients (OR = 0.28; CI: 0.08–0.96; P = 0.044) were more likely to be cited by physicians. X-rays (OR = 3.34; CI: 1.04–10.71; P = 0.043), confusion of patients or records (OR = 3.28; CI: 1.55–6.94; P = 0.002), hygiene (OR = 3.21; CI: 1.12–9.19; P = 0.030), safety of office rooms (OR = 6.70; CI: 1.46–30.73; P = 0.014), and confidentiality (OR = 7.38; CI: 1.63–33.50; P = 0.010) were more likely to be described by nurses. | | |
| **Key finding** | Physicians and nurses are concerned about diverse threats to patient safety in primary healthcare. The most common concerns were around safety of medication, nurse triage and drug interactions. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Schwartz, A. et al. 2012[105]** | | |
| **Title** | *Uncharted territory: measuring costs of diagnostic errors outside the medical record* | | |
| **Aim** | To estimate the avoidable direct costs associated with contextual errors. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | In the study, Unannounced standardised patients (USPs) visited 111 internal medicine attending physicians from fourteen practice locations, including two academic clinics, two community-based primary healthcare networks with multiple sites, a core safety net provider, and three Veteran Administration government facilities. They presented variants of four previously validated cases that jointly manipulate the presence or absence of contextual and biomedical factors that could lead to errors in management if overlooked. The main outcome measure was contribution of errors to | | |

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| | care costs | | |
| **Results** | Overall, errors in care resulted in predicted costs of approximately $174,000 across 399 visits, of which only $8745 was discernible from a review of the medical records alone (without knowledge of the correct diagnoses). The median cost of error per visit with an incorrect care plan differed by case and by presentation variant within case. | | |
| **Key finding** | Experimental methods, such as the use of USPs, may reveal more information about contextual errors and their substantial costs to the healthcare system. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Singh, H. et al. 2013b[68]** | | |
| **Title** | *Types and origins of diagnostic errors in primary care settings* | | |
| **Aim** | To determine the types of diseases missed and the diagnostic processes involved in cases of confirmed diagnostic errors in primary healthcare settings and to determine whether record reviews could shed light on potential contributory factors to inform future interventions. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Medical records of 190 diagnostic errors detected in primary healthcare visits between 1 October 2006 and 30 September 2007 at two sites via electronic health record triggers were reviewed. Triggers were based on patterns of unexpected return visits after an initial primary healthcare index visit. Information on presenting symptoms, types of missed diagnoses, process breakdowns, potential contributory factors and potential for harm were evaluated. | | |
| **Results** | Most missed diagnoses were common primary healthcare conditions. In total 65 diagnoses were missed across eh 190 errors. Pneumonia (6.7%), decompensated congestive heart failure (5.7%), acute renal failure (5.3%), cancer (5.3%), and urinary tract infections (4.8%) were the most commonly missed diagnoses. Process breakdowns most frequently involved the patient-practitioner clinical encounter (78.9%) but were also related to referrals (19.5%), patient-related factors (16.3%), follow-up and tracking of diagnostic information (14.7%), and performance and interpretation of diagnostic tests (13.7%). A total of 43.7% of cases involved more than one of these processes. Patient-practitioner encounter breakdowns were primarily related to problems with history-taking (56.3%), examination (47.4%), and/or ordering diagnostic tests for further workup (57.4%). Most errors were associated with potential for moderate to severe harm. | | |
| **Key finding** | Diagnostic errors identified in our study involved a large variety of common diseases and had significant potential for harm. Most errors were related to process breakdowns in the patient-practitioner clinical encounter. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Singh, H. et al. 2010b[153]** | | |
| **Title** | *Notification of abnormal lab test results in an electronic medical record: do any safety concerns remain* | | |
| **Aim** | To determine if automated notifications of abnormal laboratory results in an integrated electronic medical record resulted in timely follow-up actions and to determine predictors of timely test follow-up. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | The study was conducted in a large multispecialty ambulatory clinic and five satellite | | |

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| | clinics. An alert tracking system determined whether the alert was acknowledged (i.e. provider clicked on and opened the message) within two weeks of transmission; acknowledged alerts were considered read. Within 30 days of result transmission, record review and provider contact determined follow-up actions (e.g. patient contact, treatment). Multivariable logistic regression models analysed predictors for lack of timely follow-up. | | |
| **Results** | Between May and December 2008, 78,158 tests (hemoglobin A1c, hepatitis C antibody, thyroid-stimulating hormone, and prostate-specific antigen) were performed, of which 1163 (1.48%) were transmitted as alerts; 10.2% of these (119/1163) were unacknowledged. Timely follow-up was lacking in 79 (6.8%), and was statistically not different for acknowledged and unacknowledged alerts (6.4% vs. 10.1%; P = 0.13). Of 1163 alerts, 202 (17.4%) arose from unnecessarily ordered (redundant) tests. Alerts for a new versus known diagnosis were more likely to lack timely follow-up (OR = 7.35; 95% CI: 4.16–12.97), whereas alerts related to redundant tests were less likely to lack timely follow-up (OR = 0.24; 95% CI: 0.07-0.84). | | |
| **Key finding** | Safety concerns related to timely patient follow-up remain despite automated notification of non-life-threatening abnormal laboratory results in the outpatient setting. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Smits, M. et al. 2010[69]** | | |
| **Title** | *Patient safety in out-of-hours primary care: a review of patient records* | | |
| **Aim** | To examine the incidence, types, causes, and consequences of patient safety incidents at general practice cooperatives for out-of-hours primary healthcare and to examine which factors were associated with the occurrence of patient safety incidents. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | A retrospective study of 1145 medical records concerning patient contacts with 17 practices from four general practice cooperatives. Reviewers identified records with evidence of a potential patient safety incident; a physician panel determined whether a patient safety incident had occurred. In addition, the panel determined the type, causes, and consequences of the incidents. Factors associated with incidents were examined in a random coefficient logistic regression analysis. | | |
| **Results** | Patient safety incidents occur in out-of-hours primary healthcare, but most do not result in harm to patients. In 1145 patient records, 27 patient safety incidents were identified, an incident rate of 2.4% (95% CI: 1.5%–3.2%). The most frequent incident type was treatment (56%). All incidents had at least partly been caused by failures in clinical reasoning. The majority of incidents did not result in patient harm (70%). Eight incidents had consequences for the patient, such as additional interventions or hospitalisation. The panel assessed that most incidents were unlikely to result in patient harm in the long term (89%). Logistic regression analysis showed that age was significantly related to incident occurrence: the likelihood of an incident increased with 1.03 for each year increase in age (95% CI: 1.01–1.04). | | |
| **Key finding** | In 1145 patient records, 27 patient safety incidents were identified. The most frequent incident type was treatment (56%). All incidents had at least partly been caused by failures in clinical reasoning. The likelihood of an incident increased with 1.03 for each year increase in age (95% CI: 1.01–1.04). | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |

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| **Author/Year** | **Söderberg, J. et al. 2009[98]** | | |
| **Title** | *Incident reporting practices in the preanalytical phase: low reported frequencies in the primary health care setting* | | |
| **Aim** | To investigate incident reporting practices regarding VBS among staff in PHC in comparison to hospital clinical laboratory staff. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | All staff responsible for venous blood sampling in 70 primary healthcare centres and in two hospital clinical laboratories (317 respondents, response rate 94%) completed a questionnaire. | | |
| **Results** | The investigated incident reporting system is likely to underreport incidents in the preanalytical phase. Of the 277 primary healthcare staff, 69% reported that they had never filed an incident report regarding venous blood sampling. Barriers for not filing incident reports often/always included lack of time (44%) and a complicated reporting procedure (27%). A higher proportion of staff with re-education (43%) had filed at least one incident report as compared to those without re-education (20%; P < 0.001). No differences in incident reporting practices were found between primary healthcare and hospital clinical laboratory staff. | | |
| **Key finding** | Of the primary health care staff, 69% reported that they had never filed an incident report regarding venous blood sampling. Barriers for not filing incident reports often/always included lack of time (44%), and a complicated reporting procedure (27%). | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Tsang, C. et al. 2013[70]** | | |
| **Title** | *Adverse events recorded in English primary care* | | |
| **Aim** | To quantify the rate of adverse events recorded in English primary healthcare and to identify predictors for iatrogenic harm from routinely collected electronic health data. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Read codes were used to identify adverse events from electronic medical records for 74,763 patients (457 practices) included in the GPRD. Adverse events were defined as Read codes chapters S (Injury and poisoning), T (Causes of injury and poisoning) and U (external causes of morbidity and mortality). | | |
| **Results** | Adverse events were experienced by 2.4% of the study population (2048 adverse events (1817 codes) recorded in 1774 patients) between 1999 and 2008. The incidence of adverse events was 6.0 adverse events per 1000 person years. Of all adverse events, 72.1% were related to surgery or medication, falling into post-operative infection (630/1477), postoperative pain (154/1477) and adverse drug reactions (693/1477). After adjustment increased age (64–85 years) (Risk Ratio (RR) =5.62, 95% CI: 4.58–6.91, P < 0.001), more consultations (RR = 2.14, 95% CI: 1.6–23.86, P < 0.001), five or more emergency admissions (RR = 2.08, 95% CI: 1.66–2.60) or a higher comorbid burden (RR = 8.46, 95% CI: 5.68–12.6) were at greater risk of an adverse event. | | |
| **Key finding** | The incidence was 6.0 adverse events per 1000 person-years (95% CI: 5.74–6.27), equivalent to eight adverse events per 10,000 consultations (n = 2,540,877). After adjustment, patients aged 65–84 years (risk ratio [RR] = 5.62, 95% CI: 4.58–6.91; P < 0.001), with the most consultations (RR = 2.14, 95% CI: 1.60–2.86; P < 0.001), five or more emergency admissions (RR = 2.08, 95% CI: 1.66–2.60; P < 0.001), or the most | | |

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| | diseases according to expanded diagnosis clusters (RR = 8.46, 95% CI: 5.68–12.6; P < 0.001) were at greater risk of adverse events. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Tsang, C. et al. 2012[74]** | | |
| **Title** | *Routinely recorded patient safety events in primary care: a literature review* | | |
| **Aim** | To determine the types of adverse events that are routinely recorded in primary healthcare. | | |
| **Design** | Systematic review | | |
| **Methods** | A literature review was conducted to determine the types of adverse events routinely recorded in primary healthcare. | | |
| **Results** | A literature review of adverse events (AEs) in primary healthcare including 15 papers reported estimates of 2.4 adverse events per 1000 population treated in emergency departments and 6.5% of acute hospitalisations were due to AEs. Mortality among AE cases was estimated to be between 0.7% and 2.3%. Prescribing errors, poor communication between clinicians and diagnostic failures were all identified as contributory factors in patient safety incidents. | | |
| **Key finding** | Between 0.7% and 2.3% of deaths following adverse events were attributed to treatment in primary healthcare. In general, there is limited use of routinely collected data to measure adverse events in primary healthcare despite large volumes of data generated. | | |
| **NHMRC evidence** | No specific classification (the studies were not all RCTs) | **Quality score** | 3/11 (Systematic review) |
| **Author/Year** | **Tsang, C. et al. 2010[71]** | | |
| **Title** | *Recording of adverse events in English general practice: analysis of data from electronic patient records* | | |
| **Aim** | To identify the rate and types of adverse events recorded in primary healthcare. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Adverse events in medical records from patients registered with general practices in NHS Brent whose GPs used computer information management systems were identified using clinical record review with Read code chapters (S, T and U). | | |
| **Results** | The rate of adverse events detected using read codes in a cohort of 680,866 consultations (69,682 registered patients, 25 practices) was 0.72 per 100 consultations for injuries due to medical or surgical care and 1.26 per 1000 consultations for adverse drug reactions. Records from the calendar year 2007 were available for 69,682 registered patients from 25 practices, consisting of 680,866 consultations. A number of adverse events could be detected through terms contained in certain chapters of the Read code system. These events include injuries due to surgical and medical care (0.72 cases of per 1000 consultations) and adverse drug reactions (1.26 reactions per 1000 consultations). | | |
| **Key finding** | Effects of drug-related treatment were the most commonly detected adverse event using Read Codes. Greater use of routinely recorded data may help overcome under-reporting of adverse events in voluntary reporting systems in primary healthcare. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |

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| **Author/Year** | **Tse, J. and You, W. 2011[154]** | | |
| **Title** | *How accurate is the electronic health record? A pilot study evaluating information accuracy in a primary care setting* | | |
| **Aim** | To review the medical information in a primary healthcare setting particularly with respect to accuracy of demographics, allergies, past history information and medication list. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Information from patient electronic health records (EHR) for demographics, allergy, medications and past history were compared with information elicited during a face to face meeting with a research assistant. | | |
| **Results** | This study was a pilot study conducted in 33 patients. High levels of accuracy were found for demographic details (94% accurate), moderate accuracy was reported for allergies (61%) Inaccuracies were reported in 51% of medication list with 32.1% medicines being recorde3d inaccurately. Omissions in past history were found for 20% of participants. A total of 33 patients gave consent to participate in this study. High levels of accuracy were found in the area of demographic details (94%). Moderately high levels of accuracy were reported for allergies (61%) but also a considerable percentage of non-recorded information was present (36%). Inaccuracies in medication lists were reported in 51% of records reviewed with 32.1% of all medications being inaccurately recorded. | | |
| **Key finding** | There were no significant associations present between inaccurate data and frequency of practice visits, or those with more than five past medical conditions listed in the EHR. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Wammes, J. J. et al. 2013[155]** | | |
| **Title** | *Organisational targets of patient safety improvement programs in primary care; an international web-based survey* | | |
| **Aim** | To identify the most important organisational items in primary healthcare which could be targeted by programs to improve patient safety. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Individuals with an interest in patients' safety were invited to complete a web-based survey. The semi-structured survey included 52 items specific organisational items based on the European Practice assessment safety indicators. Respondents rated each item with respect to patient safety using a five-point Likert scale. The response frequencies per item were calculated. | | |
| **Results** | Seven organisational items were regarded as 'extremely important' by more than 50% of experts. These were: use of sterile equipment with small surgical procedures (63%), availability of adequate emergency drugs in stock (60%), regular cleaning of facilities (59%), use of sterile gloves when recommended (57%), availability of at least one trained staff member to deal with collapse and the need for resuscitation (56%), adequate information handover when a patient is discharged from the hospital (56%), and periodically training of GPs in basic life support and other medical emergencies (53%). | | |

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| **Key finding** | The authors recommend the evaluation of interventions aimed at the seven organisational items that were consistently prioritised as important for patient safety as the next step for the development of patient safety improvement programmes. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |

### A1.2 Setting: home care setting

| Home care: studies with evidence on risks associated with patient safety in primary healthcare (N = 6 papers) | | | |
|---|---|---|---|
| **Author/Year** | **Abusalem, SK. And Coty, MB. 2011[85]** | | |
| **Setting** | Nursing | | |
| **Title** | *Home health nurses coping with practice care errors* | | |
| **Aim** | To identify home health nurses coping strategies following practice care errors; and to examine the effects of practice care errors on nurses clinical practice. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | The agency directors of 104 home health agencies within a southeastern US state were invited to paticipate. Surveys were sent to home health nursing staff at these agencies via the directors, and returned to the researchers. The survey included sociodemographic data, and the Modified Wu et al. 2003 care erros survey. This hospital physician survey was adapted for the home nursing setting. The study addressed: a) causes of errors, b) nurse's feelings and emotional distress (ways of coping), and c) changes in practice. To assess coping mechanisms and emotional responses to errors, coping mechanism scales were used for emotional distress, accepting responsibility, seeking emotional support and emotional self-control. To assess changes in practice, 11 individual items were used. | | |
| **Key finding** | The most commonly reported change in practice following a care error experience was paying more attention to detail, personally confirming patient detail and changing the organisation of data. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Blais, R. et al. 2013[60]** | | |
| **Title** | *Assessing adverse events among home care clients in three Canadian provinces using chart review* | | |
| **Aim** | The objectives of this study were to document the incidence rate and types of adverse events (AEs) among home care (HC) clients in Canada; identify factors contributing to these AEs; and determine to what extent evidence of completion of incident reports were documented in charts where AEs were found. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | A retrospective cohort study based on expert chart review of a random sample of 1200 charts of clients discharged in fiscal year 2009–2010 from publicly funded Home Care programmes in Manitoba, Quebec and Nova Scotia, Canada. Selected charts were reviewed using an adaptation for HC of the standard method developed for hospital chart review used in Ontario Canada. Each selected HC chart was first assessed by one member of a team of trained nurses for the presence of one or more of 24 screening criteria potentially sensitive to the occurrence of an AE. An Adverse Event (AE) was identified when a physician reviewer determined that all three AE criteria were met: there was an injury and the client experienced disability, death or increased use of services, and it was likely caused by healthcare. Physician reviewers determined whether the client suffered any unintended injury, harm or complication. If there was no injury, the review process stopped. If there was an injury reviewers determined if the injury resulted in disability, death or increased use of healthcare services. Physician | | |

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| | reviewers also judged the preventability of each AE using the six-point scale (1 = virtually unpreventable, 2 = slight to modest preventability, 3 = preventability not quite likely (less than 50/50, but 'close call'), 4 = preventability more than likely (more than 50/50, but 'close call'), 5 = strongly preventable, 6 = virtually certain for preventability). At both stages of the review process, inter-rater reliability was also assessed on a random sample of 10% of the charts using the κ statistic. Client demographics were recorded and an adverse event rate was calculated. Bivariate analysis and forward stepwise multivariate logistic regression were used to identify factors associated with the risk of having an AE. | | |
| **Results** | 4.2% (95% CI: 3.0%–5.4%) of HC patients discharged in a 12-month period experienced an AE. For clients with lengths of stay in HC of less than one year, the AE incidence rate per client-year was 10.1% (95% CI: 8.4%–11.8%); 56% of AEs were judged preventable. The most frequent AEs were injuries from falls, wound infections, psychosocial, behavioural or mental health problems and adverse outcomes from medication errors. More comorbid conditions (OR = 1.15; 95% CI: 1.05–1.26) and a lower instrumental activities of daily living score (OR = 1.54; 95% CI: 1.16–2.04) were associated with a higher risk of experiencing an AE. Clients' decisions or actions contributed to 48.4% of AEs, informal caregivers 20.4% of AEs, and healthcare personnel 46.2% of AEs. Only 17.3% of charts with an AE contained documentation that indicated an incident report was completed, while 4.8% of charts without an AE had such documentation. | | |
| **Key finding** | 4.2% (95% CI: 3.0%–5.4%) of home care clients experienced an adverse event. Injurious falls were the most common events. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Doran, D. M. et al. 2014[47]** | | |
| **Title** | *Identification of serious and reportable events in home care: a Delphi survey to develop consensus* | | |
| **Aim** | To assess which client events should be considered reportable and preventable in home care (HC) settings in the opinion of HC safety experts. | | |
| **Design** | Descriptive (Consensus method) | | |
| **Methods** | 26 people with recognised expertise in home care client safety were recruited to participate. A 29-item electronic survey that included potential HC safety issues was used in a two-round Delphi study. 24 completed round one (19 of these were 'regulated health professionals including nurses, dietitians, therapists and pharmacists). 21 participants completed round two. The main outcome measures were perceived reportability and preventability of patient safety events in the Home Care setting. | | |
| **Results** | The events perceived as being most reportable and preventable included the following: a serious injury related to inappropriate client service plan (e.g. incomplete/inaccurate assessments, poor care plan design, flawed implementation); an adverse reaction requiring emergency room visit or hospitalisation related to a medication-related event; a catheter-site infection (e.g. a new peritoneal dialysis infection or peritonitis); any serious event related to care or services that are contrary to current professional or other practice standards (e.g. incorrect treatment regimen, theft, retention of a foreign object in a wound, individual practicing outside scope or competence).The researchers call for a | | |

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| | standardised, coordinated HC adverse event reporting system to improve the collection of meaningful data about safety in home care. | | |
| **Key finding** | A list of reportable and preventable patient safety incidents in the homecare setting was generated by a group of experts in this field. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Doran, D. M. et al. 2009[56]** | | |
| **Title** | *The nature of safety problems among Canadian homecare clients: evidence from the RAI-HC© reporting system* | | |
| **Aim** | To identify the nature of patient safety problems among Canadian homecare (HC) clients, using data collected through the RAI-HC assessment instrument (standard assessment in Canadian Home Care setting). | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | A secondary analysis of data collected through the CIHI Home Care Reporting System and the Ontario HC reporting system. The safety risk analyses used intake assessments from all three jurisdictions, whereas the adverse event/unsafe care analyses used pairs of the intake assessment and the subsequent assessment. There were 89,023 cases with paired data available for determining incidence of adverse events. Two types of safety indicators were studied: safety risk and adverse events. Safety risks are defined as characteristics of the client or the living situation that place a client at risk of adverse outcome. Adverse events are defined as an unintended injury or complications that result in disability, death or increased use of HC resources and is caused by health care management. The safety risks were largely based on what was identified in the previous literature and on data collected in the RAI-HC assessment instrument. The safety risks were categorised into four types: client physical or cognitive factors, behavioural factors, living situation and health care management factors. | | |
| **Results** | A list of patient safety risk factors was found that included specific detail in the areas of client characteristics (e.g. a decline in cognitive function); client behavioural characteristics (e.g. a history of two or more falls); client living situations (e.g. unsafe housing); and health care management factors (e.g. polypharmacy). Polypharmacy was the most common safety risk. New fall (11%), unintended weight loss (9%), new emergency room (ER) visits (7%) and new hospital visits (8%) were the most prevalent potential adverse events identified. A small proportion of the HC clients experienced a new urinary tract infection (2%). | | |
| **Key finding** | New fall (11%), unintended weight loss (9%), new emergency room (ER) visits (7%) and new hospital visits (8%) were the most prevalent potential adverse events identified in our study. A small proportion of the HC clients experienced a new urinary tract infection (2%). | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Masotti, P. et al. 2010[120]** | | |
| **Title** | *Adverse events experienced by homecare patients: a scoping review of the literature* | | |
| **Aim** | To map the extent and range of literature relevant to adverse events experienced by homecare patients. | | |
| **Design** | Non-systematic review | | |
| **Methods** | Papers included research studies, review articles, policy papers, opinion articles | | |

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| | and legal briefs. Inclusion criteria were: (i) homecare directed services provided in the home by healthcare professionals or caregivers, (ii) addressed a characteristic relevant to patient experienced adverse events (e.g. occurrences, rates, definitions, prevention or outcomes), and (iii) were in English. Data extraction A pool of 1007 articles was reduced to 168 after analysis. Data were charted according to six categories: definitions, rates, causes, consequences, interventions and policy. | | |
| **Results** | Eight categories emerged: adverse drug events, line-related, technology-related, infections and urinary catheters, wounds, falls, studies reporting multiple rates and other. Reported overall rates of adverse events ranged from 3.5–15.1% with higher rates for specific types. Few intervention studies were found. Adverse events were commonly associated with communication problems. Policy suggestions included the need to improve assessments, monitoring, education, coordination and communication. | | |
| **Key finding** | The key categories identified in the small body of literature were: adverse drug events, line related, technology related, infections/urinary catheters, wounds and falls. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Sears, N. et al. 2013[67]** | | |
| **Setting** | Home care | | |
| **Title** | *The incidence of adverse events among home care patients* | | |
| **Aim** | To estimate the incidence of adverse events (AEs) among home care patients and preventability ratings and identify risk factors, AE types and factors associated with AEs. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | This study used a stratified, randomised sample of home care patients discharged in the fiscal year 2004/05. Trained nurse reviewers completed retrospective chart abstractions; charts for cases that were positive for screening criteria suggesting the presence of AEs were reviewed by trained physicians to determine the presence of and preventability of AEs. The main out come measures were prevalence and types of AEs; ratings of preventability. | | |
| **Results** | At least one screening criterion was positively identified in 286 (66.5%) of 430 cases. Physician reviewers identified 61 AEs in 55 (19.2%) of the 286 (12.8% of the 430) cases. The AE rate was 13.2 per 100 home care cases [95% CI: 10.4%–16.6%; standard error 1.6%]. 32.7% (20 of 61 AEs) of the AEs were rated as having >50% probability of preventability; six deaths (10.9% of patients with an AE; 1.4% of all patients) occurred in AE-positive patients. The most common AEs were falls and adverse drug events. | | |
| **Key finding** | The incidence rate of AEs of 13.2% suggests a significant number of home care patients experience AEs, one-third of which were considered preventable. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |

### A1.3 Setting: midwifery setting

| Midwifery: studies with evidence on risks associated with patient safety in primary healthcare (N = 4 papers) | | | |
|---|---|---|---|
| **Author/Year** | **Lawton, R. et al. 2010[36]** | | |
| **Title** | *Using vignettes to explore judgments of patients about safety and quality of care: the role of outcomes and relationship with the care provider* | | |
| **Aim** | To investigate the extent to which outcome of care and relationship with the care provider impact on the judgments of responsibility and blame as well as decisions about likelihood of making a complaint. | | |
| **Design** | Quasi-experimental (one group post-test) | | |
| **Methods** | Ninety-eight mothers made seven ratings of responsibility, blame and action in response to four hypothetical vignettes in a questionnaire. The vignettes described poor quality ante-natal care in which outcome and relationship with the health-care provider were systematically manipulated across different versions of the questionnaire. | | |
| **Results** | Participants made significantly more negative ratings in response to vignettes describing a bad outcome and those that described a poor relationship with the health professional. However, whilst ratings of seriousness and likelihood of making a complaint were most influenced by the manipulation of outcome in the vignettes, judgments of blame and responsibility were most effected by the depiction of relationship with the health professional as good or bad. Moreover, for three of the four vignettes, relationship rather than outcome most strongly influenced overall ratings of care. | | |
| **Key finding** | Patients' judgments about the quality and safety of care they receive are affected by the perceived relationship with the carer and the outcome of the procedure. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Martijn, L. et al. 2013[121]** | | |
| **Title** | *Adverse outcomes in maternity care for women with a low risk profile in the Netherlands: a case series analysis* | | |
| **Aim** | To perform a structural analysis of determinants of risk of critical incidents in care for women with a low risk profile at the start of pregnancy with a view on improving patient safety. | | |
| **Design** | Descriptive (case series) | | |
| **Methods** | We included 71 critical incidents in primary midwifery care and subsequent hospital care in case of referral after 36 weeks of pregnancy that were related to substandard care and for that reason were reported to the Health Care Inspectorate in the Netherlands in 36 months (n = 357). We performed a case-by-case analysis, using a previously validated instrument which covered five broad domains: healthcare organisation, communication between healthcare providers, patient risk factors, clinical management, and clinical outcomes. | | |
| **Results** | Determinants that were associated with risk concerned healthcare organisation (n = 39 incidents), communication about treatment procedures (n = 19), risk assessment by the (n = 12), clinical management by telephon out-of-hours setting (n = 9). There were five cases of maternal death, eight cases of severe maternal morbidity, 42 perinatal deaths and 12 critical | | |

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| | incidents with severe morbidity for the child. Suboptimal prenatal risk assessment, a delay in availability of health care providers in urgent situations, miscommunication about treatment between care providers, and miscommunication with patients in situations with a language barrier were associated with safety risks. | | |
| **Key finding** | Suboptimal prenatal risk assessment, a delay in availability of health care providers in urgent situations, miscommunication about treatment between care providers, and miscommunication with patients in situations with a language barrier were associated with safety risks. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Martijn, L. L. M. et al. 2013[52]** | | |
| **Title** | *Patient safety in midwifery-led care in the Netherlands* | | |
| **Aim** | To describe the incidence and characteristics of patient safety incidents in midwifery-led care for low-risk pregnant women. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Multi methods study of prospective incident reporting by midwives from 20 midwifery practices during two weeks; questionnaire on safety culture and retrospective content analysis of 1000 patient records in 2009. The main outcome measures were incidence, type, impact and causes of safety incidents. | | |
| **Results** | In the 1000 patient records involving 14,888 contacts, 86 safety incidents were found with 25 of these having a noticeable effect on the patient. Low-risk pregnant women in midwifery care had a probability of 8.6% for a safety incident (95% CI: 4.8–14.4). In nine safety incidents, temporary monitoring of the mother and/or child was necessary. In another six safety incidents, reviewers reported psychological distress for the patient. Hospital admission followed from one incident. No safety incidents were associated with mortality or permanent harm. The majority of incidents found in the patient records concerned treatment and organisational factors. | | |
| **Key finding** | Low-risk pregnant women in midwifery care had a probability of 8.6% for a safety incident (95% CI: 4.8–14.4). The majority of incidents found in the patient records concerned treatment and organisational factors. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Not applicable |
| **Author/Year** | **Martijn, L. 2012[156]** | | |
| **Title** | *Patient safety in midwifery care for low-risk women: instrument development* | | |
| **Aim** | To develop and test an instrument for safety assessment of midwifery care. | | |
| **Design** | Mixed methods | | |
| **Methods** | A structured approach was followed for instrument development. First, we reviewed the literature on patient safety in general and obstetric and midwifery care in particular. We identified five domains of patient risk: organisation, communication, patient-related risk factors, clinical management, and outcomes. We then developed a prototype to assess patient records and, in an iterative process, reviewed the prototype with the help of a review team of midwives and safety experts. The instrument was pilot tested for content validity, reliability, and feasibility. | | |
| **Results** | Five domains of midwifery care were identified from the literature review: organisation, communication, patient risk factors, clinical management, and outcomes. A 32 item instrument was piloted in 18 midwifery practices and shown to have good reliability (level of agreement 75%) and content validity. | | |

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| **Key finding** | A reliable and valid tool for safety assessment in midwifery care was developed. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |

### A1.4 Setting: occupational therapy setting

| Occupational therapy: studies with evidence on risks associated with patient safety in primary healthcare (N = 1 paper) | | | |
|---|---|---|---|
| **Author/Year** | **Mu, K. et al. 2011[115]** | | |
| **Title** | *Improving client safety: strategies to prevent and reduce practice errors in occupational therapy* | | |
| **Aim** | To investigate strategies to prevent or reduce practice errors used by occupational therapists practicing in physical rehabilitation and geriatrics. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Four focus groups (n = 34 occupational therapists) were held. Participants responded to open ended, guiding questions regarding practice error. Data collected was analysed thematically. | | |
| **Results** | Four main themes concerning strategies to reduce practice error were identified from four focus groups held with occupational therapists (n = 34): 1) strengthen orientation and mentoring for new therapist; 2) ensure competency through performance competency checks; 3) enhance existing or establish new safety policies and procedures; and 4) advocate for the professional for systemic change. | | |
| **Key finding** | Occupational therapists implement various discreet strategies to prevent or reduce practice errors and improve patient safety. The authors call for a functional national database for error reporting. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |

### A1.5 Setting: pharmacy setting

| Pharmacy: studies with evidence on risks associated with patient safety in primary healthcare (N = 1 paper) | | | |
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| **Author/Year** | **Newham, R. et al. 2014[35]** | | |
| **Title** | *Development and psychometric testing of an instrument to measure safety climate perceptions in community pharmacy* | | |
| **Aim** | To develop a psychometrically sound instrument to measure perceptions of safety climate within Scottish CPs. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | The first stage, development of a preliminary instrument, comprised three steps: (i) a literature review, (ii) focus group feedback, and (iii) content validation. The second stage, psychometric testing, consisted of three further steps: (iv) a pilot survey, (v) a survey of all CP staff within a single health board in NHS Scotland, and (vi) application of statistical methods, including principal components analysis and calculation of Cronbach's reliability coefficients, to derive the final instrument. The instrument was piloted using a modified Delphi technique in 50 community pharmacies. | | |
| **Results** | The preliminary questionnaire was developed through a process of literature review and feedback. This questionnaire was completed by staff in 50 CPs from the 131 (38%) sampled. 250 completed questionnaires were suitable for analysis. Psychometric evaluation resulted in a 30-item instrument with five positively correlated safety climate factors: leadership, teamwork, safety systems, communication and working conditions. Reliability coefficients were satisfactory for the safety climate factors ($\alpha > 0.7$) and overall ($\alpha = 0.93$). | | |
| **Key finding** | A psychometrically sound instrument to measure perceptions of safety climate within Scottish community pharmacies was developed. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |

### A1.6 Setting: chiropractic setting

| Chiropractic: studies with evidence on risks associated with patient safety in primary healthcare (N = 1 paper) | | | |
|---|---|---|---|
| **Author/Year** | **Zaugg, B. and Wangler, M. 2009[75]** | | |
| **Title** | *A model framework for patient safety training in chiropractic: a literature synthesis* | | |
| **Aim** | To develop an evidence-focused and work-based model framework for patient safety training in chiropractic care. | | |
| **Design** | Non-systematic review | | |
| **Methods** | A literature search was conducted using ERIC, EBESCO host, PubMed and Google Scholar. Associations between Bland's adapted characteristics were explored. | | |
| **Results** | A non-systematic review including 57 papers was conducted. Associations were found between the literature and "mission and goals", "leadership", "need for change", "organisational structure", "scope and complexity of innovation", "cooperative climate", "participation by organisation's members", "training support and reward structure" and "evaluation" | | |
| **Key finding** | Based on findings from a systematic review of 55 articles, leadership, commitment, and communication together with trust and openness to build a culture of patient safety are prerequisites for successful reporting and learning. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |

### A1.7 Setting: dentistry

| Dentistry: studies with evidence on risks associated with patient safety in primary healthcare (N = 2 papers) | | | |
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| **Author/Year** | **Hiivala, N. et al. 2013[116]** | | |
| **Setting** | Dentistry | | |
| **Title** | *Patient safety incident prevention and management among Finish dentists* | | |
| **Aim** | To assess current patient safety incident (PSI) prevention measures and risk management practices among Finnish dentists. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | A total of 1041 dentists practicing in the private or public sectors in southern Finland completed an online questionnaire concerning PSI prevention, PSI-reporting systems, feedback and knowledge gained from device incidents and patient-generated safety information and the knowledge of national PS-guidance. The answers were handled anonymously. Statistical evaluations were performed using chi-square analysis. | | |
| **Results** | Dentists suggested multiple methods for preventing PSIs related to dental diagnostics, various treatments, equipment and devices, medications, communication, infection control and general practice safety. Preventive methods reported most frequently included working with caution and forethought, keeping accurate patient records and the availability of correct patient information. A special PSI-reporting system was used by less than one third of respondents. Feedback received on PS-related data and the utilisation of guidebooks varied significantly between the studied dentist groups. | | |
| **Key finding** | Wide variation exists in PSI prevention and risk management practices among Finnish dentists. The more dentists know about PS risks, the easier it is for them to recognise situations possibly leading to patient harm. Anonymous PSI reports, patient complaints and claims data should, therefore, be actively used for mutual learning. Increased patient safety education in dentistry is also needed. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Jonsson, L. and Gabre, P. 2014[53]** | | |
| **Setting** | Dentistry | | |
| **Title** | *Adverse events in public dental service in a Swedish county – a survey of reported cases over two years* | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Aim** | To analyse the adverse events reported by dental personnel and patients in the public dental service (PDS) in a Swedish county, and to determine if reported cases of adverse events were also detectable in the patient's records. | | |
| **Methods** | All reports made during 2010 and 2011 by dental staff to an electronic incident reporting system were examined to determine the nature, severity and cause of the adverse events and the associated demographics of the reporter and the affected patients. In addition, all reported incidents from patients to the insurance company and the patient complaint committee for the same time period was examined. Duplicate reports and those with no relevance to patient safety (e.g. an incorrect invoice) were excluded. For the 2011 period, all of the electronic incident reports were matched to the patient's records which were examined to see if the event was described, and whether there was a record of any information given to the patient. | | |

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| **Results** | 273 events reported by dental personnel, 53 events reported by patients to the insurance company and 53 events reported by patients to the patient committee were analysed. The nature of the adverse events was classified in 13 groups. Among young patients, delayed diagnosis and therapy dominated and among patients over 20 years the most frequent reports dealt with inadequate treatments, especially endodontic treatments. In 29% of the events there was no documentation of the adverse event in the records, which has implications for retrospective record review and the use of trigger tools. 49% of cases had no report about patient information. The majority of the reports from dental personnel were made by dentists (69%). The estimate of 'serious' events was 4%, and usually associated with delayed diagnoses. | | |
| **Key finding** | Inadequate treatment was the most common adverse event (29%) reported in a database of 379 dental adverse events. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Weak |

### A1.8 Setting: mixed primary healthcare settings

| Mixed primary healthcare settings: studies with evidence on risks associated with patient safety in primary healthcare (N = 18 papers) | | | |
|---|---|---|---|
| **Author/Year** | **Bodur, S and Filiz, E. 2009[45]** | | |
| **Setting** | Mixed primary healthcare services | | |
| **Title** | *A survey on patient safety culture in primary healthcare services in Turkey* | | |
| **Aim** | To evaluate the patient safety culture in primary healthcare units. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Twelve primary healthcare services were randomly selected from 37 primary healthcare services in the metropolitan city centre of Konya, Turkey. Each centre serves 20,000 people. Primary healthcare services are staffed by a team of four to six GPs, a nurse or midwife for every 3000 people, several health officers and other ancillary staff. A self-administered questionnaire survey was completed in 2008, being a modification of the Hospital Survey on Patient Safety Culture (HSOPSC) developed by the AHRQ for hospitals. Questionnaires and informed consent forms were hand-distributed to 212 staff. | | |
| **Results** | One-hundred-and-eighty-five participants who gave consent completed the survey (response rate 85%). The numbers of the four types of healthcare staff included in the study were: 54 GPs (30%), 48 (27%) nurses, 51 (28%) midwives and 27 (15%) health officers. The percentage of positive responses was highest for 'teamwork within units' (76%), 'overall perceptions of safety' (59%) and 'teamwork across hospital units' (56%). The lowest scores were for 'frequency of event reporting' (12%) and 'non-punitive response to error' (18%). In the multivariate analysis, staff who had been working more than 10 years in their present unit displayed a significantly lower patient safety culture score (P = 0.05). The percentage of staff who rated the level of patient safety in primary healthcare units as 'good' or 'perfect' was 42%, which was lower than the US benchmark score (obtained from 58 US hospitals having a bed size between six and 24) for the survey of 76% (P = 0.001) (Table 4). In addition, 87% of GPs, 92% of nurses and 91% of other healthcare staff were shown as 'never' reporting errors. This frequency of event reporting (10%) was very much lower than the US benchmark score of 50% (P = 0.001). | | |
| **Key finding** | This study used the AHRQ patient safety culture questionnaire developed for hospitals to explore patient safety in primary healthcare. The authors conclude that non-punitive responses to error and error-reporting should be improved, and the development of error reporting based on voluntary and consistent event reports is recommended to improve patient safety in primary healthcare services. An environment in which healthcare staff can report present or possible errors without fear of punishment should be established. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Buetow, S. et al. 2010[157]** | | |
| **Setting** | GP and community pharmacy, and patients | | |
| **Title** | *Approaches to reducing the most important patient errors in primary health-care: patient and professional perspectives* | | |
| **Aim** | To assess how patients and primary healthcare professionals perceive the relative importance of different patient errors as a threat to patient safety; to suggest what | | |

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| | these groups believe may be done to reduce the errors, and how. | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Eleven purpose designed focus groups (eight patient and three professional) were invited to discuss the main types of errors that patients can make, and then the individuals in the group selected the five individual errors that they felt had the most important impact on patient safety. They were also asked to suggest and discuss approaches to managing the errors ranked as most important by the group overall. Strategies for reducing patient error were categorised on the basis of emergent themes. | | |
| **Results** | The total number of participants was 83, including 64 patients. Each group ranked the importance of possible patient errors identified through the nominal group exercise. Approaches to managing the most important errors were then discussed. There was considerable variation among the groups in the importance rankings of the errors. Two key patient errors identified were non-adherence and forgetfulness. The authors suggest four inter-related actions to manage patient error ('GERM'): Grow relationships; Enable patients and professionals to recognise and manage patient error; be Responsive to their shared capacity for change; and Motivate them to act together for patient safety. Cultivation of this GERM of safe care was suggested to benefit from 'individualised community care'. In this approach, primary healthcare professionals individualise, in community spaces, population health messages about patient safety events. This approach may help to reduce patient error and the tension between personal and population health-care. | | |
| **Key finding** | Four inter-related actions to manage patient error were identified: Grow relationships; Enable patients and professionals to recognise and manage patient error; be Responsive to their shared capacity for change; and Motivate them to act together for patient safety. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Callen, J. et al. 2012[76]** | | |
| **Setting** | Mixed primary healthcare | | |
| **Title** | *Failure to follow up test results for ambulatory patients: a systematic review* | | |
| **Aim** | To systematically review evidence quantifying the extent of failure to follow up test results and the impact for ambulatory patients. | | |
| **Design** | Systematic review | | |
| **Methods** | Medline, CINAHL, Embase, Inspec and the Cochrane Database were searched for English-language literature from 1995–2010. Studies which provided documented quantitative evidence of the number of tests not followed up for patients attending ambulatory settings including: outpatient clinics, academic medical or community health centres, or primary healthcare practices. Four reviewers independently screened 768 articles. | | |
| **Results** | Nineteen studies met the inclusion criteria and reported wide variation in the extent of tests not followed-up: 6.8% (79/1163) to 62% (125/202) for laboratory tests; 1.0% (4/395) to 35.7% (45/126) for radiology. The impact on patient outcomes included missed cancer diagnoses. Test management practices varied between settings with many individuals involved in the process. There were few guidelines regarding responsibility for patient notification and follow-up. Quantitative evidence of the effectiveness of electronic test management systems was limited although there was a | | |

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| | general trend towards improved test follow-up when electronic systems were used, and a suggestion that having test management processes supported by hybrid paper and electronic systems has also been shown to create problems with test follow-up. Solutions suggested included policies relating to responsibility, timing and process of notification; integrated information and communication technologies facilitating communication; and consideration of the multidisciplinary nature of the process and the role of the patient. | | |
| **Key finding** | Failure to follow up test results is an important safety concern which requires urgent attention. Solutions should be multifaceted and include: policies relating to responsibility, timing and process of notification; integrated information and communication technologies facilitating communication; and consideration of the multidisciplinary nature of the process and the role of the patient. | | |
| **NHMRC evidence** | No specific level (studies were not all RCTs) | **Quality score** | 4/11 (Systematic review) |
| **Author/Year** | **Creswell, K. et al. 2013[9]** | | |
| **Setting** | Mixed primary healthcare | | |
| **Title** | *Global research priorities to better understand the burden of Iatrogenic harm in primary care: an international Delphi exercise* | | |
| **Aim** | To identify a shared vision on relevant contexts of primary healthcare and areas that would need further study to better understand the burden of harm in primary healthcare settings internationally. | | |
| **Design** | Descriptive other | | |
| **Methods** | A three-stage modified Delphi exercise was undertaken during a two-day expert meeting in February 2012 at the WHO headquarters in Geneva, Switzerland. Attendees were experts from academic, policy, and clinical backgrounds with expertise relating to patient safety in primary healthcare settings. Participants were provided with a review of the literature surrounding the frequency of patient safety incidents, burden of harm, and preventability of these incidents in primary healthcare. A list of candidate areas identified from the literature were grouped into three sections with corresponding statements for low-, middle-, and high-income countries. The participants scored items in terms of importance and were able to add free-text comments. | | |
| **Results** | There was over 80% agreement across 15 items in low-income country contexts, 16 items in middle-income country contexts, and 16 items in high-income country contexts. Family practice and pharmacy were important primary healthcare contexts across all income categories. Additional contexts identified as warranting particular attention were community midwifery and nursing in low-income countries, and care homes in high-income countries. The factors responsible for patient safety incidents that were identified as particularly needing further investigation in low- and middle-income settings included counterfeit drugs and errors in the execution of clinical tasks, whilst additional items in high-income settings were systems management and technology-related issues. | | |
| **Key finding** | Nine patient safety priority areas for future research were identified; chart/records completeness, communication within health professional teams, communication between health professional teams, data management, laboratory investigations, teamwork, care transitions, wrong or missed diagnoses, wrong treatment decision. | | |

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| **NHMRC evidence** | No specific level | **Quality score** | Not applicable |
| **Author/Year** | **Holden, L. M. et al. 2009[38]** | | |
| **Setting** | GP, nursing, pharmacy, technicians | | |
| **Title** | *Patient safety climate in primary care: age matters* | | |
| **Aim** | To determine of comparable differences in safety climate exist among professional groups in ambulatory care settings and what difference exist regarding safety climate score among different age groups working primary healthcare. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | All professional primary healthcare staff working at four air force ambulatory care clinics: physicians, nurse practitioners, registered nurses, pharmacists and technicians were invited to participate in a questionnaire. The Safety Attitudes Questionnaire was used to measure perceived safety climate. | | |
| **Results** | There were no significant differences between professional groups on total safety score on five of the six subscales. There were significant differences on total safety score based on age with staff members younger than 31 years scoring lower on the overall safety score mean (64.8; $P < 0.001$) compared with the 32–41 year old group (74.3) and the 42–63 year group (73.8). The youngest age group also had the lowest scores on the subscales of teamwork climate, safety climate, perception of management and job satisfaction (all subscales $P < 0.03$). These differences persisted after controlling for professional group. | | |
| **Key finding** | Difference between professional groups regarding safety culture are limited, however age related differences were noted with younger professionals having lower safety culture scores. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Lang, S. et al. 2014[158]** | | |
| **Setting** | Primary Healthcare | | |
| **Title** | *Immunisation errors reported to a vaccine advice service: intelligence to improve practice* | | |
| **Aim** | To review and describe all errors reported from a population-based vaccine advice service. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | All enquiries from 2009–2011, categorised on the VACCSline database as 'vaccine error' were analysed and subjected to a detailed free-text review. The VACCSline database in an advice service provided jointly by the Thames Valley Public Health Service and the Oxford Vaccine group. | | |
| **Results** | Of 4301 enquiries, 158 (3.7%) concerned vaccine errors. The greatest frequency of errors, 145 (92.9%) concerned immunisations delivered in primary healthcare services; 92% of all errors occurred during either vaccine selection and preparation or history checking and scheduling. Administration of the wrong vaccine was the most frequent error recorded in 33.3% of reports. A shared first letter of the vaccine name was noted to occur in 13 error reports in which the incorrect vaccine was inadvertently administered. Consultations involving pairs of siblings were associated with various errors in seven enquiries. Failure to revaccinate after spillage (seven reports) showed a widespread knowledge gap in this area. None of the errors were identified as leading to patient harm. | | |

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| **Key finding** | Of 4301 enquiries to the Vaccine Advice for CliniCians Service, 158 (3.7%) concerned vaccine errors. Substantial harm does not appear to occur as a result of vaccine errors. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Marchon, S. G. and Mende, W. V. Jr 2014[55]** | | |
| **Setting** | Mixed primary healthcare | | |
| **Title** | *Patient safety in primary care: a systematic review* | | |
| **Aim** | The aim of this study was to identify methodologies to evaluate incidents in primary healthcare, types of incidents, contributing factors, and solutions to make primary healthcare safer. | | |
| **Design** | Systematic review | | |
| **Methods** | A systematic literature review was performed in the following databases: PubMed, Scopus, LILACS, SciELO, and Capes, from 2007–2012, in Portuguese, English, and Spanish. | | |
| **Results** | Thirty-three articles were selected: 26% on retrospective studies, 44% on prospective studies, including focus groups, questionnaires, and interviews, and 30% on cross-sectional studies. The most frequently used method was incident analysis from incident reporting systems (45%). The most frequent types of incidents in primary healthcare were related to medication and diagnosis. The most relevant contributing factors were communication failures among member of the healthcare team. | | |
| **Key finding** | The most frequently used method was incident analysis from incident reporting systems (45%). The most frequent types of incidents in primary healthcare were related to medication and diagnosis. The most relevant contributing factors were communication failures among member of the healthcare team. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | 5/11 |
| **Author/Year** | **Martijn, L. et al. 2013[159]** | | |
| **Setting** | General practice, dental, midwifery, allied health | | |
| **Title** | *Are health professionals' perceptions of patient safety related to figures on safety incidents?* | | |
| **Aim** | To explore whether health care professionals' perceptions of patient safety in their practice were associated with the number of patient safety incidents identified in patient records. | | |
| **Design** | Mixed methods | | |
| **Methods** | A retrospective audit of 50 patient records in each practice was performed to identify patient safety incidents in each of the practices and a survey among health professionals to identify their perceptions of patient safety. In total seventy primary healthcare practices of general practice, general dental practice, midwifery practices and allied health care practices were used in the study. | | |
| **Results** | All health professions felt that 'communication breakdowns inside the practice' as well as 'communication breakdowns outside the practice' and 'reporting of patient safety concerns' were a threat to patient safety in their work setting. We found little association between the perceptions of health professionals and the number of safety incidents. The only item with a significant relation to a higher number of safety incidents referred to the perception of 'communication problems outside the practice' as a threat to patient safety. | | |
| **Key finding** | There was little association between health professionals' perceptions of safety and | | |

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| | number of incidents. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Scobie, A. et al. 2009[160]** | | |
| **Setting** | Primary healthcare | | |
| **Title** | *The medical home in Canada: patient perceptions of quality and safety* | | |
| **Aim** | To explore the relationship of a medical home to self-reported risk factors for medical error and self-reported indicators for quality of care. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | Canadian data from 3003 respondents to the 2007 International health policy Survey in Seven Countries was used. Patients were considered to have a medical home if: 1) they had a regular doctor or point of care, 2) the doctor/staff at the place of care always know important information about their medical history, 3) the place of care is easy to contact by telephone during regular office hours, and 4) the doctor/staff always coordinate care from other sources of care. | | |
| **Results** | Almost half of all respondents (48.8%) has a medical home. Individuals with a medical home reported greater access to health services. Fewer individuals with a medical home reported they had been given the wrong medicine in the past two years. A greater percentage of individuals with a medical home (35.8% versus 20.6%) were confident in the quality and safety of the care they receive. Respondents with a medical home had better patient knowledge than those without (86.6% versus 54.0%) There was no difference in emergency department use. | | |
| **Key finding** | The presence of a medical home is associated with improved self-reported access to health care services, coordination of and confidence in services received, and provider knowledge and fewer medical errors. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Singh, H. et al. 2010b[153]** | | |
| **Setting** | General practice | | |
| **Intervention** | Automated notification of abnormal laboratory test rests | | |
| **Title** | *Notification of abnormal lab test results in an electronic medical record: do any safety concerns remain* | | |
| **Aim** | To determine if automated notifications of abnormal laboratory results in an integrated electronic medical record resulted in timely follow-up actions and to determine predictors of timely test follow-up. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | The study was conducted in a large multispecialty ambulatory clinic and five satellite clinics. An alert tracking system determined whether the alert was acknowledged (i.e. provider clicked on and opened the message) within two weeks of transmission; acknowledged alerts were considered read. Within 30 days of result transmission, record review and provider contact determined follow-up actions (e.g. patient contact, treatment). Multivariable logistic regression models analysed predictors for lack of timely follow-up. | | |
| **Results** | Between May and December 2008, 78,158 tests (haemoglobin A1c, hepatitis C antibody, thyroid-stimulating hormone, and prostate-specific antigen) were performed, of which 1163 (1.48%) were transmitted as alerts; 10.2% of these (119/1163) were unacknowledged. Timely follow-up was lacking in 79 (6.8%), and was | | |

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| | statistically not different for acknowledged and unacknowledged alerts (6.4% vs. 10.1%; P = 0.13). Of 1163 alerts, 202 (17.4%) arose from unnecessarily ordered (redundant) tests. Alerts for a new versus known diagnosis were more likely to lack timely follow-up (OR = 7.35; 95% CI: 4.16–12.97), whereas alerts related to redundant tests were less likely to lack timely follow-up (OR = 0.24; 95% CI: 0.07–0.84). | | |
| **Key finding** | Safety concerns related to timely patient follow-up remain despite automated notification of non-life-threatening abnormal laboratory results in the outpatient setting. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Moderate |
| **Author/Year** | **Singh, H. and Weingart S. N. 2009**[117] | | |
| **Setting** | Not specified | | |
| **Title** | *Diagnostic errors in ambulatory care: dimensions and preventative strategies* | | |
| **Aim** | Not reported | | |
| **Design** | Descriptive (qualitative) | | |
| **Methods** | Five dimensions of ambulatory care from which errors may arise were identified and presented to 40–50 conference participants across two group discussions to elicit their views about sources of and solutions to diagnostic error. The five dimensions were: 1) the provider-patient encounter, 2) performance and interpretation of diagnostic tests, 3) follow-up of patients and diagnostic test results, 4) subspecialty consultation and 5) patients seeking care and adhering to instructions. | | |
| **Results** | The group's discussions identified a number of themes relevant to diagnostic errors. Errors may propagate when inaccurate or insufficient data is received by physicians. Diagnostic errors commonly occur when unnecessary tests are ordered or when incorrect or inappropriate tests are ordered. Inadequate follow-up of diagnostic test results may occur if test management systems do not communicate abnormal results to clinicians in a timely manner. The subspecialty consultation process is another area vulnerable to diagnostic errors. Health literacy is a significant problem which affects patient-related behaviours. | | |
| **Key finding** | Five dimensions of ambulatory care from which errors may arise were identified: 1) the provider-patient encounter, 2) performance and interpretation of diagnostic tests, 3) follow-up of patients and diagnostic test results, 4) subspecialty consultation, and 5) patients seeking care and adhering to their instruction/appointments, i.e. patient behaviors. | | |
| **NHMRC evidence** | No specific level | **Quality score** | Not applicable |
| **Author/Year** | **Smith, J. 2012**[161] | | |
| **Setting** | Not specified | | |
| **Title** | *Avoiding vaccination errors: learning from reports of 'misuse'* | | |
| **Aim** | Not reported | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | A retrospective review of 541 vaccine misuse cases reported to Sanofi Pasteur in 2009 was conducted. | | |
| **Results** | Of the 541 reports, 18 were associated with adverse events. The majority of reports related to inappropriate schedule of administration (188) and expired vaccines (169). The wrong vaccine was administered in 98 cases, the wrong dose administered in 37 cases. | | |

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| **Key finding** | Incidents can best be avoided by ensuring the competency of staff delivering vaccinations and robust systems for the management of vaccine storage. Vaccine training programmes are recommended. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Söderberg, J. et al. 2009b[34]** | | |
| **Setting** | Mixed blood sampling staff in primary healthcare and laboratories | | |
| **Title** | *Preanalytical errors in primary healthcare: a questionnaire study of information search procedures, test request management and test tube labelling* | | |
| **Design** | Observational (cross-sectional) | | |
| **Aim** | To compare information search procedures, test request management and test tube labelling in primary healthcare compared to the same procedures amongst clinical laboratory staff. | | |
| **Methods** | A questionnaire was completed by 317 venous blood sampling staff in 70 primary healthcare centres and in two clinical laboratories (response rate = 94%). | | |
| **Results** | Correct procedures were not always followed. Only 60% of the primary healthcare staff reported that they always sought information in the updated, online laboratory manual. Only 12% reported that they always labelled the test tubes prior to drawing blood samples. No major differences between primary healthcare centres and clinical laboratories were found, except for test tube labelling, whereby the laboratory staff reported better practices. Re-education and access to documented routines were not clearly associated with better practices. | | |
| **Key finding** | Only 60% of the primary healthcare staff reported that they always sought information in the updated, online laboratory manual. Only 12% reported that they always labelled the test tubes prior to drawing blood samples. | | |
| **NHMRC evidence** | Level III | **Quality score** | Moderate |
| **Author/Year** | **Söderberg, J. et al. 2010[33]** | | |
| **Setting** | Pathology and primary healthcare staff (nurses, technicians) | | |
| **Title** | *Is the test result correct? A questionnaire study of blood collection practices in primary health care* | | |
| **Design** | Observational (cross-sectional) | | |
| **Aim** | To investigate venous blood sampling (VBS) practices (patient identification, patient rest, stasis removal and test tube handling) in primary healthcare centres (PHCs) compared with clinical laboratories, and to determine if re-education or documented routines in PHCs were associated with correct VBS practices. | | |
| **Methods** | A cross-sectional online survey of 70 primary healthcare centres and two clinical laboratories was conducted. All staff responsible for venous blood tests completed a questionnaire (317 participants – 298 PHC and 40 laboratory, 94% response rate). Staff in 18 (n = 68) PHCs had received VBS re-education on four occasions in the past 10 years, staff in another 18 PHCs (n = 58) had received re-education four times in the past 12 months and staff in the remaining 34PHCs (n = 151) had received no VBS education. Staff in 36 PHCs (n = 118) had access to documented routines. | | |
| **Results** | Clinically important risks for venous blood sampling were identified. Fewer PHC staff reported correct procedures than laboratory staff. 54% of PHC staff reported always identifying patient by name/ national ID number compared with 95% of laboratory staff. Documented VBS routines and re-education were not associated with correct | | |

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| | VBS practices. | | |
| **Key finding** | In the surveyed primary healthcare centres, there were clinically important risks for misidentification of patients and erroneous test results, with consequences for the diagnosis and treatment of patients. | | |
| **NHMRC evidence** | Level III | **Quality score** | Weak |
| **Author/Year** | **Spencer, R. and Campbell, S. M. 2014[73]** | | |
| **Setting** | General Practice | | |
| **Title** | *Tools for primary care patient safety: a narrative review* | | |
| **Aim** | To identify tools that can be used by family practitioners as part of a patient safety toolkit to improve the safety of care and services provided by their practices. | | |
| **Design** | Non-systematic review | | |
| **Methods** | A narrative review of tools to improve, measure and monitor patient safety in primary healthcare with a focus on family practice was conducted. | | |
| **Results** | In total 114 tools were identified including 26 from the grey literature. Tools most commonly addressed medication error (55%) followed by safety climate (8%) and adverse event reporting (8%). There was a lack of tools focussed on diagnostics, systems safety and results handling. | | |
| **Key findings** | Many of the tools are yet to be used in quality improvement strategies and formally evaluated in intervention studies. | | |
| **NHMRC evidence** | No specific classification | **Quality score** | Not applicable |
| **Author/Year** | **Tabrizchi, N. and Sedaghat, M. 2012[32]** | | |
| **Setting** | Mixed | | |
| **Title** | *The first study of patient safety culture in Iranian primary health centres* | | |
| **Aim** | To determine patient safety culture scores in health centres. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | Self-administered questionnaires consisting of the HSOPSC compiled by the Agency for Healthcare Research and Quality were completed by participants (n = 100 staff from 16 health centres). | | |
| **Results** | A questionnaire based on the HSOPSC was completed by 100 staff from 16 health centres in Iran. The majority of participants were health workers. Most positive responses were in the following domains: teamwork cross unit, (77%), management support for patient safety (75%), teamwork within unit (74%) and continuous organisational learning (72%). Approximately 67% of staff rated the patient safety in their centre as "good" or "perfect". | | |
| **Key finding** | Safety dimensions that received a higher positive response rate were "teamwork across units of health centre", "teamwork within units", "head of centre support for patient safety". The lowest percentage of positive responses was "Non punitive response to error". No relationship was found between working years, professional, gender and total patients safely culture score. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **van Dulmen, S. A. et al. 2011[51]** | | |
| **Setting** | Physical therapy, exercise therapy, occupational therapy | | |
| **Title** | *Patient safety in primary allied health Care. What can we learn from incidents in a Dutch exploratory cohort study?* | | |
| **Aim** | To document patient safety in allied healthcare and identify factor associated with | | |

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| | incidents. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | A retrospective study of 1000 patient records in a sample of 20 Primary Allied Healthcare practices (11 physical therapy, six exercise therapy and three occupational therapy practices). Practitioners also reported all incidents prospectively over a two week period. Incidents were classified using the Prevention and Recovery Information System for Monitoring and Analysis method. | | |
| **Results** | Incidents were recorded in 18/1000 (1.8%; 95% CI: 1.0–2.6) records. The main causes of incidents related to errors in clinical decisions (89%), communication with other healthcare providers (67%) and monitoring (56%). The risk of an incident increased with multiple care providers and with incomplete medical records. | | |
| **Key finding** | In 18 out of 1000 (1.8%; 95% CI: 1.0–2.6) records an incident was detected. The main causes of incidents were related to errors in clinical decisions (89%), communication with other healthcare providers (67%), and monitoring (56%). The probability of incidents was higher if more care providers had been involved and if patient records were incomplete. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Verbakel, N. J. et al. 2013a[30]** | | |
| **Setting** | Other – multiple | | |
| **Intervention** | Safety culture questionnaire | | |
| **Title** | *Measuring safety culture in Dutch primary care: psychometric characteristics of the SCOPE-PC questionnaire* | | |
| **Aim** | To modify and validate a validated Dutch general practice safety questionnaire for use with all primary healthcare professions. | | |
| **Design** | Descriptive – other | | |
| **Methods** | Eleven health care professions participated in the validation: dental care, dental hygienist care, occupational therapy, midwifery, anticoagulation clinics, general practice, skin therapy and speech therapy. Random sample of 200 members from each professional database invited to participate and to invite colleagues from own practice. Members working in solo practices were excluded as culture is a group characteristics. | | |
| **Results** | The proposed SCOPE-PC tool had good reliability and construct validity. The validation analysis involved 625 individuals. The resulting questionnaire had 41 items covering seven domains: open communication and learning from errors, handover and teamwork, adequate procedures and working conditions, patient safety management, support and fellowship, intention to report events, and organisational learning. | | |
| **Key finding** | The SCOPE-PC questionnaire has sound psychometric characteristics for use by the different professions in Dutch primary healthcare to gain insight in their safety culture. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Wallis, K. and Dovey, S. 2011[103]** | | |
| **Setting** | Primary healthcare | | |
| **Title** | *No-fault compensation for treatment injury in New Zealand: identifying threats to patient safety in primary care* | | |
| **Aim** | To determine the type, incidence and severity of injury in primary healthcare and to | | |

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| | identify the events in primary healthcare associated with the most severe potential consequences. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | The study analysed treatment injury data from the Accident compensation corporation, a tax-payer funded accident insurance scheme. Claims were classified as: Minor-an event which reuslts in minimal lessening of body function and which may require an increased level of care, review and evalution, futher investigation of referral to another clinician. Major-results in short-to-medium lessening of body function unrelated to the natural course of the illness and differing from the expected outcome of patient management.Serious-potential to result in death or major permenant loss of function not related to the natural course of the claimant's illness. Sentinal-resulted in an unanticipated death or major permnenant loss of function not related to the natural course of the claimant's illness, pregnancy or childbirth. | | |
| **Results** | In the four year period from 2005–09, 6007 treatment injury claims from primary healthcare were registered. Most claims were minor (83%), 12% major, 4% serious and 1% sentinal. Most primary healthcare claims arose in general practice settings (62%), dental clinics (22%), laboratories (4%), and physiotherapy rooms (4%). Medications cause most injuries (38%). Dental treatment resulted in 16% of injuries, injections and vaccinations 10%, venepuncture, cryotherapy and ear syringing (combined) 13.5%. 'Delay in diagnosis' caused 2% of overall injuries but 16% of serious and sentinal injuries and 50% of deaths. Spinal/ neck manipulation caused 2% of serious and sentinal injuries. | | |
| **Key finding** | Most primary healthcare treatment injury compensation claims arose in general practice settings (62%) and medications caused the most injuries (38%). Other primary healthcare activites (dental care, injections, venepuncture, cryotherapy and ear syringing) also posed patient harm risk. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **West, D. R. et al. 2014[162]** | | |
| **Setting** | Mixed | | |
| **Title** | *Laboratory medicine handoff gaps experienced by primary care practices: a report from the shared networks of collaborative ambulatory practices and partners* | | |
| **Aim** | To understand the perceived gaps in laboratory processes based on information from primary healthcare practice personnel. | | |
| **Design** | Descriptive (cross-sectional) | | |
| **Methods** | A general practice questionnaire was administered. The questionnaire focused on routine tests and did not include imaging, body function, biopsy, endoscopy or special studies. Questions were tailored for clinicians (physicians, nurse practitioners, physician assistants, pharmacists and psychologists), practice staff and practice managers. Questions covered perceptions of handoff before and after analytics processes, transitions within processes, perceptions of roles and responsibilities. Most questions had structured response categories. Open-ended questions were included to explore perceived gaps in their processes. | | |
| **Results** | Test ordering processes: clinicians identified the electronic health record (52%) and clinical flow sheets and guidelines (50%) as primary aids for test ordering. Most common methods of ordering were hard copy forms (40%) and computer provider | | |

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| | entry (38%). Test tracking processes: Automated systems were used by 61% of practices to track tests once ordered. 37% of clinicians and 18% of staff reported they had no system for tracking. Practices with a large medicaid mix and those in urban settings were more likely to report "poor" tracking (P = 0.01). Patient notification: There was no difference in notification between HER (electronic health record) and non-EHR practices. 74% of clinicians reported that the clinic directly notified patients re abnormal result at least 96% of time.20% of clinicians and 11% of staff rated their patient notification processes as "poor".<br>Tools and reminders for follow-up testing: HER-based reminder systems and internal "tickler" systems were the most common mechanisms for follow test reminders. 30% of clinicians and 17% of staff had no system. Staff and clinicians differed regarding who was considered responsible for documenting patient follow-up 57% of staff versus 81% of clinicians felt this was the role of the clinician. Other themes: human error and communication breakdown at the point of handoffs, difficulty in sorting and handling results returned from laboratories, patients not visiting laboratory and outdated patient contact information were all reported. | | |
| **Key finding** | Lack of standardisation and definition of roles in handoffs in primary healthcare laboratory practices for test ordering, monitoring, and receiving and reporting test results which impact efficiency, cost and safety of care. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |

## Appendix 2: Data extraction table for findings of the systematic review relating to Question 2

Presented below is a series of tables containing the papers from the systematic review of the scientific literature which underwent full-text review and inclusion in the group that addressed Question 2: What interventions have been shown to be effective in minimising risks to patient safety in primary healthcare? These are organised by type of intervention.

### A2.1 Studies with evidence on the effect of interventions that reduce risks to patient safety in primary healthcare

| **Studies with evidence on interventions to reduce risks to patient safety in primary healthcare (n = 28)** | | | |
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| **Author/Year** | **Arora et al. 2014[21]** | | |
| **Setting** | Other – Emergency Department | | |
| **Intervention** | Intervention to improve safety in transitions of care | | |
| **Title** | *Improving attendance at post-emergency department follow-up via automated text message appointment reminders: a randomised controlled trial* | | |
| **Aim** | To evaluate the ability of an automated text message reminder system to increase attendance at post-ED discharge follow-up appointments. | | |
| **Design** | Randomised control trial | | |
| **Methods** | In the three-month enrolment period, 2365 consecutive ED patients were screened for enrolment, and 374 met eligibility requirements, consented for enrolment, and were randomised. The overall study population had a mean age of 45.6 years, was predominantly Hispanic (70.4%), and included both English- and Spanish-speakers (Spanish-speaking 42.1%). Characteristics of the study population, including age, language, and ethnicity were similar between the two groups. English- and Spanish-speaking patients with text capable mobile phones were enrolled. Patients in the intervention arm received automated, personalised text message appointment reminders including date, time, and clinic location at seven-, three-, and one-day before scheduled visits. A t-test of proportions was used to compare outcomes between intervention and control groups. | | |
| **Results** | The overall appointment adherence rate was 72.6% in the intervention group compared with 62.1% in the control group (difference between groups = 10.5%; 95% CI: 0.3%–20.8%; P = 0.045. Automated text message appointment reminders resulted in improvement in attendance at scheduled post-ED discharge outpatient follow-up visits and represent a low cost and highly scalable solution to increase attendance at post-ED follow-up appointments. | | |
| **Key finding** | Automated text message appointment reminders resulted in improvement in attendance at scheduled post-ED discharge outpatient follow-up visits and represent a low-cost and highly scalable solution to increase attendance at post-ED follow-up appointments. | | |
| **NHMRC evidence** | Level II | **Quality score** | Strong |

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| **Author/Year** | **El-Kareh, R. et al. 2009[136]** | | |
| **Setting** | General practice | | |
| **Intervention** | Computerised Clinical Decision Support Systems | | |
| **Title** | *Trends in primary care clinician perceptions of a new electronic health record* | | |
| **Aim** | To measure changes in primary healthcare clinician attitudes toward an electronic health record's impact on quality, safety, communication and efficiency during the first year following implementation. | | |
| **Design** | Observational (cross-sectional) | | |
| **Methods** | All primary healthcare clinicians at three health centres within a large network of 19 ambulatory care centres in eastern Massachusetts were invited to participate. 86 primary healthcare clinicians (73 physicians, 10 nurse practitioners and three physician assistants) were surveyed between December 2006 and January 2008 to determine the perceived impact on overall quality of care, patient safety, communication, and efficiency at one, three, six, and 12 months following implementation of a new electronic health record (EHR). The centre staff underwent training as the EHR was implemented. It was virtually paperless, supporting electronic entry of clinical notes, diagnostic codes, procedure codes, and laboratory results, as well as computerised ordering of all medications, laboratory tests, procedures, and referrals. Clinical decision support in the form of electronic reminders was also used for preventive services and chronic disease management. The survey specifically addressed whether the EHR "reduces medication-related errors" and "improves follow up of test results". | | |
| **Results** | Response rates for months one, three, six, and 12 were 92%, 95%, 90%, and 82%, respectively. The proportion of clinicians agreeing that the EHR improved the overall quality of care (63%– 86%; P < 0.001), reduced medication-related errors (72%–81%; P = 0.03), improved follow up of test results (62%–87%; P < 0.001), and improved communication among clinicians (72%–93%; P < 0.001) increased from month one to month 12. During the same time period, a decreasing proportion of clinicians agreed that the EHR reduced the quality of patient interactions (49%–33%; P = 0.001), resulted in longer patient visits (68%–51%; P = 0.001), and increased time spent on medical documentation (78%–68%; P = 0.006). Significant improvements in perceptions related to test result follow-up were first detected at six months, while those related to overall quality, efficiency, and communication were first identified at 12 months. | | |
| **Key finding** | Primary healthcare physicians perceive that using an electronic health record instead of a paper based record reduces medication related errors and improves test result follow-up. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Weak |
| **Author/Year** | **Garment, A. R. et al. 2012[138]** | | |
| **Setting** | General practice | | |
| **Intervention** | Interventions to improve safety in transitions of care | | |
| **Title** | *Development of a structured tear-end sign-out program in an outpatient community practice* | | |
| **Aim** | To develop a structured transfer of care program in an academic outpatient continuity practice and evaluate whether this program improved patient safety as measured by the documented completion of patient care tasks at three months post-transition | | |
| **Design** | Randomised control trial | | |

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| **Methods** | Graduating residents and the corresponding incoming interns inheriting their continuity patient panels were randomised to the pilot structured transfer group or the standard transfer group. The structured transfer group residents were asked to complete written and verbal sign-outs with their interns; the standard transfer group residents continued the current standard of care. Three months after the transition, study investigators evaluated whether patient care tasks assigned by the graduating residents had been successfully completed by the interns in both groups. In addition, follow-up appointments, continuity of care and house officer satisfaction with the sign-out process were evaluated. | | |
| **Results** | Three months after the transition, study investigators evaluated whether patient care tasks assigned by the graduating residents had been successfully completed by the interns in both groups. In addition, follow-up appointments, continuity of care and house officer satisfaction with the sign-out process were evaluated. | | |
| **Key finding** | A structured outpatient sign-out improved the odds of follow-up of important clinical care tasks after the year-end resident clinic transition. | | |
| **NHMRC evidence** | Level II | **Quality score** | Weak |
| **Author/Year** | **Gurwitz, JH. 2014[125]** | | |
| **Setting** | General practice | | |
| **Intervention** | Intervention to improve safety in transitions of care | | |
| **Title** | *An electronic health record-based intervention to increase follow-up office visits and decrease hospitalisation in older adults* | | |
| **Aim** | The aim of this study was to explore what problems are reported by healthcare professionals in primary healthcare concerning the use of interpreters and what the problems lead to. | | |
| **Design** | Randomised control trial | | |
| **Methods** | In addition to notifying primary healthcare providers about the individual's recent discharge, the system provided information about new drugs added during the inpatient stay, warnings about drug-drug interactions, recommendations for dose changes and laboratory monitoring of high-risk medications, and alerts to the primary healthcare provider's support staff to schedule a post hospitalisation office visit. The primary outcome were an outpatient office visit with a primary healthcare provider after discharge and rehospitalisation within 30 days after discharge. | | |
| **Results** | Of the 1870 discharges in the intervention group, 27.7% had an office visit with a primary healthcare provider within seven days of discharge. Of the 1791 discharges in the control group, 28.3% had an office visit with a primary healthcare provider within seven days of discharge. In the intervention group, 18.8% experienced a rehospitalisation within the 30-day period after discharge, compared with 19.9% in the control group. The hazard ratio for an office visit with a primary healthcare physician did not significantly differ between the intervention and control groups. The hazard ratio for rehospitalisation in the 30-day period after hospital discharge in the intervention versus the control group was 0.94 (95% CI: 0.81–1.1). | | |
| **Key finding** | The intervention tested was an electronic health-record based system, and it did not have a significant effect on the timeliness of office visits to primary care providers after hospitalisation or risk of re-hospitalisation. | | |

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| **NHMRC evidence** | Level II | **Quality score** | Strong |
| **Author/Year** | **Hoffmann, B. et al. 2014[19]** | | |
| **Setting** | General practice | | |
| **Intervention** | Educational intervention to improve patient safety practices | | |
| **Title** | *Effects of a team-based assessment and intervention on patient safety culture in general practice: an open randomised controlled trial* | | |
| **Aim** | To assess the effects of FraTrix (the Frankfurt Patient Safety Matrix) on safety culture in general practice. | | |
| **Design** | Randomised control trial | | |
| **Methods** | An open randomised controlled trial was conducted in 60 general practices. FraTrix (Frankfurt Patient Safety Matrix), a German language version of the Manchester Patient Safety Framework was applied over a period of nine months during three facilitated team sessions in intervention practices. At baseline and after 12 months, scores were allocated for safety culture as expressed in practice structure and processes (indicators), in safety climate and in patient safety incident reporting. The primary outcome was the indicator error management. | | |
| **Results** | During the team sessions, practice teams reflected on their safety culture and decided on about 10 actions per practice to improve it. After 12 months, no significant differences were found between intervention and control groups in terms of error management (competing probability = 0.48; 95% CI: 0.34–0.63; P = 0.823), 11 further patient safety culture indicators and safety climate scales. Intervention practices showed better reporting of patient safety incidents, reflected in a higher number of incident reports (mean (SD) 4.85 (4.94) vs. 3.10 (5.42); P = 0.045) and incident reports of higher quality (scoring 2.27 (1.93) vs. 1.49 (1.67); P = 0.038) than control practices. | | |
| **Key finding** | Use of the FraTrix tool was not associated with a change in patient safety climate score after 12 months, but was associated with more frequently reported incidents with richer information. | | |
| **NHMRC evidence** | Level II | **Quality score** | Moderate |
| **Author/Year** | **Marsteller, J. et al. 2010[25]** | | |
| **Setting** | General practice | | |
| **Intervention** | Educational intervention to improve patient safety practices | | |
| **Title** | *A simple intervention promoting patient safety improvements in small internal medicine practices* | | |
| **Aim** | To assess changes in patient safety measures in small primary healthcare practices and describe simple mechanisms that appear to have facilitated change. | | |
| **Design** | Quasi-experimental | | |
| **Methods** | A pre post design was used to determine the effect of a quality improvement intervention provided by the Center for Practice Innovation (CPI) of the American College of Physicians (ACP) to 34 small internal medicine practices. Compliance with safety measures was reassessed in 30 practices after the intervention. The CPI intervention involved two site visits, a practice assessment, self-selection of clinical, operational and financial focus areas for improvement and ongoing 'directed guidance' of the practices in their efforts, including weekly 'Practice tips' email alerts. Data used in this study came from the practice assessment form completed by the CPI team, which | | |

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| | included 21 safety measures. The Wilcoxon signed-rank test and McNemar's test were used to compare the practices' safety compliance before and after the intervention. | | |
| **Results** | Many safety measures had high compliance rates at the first site visit; for other safety measures, fewer than half the practices followed the recommended procedures. The intervention was associated with statistically significant positive change on over 70% of the 21 safety issues. The positive effects were most profound in safety measures regarding how a practice managed sharps, hazardous materials, medications and vaccines. | | |
| **Key finding** | Implementation of a multifaceted intervention improved safety in 21 areas across 34 small primary healthcare practices. | | |
| **NHMRC evidence** | Level III–3 | **Quality score** | Weak |
| **Author/Year** | **Singh, R. et al. 2009[23]** | | |
| **Setting** | General practice | | |
| **Intervention** | Educational intervention to improve patient safety practices | | |
| **Title** | *A patient safety objective structured clinical examination* | | |
| **Aim** | To develop and implement an objective structured clinical examination (OSCE) for family medicine residency trainees to evaluate the impact of a patient safety curriculum. | | |
| **Design** | Quasi-expermental | | |
| **Methods** | A patient safety curriculum was developed for a family medicine training program which addressed safety in an interdisciplinary manner, and contained didactic and experimental components. These include behavioural skills for patient safety, medication safety and a systems approach to patient safety. The curriculum was implemented in a family medicine residency program with 47 trainees. Two years after commencing the curriculum, a patient safety OSCE (objective structured clinical examination) was developed and administered at this program and, for comparison purposes, to 16 incoming residents at the same program and to 12 residents at a neighboring residency program. | | |
| **Results** | All 47 residents exposed to the training, all 16 incoming residents, and 10 of 12 residents at the neighboring program participated in the OSCE. In a standardised patient case, error detection and error disclosure skills were better among trained residents. In a chart-based case, trained residents showed better performance in identifying deficiencies in care and described more appropriate means of addressing them. Third year residents exposed to a "Systems Approach" course performed better at system analysis and identifying system-based solutions after the course than before. The main weaknesses of the study are its small size and suboptimal design. Much further investigation is needed into the effectiveness of patient safety curricula. | | |
| **Key finding** | GP trainees exposed to a "Systems Approach" course performed better at system analysis and identifying system-based solutions after the course than before. | | |
| **NHMRC evidence** | Level III–2 | **Quality score** | Weak |
| **Author/Year** | **Souza, N. M. et al. 2011[72]** | | |
| **Setting** | General practice | | |
| **Intervention** | Computerised Clinical Decision Support Systems | | |

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| **Title** | *Computerised clinical decision support systems for primary preventative care: a decision-maker-researcher partnership systematic review of effects on process of care and patient outcome* | | |
| **Aim** | To review RCTS assessing the effects of CCDSSs for primary preventative care on process of care, patient outcomes, harms and costs. | | |
| **Design** | Systematic review | | |
| **Methods** | This study updated a 2005 systematic review looking at computerised clinical decision support systems (CCDSSs) for primary preventative care (PPC). | | |
| **Results** | 17 RCTs that evaluated computerised clinical decision support systems (CCDSS) for primary preventative care (PPC). CCDSSs improved process of care in 25/40 (63%) studies. Evidence supports the use of CCDSSs in screening and management of dyslipidemia. Mixed evidence for cancer screening, mental health and vaccinations. Adverse event data was only reported in two studies. | | |
| **Key finding** | Evidence supports the effectiveness of computerised clinical decision support systems for screening and treatment of dyslipidaemia in primary healthcare with less consistent evidence their use in screening for cancer and mental health-related conditions, vaccinations, and other preventive care. Effects on patient outcomes, safety, costs of care, and provider satisfaction remain poorly supported. | | |
| **NHMRC evidence** | Level I | **Quality score** | 6/11 (Systematic review) |
| **Author/Year** | **Verbakel, N. J. et al. 2015[48]** | | |
| **Setting** | General practice | | |
| **Intervention** | Improvement of incident reporting systems | | |
| **Title** | *Effects of patient safety culture interventions on incident reporting in general practice: a cluster randomised trial* | | |
| **Aim** | To assess the effect of administering a culture questionnaire with digital feedback or the questionnaire combined with a practice-based workshop including feedback in general practice. | | |
| **Design** | Randomised controlled trial | | |
| **Methods** | A three armed cluster randomised trial was conducted in a mixed methods study. Twenty eight practices (235 staff, 82 GPs, 93 assistants, 51 nurses) participated in the study. Two interventions were studied: administration and feedback of a patient safety questionnaire and administration of the questionnaire complemented with a patient safety workshop. The control group received no intervention. The primary outcome was number of reported incidents per practice at follow-up measured by a questionnaire. Patient safety culture was measured at all sites using the SCOPE questionnaire. | | |
| **Results** | Administering a safety culture questionnaire increased reporting of incidents, with the greatest increase seen in those practices who also participated in a patient safety workshop. Incident reports in the questionnaire and feedback group (intervention 1) increased from 15 to 82, those in the questionnaire and workshop increased from 70 to 224 while those in the control group decreased from 18 to four. Based on an intention to treat analysis, intervention 1 resulted in 5.45 (95% CI: 1.17–25.49) and intervention II 41.72 (9.81–177.50) more incident reports. With respect to patient safety multilevel analysis showed no difference between groups at follow-up. | | |
| **Key finding** | Educating staff and facilitating discussion about patient safety culture in their own practice leads to increased reporting of incidents. | | |

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| **NHMRC evidence** | Level II | **Quality score** | Moderate |
| **Author/Year** | **Yao, G. L. et al. 2012[123]** | | |
| **Setting** | General practice | | |
| **Intervention** | Intervention to improve safety in transitions of care | | |
| **Title** | *Evaluation of a predevelopment service delivery intervention: an application to improve clinical handovers* | | |
| **Aim** | To develop a method to estimate the expected cost-effectiveness of a service intervention at the design stage and to test the method on an intervention to improve patient handover between hospital and community. | | |
| **Design** | Descriptive other | | |
| **Methods** | A framework for evaluating generic service delivery interventions was developed based on nine steps: 1) identification and classification is suitable end points, 2) estimation of the baseline risk associated with each end point, 3) elicitation of expected effectiveness, 4) estimation of utility values, 5) estimation of intervention costs, 6.Healthcare costs associated with adverse events, 7) expected health benefits and net costs, 8) estimation of cost-effectiveness and cost-benefit analysis, 9) sensitivity analysis and headroom calculation.<br>The model was applied to the HANDOVER study. | | |
| **Results** | Literature review suggested that adverse events follow 19% of patient discharges, and that one-third are preventable by improved handover (i.e. 6.3% of all discharges). The intervention to improve handover would reduce the incidence of adverse events by 21% (i.e. from 6.3%–4.7%) according to the elicitation exercise. Potentially preventable adverse events were classified by severity and duration. Utilities were assigned to each category of adverse event. The costs associated with each category of event were obtained from the literature. The unit cost of the intervention was e16.6, which would yield a Quality Adjusted Life Year (QALY) gain per discharge of 0.010. The resulting cost saving was e14.3 per discharge. The intervention is cost-effective at approximately e214 per QALY under the base case, and remains cost-effective while the effectiveness is greater than 1.6%. | | |
| **Key finding** | A framework to assess potential health economic evaluations of health service interventions was developed. | | |
| **NHMRC evidence** | Level IV | **Quality score** | Not applicable |

| Author/Year | Zwart, D. L. et al. 2011[50] | | |
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| **Setting** | General practice out-of-hours services | | |
| **Intervention** | Improvement of incident reporting systems | | |
| **Title** | *Central or local incident reporting? A comparative study in Dutch GP out-of-hours services* | | |
| **Aim** | To determine if implementation of a Local Incident Reporting Procedure (LIRP) changes the number and nature of incident reports in a collaborative GP out-of-hours service (OHS). | | |
| **Design** | Quasi-experimental | | |
| **Methods** | Local Incident Reporting Procedure (LIRP) implemented in OHS1 in Dec 2006. LIRP comprised paper form, local incident mail box and review and analysis by local multidisciplinary committee. Usual Central Incident Reporting Procedures (CRIP) used by OHS 2 & 3. CIRP comprised paper reports sent by mail to central advisory committee. | | |
| **Results** | Implementation of LIRP with a fast track review process was associated with an increase in incident reporting. Increase in incidents reported with LIRP (10 versus 162; P = 0.004) but not in control OHS 2 & 3 (31 vs. 39). Incident types on baseline were: Process of care (5/10), Knowledge and skills (2/10), Materials and logistics (2/10) and communications/teamwork (1/10). There was no change in the distribution of incident types or in potential harms following implementation of the LIRP. Half of reports were from GPs and half were from nurses. | | |
| **Key finding** | Local incident-reporting procedure increases the willingness to report and facilitates faster implementation of improvements. In contrast, the central procedure, by collating reports from many settings, seems better at addressing generic and recurring safety issues. | | |
| **NHMRC evidence** | Level III–2 | **Quality score** | Weak |

## Appendix 3: Data extraction table for the grey literature findings relating to Question 1

### A3.1 Grey literature findings relating to Question 1: Risks associated with patient safety in primary healthcare

| Grey literature findings relating to Question 1 (N = 8) | |
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| **Author (Organisation)**<br>**Title**<br><br>**Publication Date** | Cloud-Buckner, JM. [163]<br>Wright State University, USA<br>*Managing patient test data in primary care: developing and evaluating a system for test tracking to enhance processes, safety, and understanding of performance*<br>2012 |
| **Resource description** | PhD |
| **URL and access date** | rave.ohiolink.edu/etdc/view?acc_num=wright1348258363<br>Accessed 26/06/15 |
| **Aim** | 1) in Phase I initial survey, assess perceptions, attitudes, and behaviors of practicing healthcare clinicians and administrators about testing, safety, and technology; 2) in Phase II system design, design a low cost system prototype that manages primary healthcare testing processes for individual patients, supports safety and resilience, and measures overall clinic testing performance for continuous improvement efforts;[145] in Phase III laboratory experiment, evaluate system prototype for effectiveness in managing testing management processes, including test ordering, results review, notification, and tracking; 4) in Phase III, evaluate effectiveness of technology specifically designed to enforce, support, nurture, and measure safety – including individual safety awareness, attitudes, actions, resilience, and safety culture; 5) in Phase III, evaluate effectiveness of the testing management system prototype for increasing understanding of overall clinic testing performance; 6) in Phase IV clinical review, evaluate a revised prototype with primary healthcare clinicians for its perceived effectiveness and potential for process, safety, and performance improvements. |
| **Methods** | Mixed methods |
| **Results** | Refer to thesis URL for detailed results – see key findings |
| **Key finding** | This research resulted in a test management system prototype that was effective in managing and standardizing testing processes; showed effectiveness for some aspects of safety, situation awareness, and resilience; and was effective in developing user understanding of clinic performance in testing processes. |
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | Echeverri, ALH. [164]<br>The University of Arizona<br>*Relationship between perceived healthcare quality and patient safety*<br>2013 |
| **Resource description** | PhD |
| **URL and access date** | arizona.openrepository.com/arizona/handle/10150/283602<br>Accessed 29/06/15 |
| **Aim** | To examine the association between patient perceived healthcare quality and self- |

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| | reported medical, medication, and laboratory errors using cross-sectional and cross-national questionnaire data from eleven countries. |
| **Methods** | The data source for this study was the Commonwealth Fund International Health Policy Survey (CWF), which was conducted in eleven countries in 2010. The CFW 103 consisted of a national representative sample of adults aged 18 years and older in Australia (AU), Canada (CA), France (FR), Germany (GER), Netherlands (NTH), New Zealand (NZ), Norway (NW), Sweden (SWE), Switzerland (SW), United Kingdom (UK), and United States (US). The CWF's purpose was to obtain insights about consumers' access to, costs of, and satisfaction with care experiences in an effort to provide comparable data across countries to monitor and compare healthcare systems. Quality of care was measured by a multi-faceted construct, which adopted the patient's perspectives. Five separated quality of care scales were assessed: access to care, continuity of care, communication of care, care coordination, and provider's respect for patients' preferences. |
| **Results** | After adjusting for potentially important confounding variables, an increase in peoples' perceptions of Coordination of Care decreased the likelihood of self-reporting medical errors (OR = 0.605; 95% CI: 0.569–0.653), medication errors (OR = 0.754; 95% CI: 0.691–0.830), and laboratory errors (OR = 0.615; 95% CI: 0.555–0.681). Finally, results showed that the healthcare system type governing care processes modifies the effect of coordination of care on self-reported medication errors. |
| **Key finding** | The findings from this investigation support a number of other published studies suggesting that coordination of care is an important predictor of perceived patient safety. |
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | Greater Manchester Primary Care Patient Safety Translational Research Centre[140]<br><br>*'Never events' developed for general practice*<br>2014 |
| **Resource description** | Other – website PPT presentation |
| **URL and access date** | www.population-health.manchester.ac.uk/primary-care-patient-safety/EventsandConferences/events/NeverEvents.pdf<br>Accessed 25/06/15 |
| **Aim** | A public event around Never Events took place on 27 March 2014 |
| **Methods** | Eighty-five percent of contacts in the NHS take place in primary healthcare and in each year in England alone there are approximately 300 million general practice consultations. Estimates of harm suggest that there are between 37–600 patient safety incidents per day in primary healthcare (some of them with serious consequences). The majority of research and funding about patient safety has focused on acute hospital care settings. However, 85 percent of contacts with the NHS are in primary healthcare and there is evidence of significant harm to patients. |
| **Results** | A list of 10 'never events' was generated: 1) prescribing a drug to a patient that is recorded in the practice system as having previously caused her/him a severe adverse reaction; 2) a planned referral of a patient, prompted by clinical suspicion of cancer, is not sent; 3) prescribing a teratogenic drug to a patient known to be pregnant (unless initiated by a clinical specialist); 4) emergency transport is not discussed or arranged when admitting a patient as an emergency; 5) an abnormal investigation result is |

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| | received by a practice but is not reviewed by a clinician; 6) prescribing aspirin for a patient ≤ 12 years old (unless recommended by a specialist for specific clinical conditions); 7) Prescribing systemic oestrogen – only hormone replacement therapy for a patient with an intact uterus 8) prescribing methotrexate daily rather than weekly (unless initiated by a specialist for a specific clinical condition e.g. leukaemia); 9) a needle-stick injury due to a failure to dispose of 'sharps' in compliance with national guidance and regulations 10) adrenaline (or equivalent) is not available when clinically indicated for a medical emergency in the practice or GP home visit. |
| **Key finding** | 'Never event' list contains 10 incidents that should never occur in primary healthcare. |
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | The Health Foundation[165]<br><br>*Improving safety in primary care*<br>November 2011 |
| **Resource description** | Report 'Evidence Scan' |
| **URL and access date** | www.health.org.uk/publications/improving-safety-in-primary-care<br>Accessed 03/06/15 |
| **Aim** | To determine initiatives that have been implemented to improve safety in primary healthcare and their impacts; to assess how patients, professionals, researchers and funders have been involved; and to identify ongoing studies in this area. |
| **Methods** | Two reviewers independently searched bibliographic databases, reference lists of identified articles and the websites of relevant agencies. All databases were searched from 2000 until August 2011. Search terms included combinations of primary care, primary healthcare, family practice, ambulatory care, pharmacy, walk-in centre, district nursing, home care, general practice, GP, practice nurse, midwife, patient safety, quality improvement, harm, risk, adverse event, incidents, error, medication errors, prevention, risk management, significant event and similes. |
| **Results** | Ten databases were searched and 83 studies were included, predominantly from North America. Researchers and policy makers tend to agree that improving patient safety in primary healthcare should be a priority, though few systematic programmes are in place to support this and there is little consensus about the best ways of doing so. The main approaches that have been researched for improving patient safety in primary healthcare include: awareness raising; campaigns and education; incident reporting; audit and feedback; and safety culture surveys. Changing staff roles (nurse practitioners and pharmacy involvement) and patient engagement have also been examined. |
| **Key finding** | The strategies that have shown most promise target the key causes of harm in primary healthcare include: clinical complexity (via computerised prescribing and alert systems); human factors (via pharmacist input); and systems issues (using learning collaboratives, audit and feedback, and discharge planning to improve interfaces with secondary care). |

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| **Author (Organisation)**<br>**Title**<br>**Publication Date** | The King's Fund[166]<br><br>*Improving the quality of care in general practice*<br>March 2011 |
| **Resource description** | Report |
| **URL and access date** | www.kingsfund.org.uk/sites/files/kf/field/field_related_document/gp-inquiry-report-state-quality-4mar11.pdf<br>Accessed 25/06/15 |
| **Aim** | To provide an overview of the quality of care in English general practice by summarising the key findings from commissioned research. |
| **Methods** | The evidence is presented within three sections: 1) core services provided within general practice (the quality of diagnosis, referral and prescribing; the management of acute illness; the management of people with long-term conditions; promoting health and preventing ill health); 2) non-clinical aspects of general practice; 3) general practice as part of a wider system of care. |
| **Results** | There were a number of general statements about the opportunities to improve quality in general practice. The report presents some evidence to suggest that the quality and cost-effectiveness of prescribing practice could be improved in a number of areas, including a focus on reducing medication errors, supporting medications management, and in standardising drug prescriptions for certain treatments. This appears to be particularly true for the more vulnerable cohorts of patients such as frail older people and those with long-term conditions. |
| **Key finding** | The majority of care provided by general practice is good. However, wide variations in performance and evidence of gaps in quality of care suggest that there is significant scope and opportunity for improvement. |
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | Sonderberg, J.[167]<br>Umea University, Sweden<br>*Sources of pre-analytical error in primary health care – implications for patient safety*<br>2009 |
| **Resource description** | PhD |
| **URL and access date** | umu.diva-portal.org/smash/get/diva2:211202/FULLTEXT02<br>Accessed 26/06/15 |
| **Aim** | To investigate venous blood sampling practices and the prevalence of haemolysed blood samples in primary healthcare |
| **Methods** | A questionnaire investigated the collection and handling of venous blood samples in primary healthcare centres in two county councils and in two hospital clinical laboratories. Haemolysis index was used to evaluate the prevalence of haemolysed blood samples sent from primary healthcare centres, nursing homes and a hospital emergency department. |
| **Results** | The results indicate that recommended preanalytical procedures were not always followed in the surveyed primary healthcare centres. Monitoring of haemolysis index could be a valuable tool for estimating preanalytical sample quality. Further studies and |

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| | interventions aimed at the preanalytical phase in primary healthcare are clearly needed. |
| **Key finding** | This thesis indicates that the preanalytical procedure in primary healthcare is associated with an increased risk of errors with consequences for patient safety and care. |
| **Author (Organisation)**<br>**Title**<br><br>**Publication Date** | World Health Organization (WHO) Patient Safety[168]<br><br>*Safer primary care: a global challenge – summary of the inaugural meeting of the safer primary care expert working group*<br>2012 |
| **Resource description** | Report – meeting summary |
| **URL and access date** | www.who.int/patientsafety/safer_primary_care/en/<br>Accessed 25/06/15 |
| **Aim** | The aim of the meeting and goals of the working group are to advance the understanding and knowledge about: 1) the risks to patients in primary healthcare; 2) the magnitude and nature of the preventable harm due to unsafe practices in these settings; 3) safe mechanisms to protect primary healthcare patients. |
| **Methods** | In February 2012, the Patient Safety Programme convened a consultation of some of the world's top experts in primary healthcare, research, and patient safety to form the inaugural Safer Primary Care Expert Working Group. The experts, from 18 Member States and the six world regions, together with senior members of WHO gathered in Geneva for two days. Together they discussed and debated the available evidence on the burden of harm resulting from errors and the global limited understanding of how to intervene to improve the safety of care in primary healthcare settings. |
| **Results** | The major outcomes of the meeting were:<br>1. Recognition of the importance of unsafe primary healthcare<br>2. Willingness to work as a network around a common agenda, and share instruments, tools, data and learning<br>3. Support aimed at integrating baseline measurement with quality improvement in low- and middle-income settings<br>4. Identification of priority areas and key knowledge gaps<br>5. Recognition of the need for increased knowledge together with practical proposals to bridge major knowledge gaps<br>6. Suggestions for a roadmap for action. |
| **Key finding** | The report provides a summary of the evidence considered and generated, a synopsis of the discussions, and provides details of essential next steps to ensure the collective work continues to improve the quality and safety of primary healthcare provision. |
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | World Health Organization (WHO) Patient Safety[8]<br><br>*The conceptual framework for the international classification for patient safety*<br>January 2009 |
| **Resource description** | Website – technical report |
| **URL and access date** | www.who.int/patientsafety/implementation/taxonomy/icps_technical_report_en.pdf<br>Accessed 29/06/15 |

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| **Aim** | To provide a detailed overview of the conceptual framework for the International Classification for Patient Safety (ICPS), including a discussion of each class, the key concepts with preferred terms and the practical applications. |
| **Methods** | A WHO Drafting Group developed the conceptual framework for the ICPS over the course of three years. It aimed to ensure that the work was an accurate convergence of international perceptions of the main issues related to patient safety. The validity of the conceptual framework for the ICPS was evaluated through a two-round web-based modified Delphi survey and an in-depth analysis by technical experts representing the fields of safety, systems engineering, health policy, medicine and the law. The conceptual framework for the ICPS and the 48 key concepts and preferred terms were also evaluated for cultural and linguistic appropriateness by native French, Spanish, Japanese and Korean speaking technical experts. |
| **Results** | Key definitions include:<br>**Patient safety**: the reduction of risk of unnecessary harm associated with health care to an acceptable minimum.<br>**Patient safety incident**: an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.<br>**Incident reporting**: collecting and analysing information about an event that could have harmed or did harm a patient in a health-care setting.<br>**Harmful incident or adverse event**: an incident that resulted in harm to a patient.<br>**Error**: failure to carry out a planned action as intended or application of an incorrect plan.<br>**Near miss**: an incident that did not reach the patient.<br>**Violation**: deliberate deviation from an operating procedure, standard or rules. |
| **Key finding** | ICPS is a conceptual framework for an international classification which aims to provide a reasonable understanding of the world of patient safety and patient safety concepts to which existing regional and national classifications can relate. It is not primary healthcare specific but incorporates primary healthcare settings. |

## Appendix 4: Data extraction table for the grey literature findings relating to Question 2

### A4.1 Grey literature findings relating to Question 2: Interventions to minimise risks to patient safety in primary healthcare

| Grey literature findings relating to Question 2 (N = 6) | |
|---|---|
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | Agency for Healthcare Research and Quality[143]<br><br>*Patient safety tools for ambulatory care settings*<br>August 2013 |
| **Resource description** | Website – a national safety organisation |
| **URL and access date** | www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/pstools/index.html#amb<br>Accessed 25/06/15 |
| **Aim** | Tools developed to assess safety practices and safety culture in ambulatory care clinics |
| **Methods** | There are four tools provided on the AHRQ website as patient safety resources for the ambulatory care setting. Tools can be used by clinicians, administrative staff and patients. |
| **Results** | 1. The Ambulatory Surgery Center (ASC) Survey on Patient Safety Culture is a new survey in the suite of AHRQ Surveys on Patient Safety Culture. The survey, designed specifically for ASC staff, asks for opinions about the culture of patient safety at their centres. The survey can be used to raise staff awareness about patient safety, assess the status of patient safety culture, identify strengths and areas for improvement, examine trends, evaluate the cultural impact of patient safety initiatives and interventions, and conduct comparisons within and across organisations.<br>2. Improving Your Office Lab Testing Process Ambulatory Toolkit increases the reliability of the lab testing process within a medical office with step-by-step guidance. Includes checklists and materials to help communicate with patients.<br>3. AHRQ Patient Safety Culture Surveys include several staff-administered surveys specifically designed for ambulatory care providers in nursing homes, medical offices, and community pharmacies.<br>4. TeamSTEPPS® for Office-Based Care adapts the core concepts of the TeamSTEPPS program to reflect the environment of office-based teams. (This resource is now archived on the AHRQ website). |
| **Key findings** | Tools to assess patient safety culture and office lab testing processes are provided on the AHRQ website as patient safety resources for the ambulatory care setting. Their intention is to measure and improve patient safety culture and practice in ambulatory care settings. |

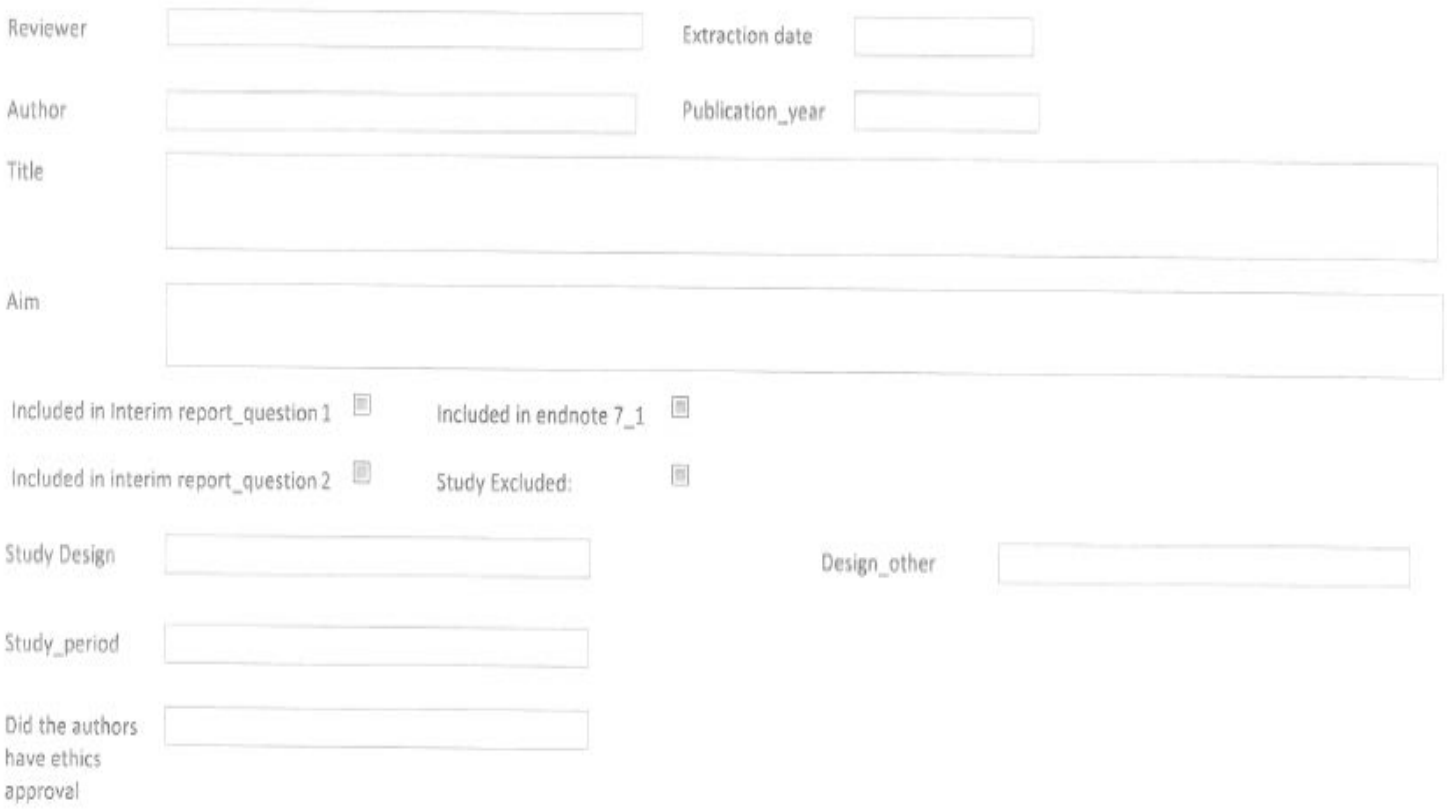
| | |
|---|---|
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | Elnour, A. et al[141]<br>Greater Green Triangle, Department of Rural Health<br>*Patient safety collaboratives manual*<br>October 2014 |
| **Resource description** | Website – downloadable report and tools |
| **URL and access date** | http://www.greaterhealth.org/resources/patient-safety-collaborative-manual<br>Accessed 25/06/15 |
| **Aim** | To support those general practices engaged in the patient safety collaborative to provide safer care. |
| **Methods** | Four approaches were used to develop the manual:<br>1. Literature review<br>2. Consultations with national and international experts on patient safety<br>3. Interviews with highly experienced AGPAL surveyors who are involved in accreditation of Australian general practices<br>4. Interviews to identify the characteristics and activities of a national sample of Australian general practices performing highly in safety and quality. |
| **Results** | Reference is made to the Australian Safety and Quality Framework for Health Care. Guidance is provided for four key concepts in safety: 1) engaging the team, 2) data quality, 3) finding harm and 4) preventing harm. The first section on 'engaging the team' suggests using a 2008 AHRQ patient safety culture survey annually (the Medical Office Survey of patient safety culture). 'Data quality' suggests improving medical records continuously in general practices through: I) developing systems for creating and maintaining accurate patient health summaries; II) checking progress by monthly audit using a data-checking tool; and III) uploading verified health summaries to the internet electronic health record (e-Health). 'Finding harm' advises practices to: I) run a trigger tool quarterly; II) randomly select at least 25 triggered patients for notes review to identify harms; and III) record harms in Prioritisation Grid which is provided (an event log). 'Preventing harm' guides practices to make systems changes within the general practice for improved patient safety through: I) identifying which events from the trigger tool and event log patients had experienced harm or risk of harm; II) prioritising which events to conduct significant event analysis; and III) recording, sharing and undertaking actions to reduce harms. |
| **Key finding** | This manual provides an overview of patient safety concepts in the general practice setting, and a practical guide to how practices could engage in improving patient safety by providing resources and tools to use. |
| **Author (Organisation)**<br>**Title**<br><br>**Publication Date** | National Health Service (NHS) – National Reporting and Learning System (NRLS)[126]<br>*NHS National patient safety agency – NRLS (National reporting and learning system)*<br>2012 |
| **Resource description** | Website – incident reporting system |
| **URL and access date** | report.nrls.nhs.uk/nrlsreporting/<br>Accessed 26/06/15 |

| | |
|---|---|
| **Aim** | The aim is to identify and reduce risks to patients receiving NHS care. This resource is a patient safety incident reporting system for England and Wales. Patient Safety was a division of the National Patient Safety Agency (NPSA). The NPSA was an arm's length body of the Department of Health. It was established in 2001 with a mandate to identify patient safety issues and find appropriate solutions and abolished in 2012. The key functions of the Patient Safety division were transferred into NHS England on 1 June 2012. |
| **Methods** | The National Reporting and Learning System (NRLS) is a central database of patient safety incident reports. Since the NRLS was set up in 2003, over four-million incident reports have been submitted. All information submitted is analysed to identify hazards, risks and opportunities to continuously improve the safety of patient care. Reports are confidential and online. |
| **Results** | After logging in, NHS staff can:<br>• Upload incident reports from your their risk management reporting system<br>• Review incident reports submitted by their organisation<br>• View incident reports submitted online to the NRLS for their organisation<br>• View feedback reports for their organisation.<br>Related Department of Health documents that are available on this website include:<br>• Safety first: a report for patients, clinicians and healthcare managers<br>• Department of Health, published December 2006<br>• Building a safer NHS for patients – implementing an organisation with a memory<br>• Department of Health, published April 2001<br>• An organisation with a memory: Report of an expert group on learning from adverse events in the NHS<br>• Department of Health, published June 2000. |
| **Key findings** | NRLS is an incident reporting system that is accessible to all health care providers and patients in the UK |
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | NHS Scotland[169]<br><br>*Scottish patient safety programme in primary care*<br>Not stated |
| **Resource description** | Website – tools, resources and patient safety information |
| **URL and access date** | www.scottishpatientsafetyprogramme.scot.nhs.uk/Media/Docs/Primary%20Care/Primary%20Care%20general/training_pack_lo.pdf<br>Accessed 26/06/15 |
| **Aim** | The aim of the Scottish Patient Safety Programme in primary healthcare is to reduce the number of events which could cause avoidable harm from healthcare delivered in any primary healthcare setting. |
| **Methods** | NHS Scotland have developed a range of tools and resources to support those working within primary healthcare to bring about a patient safety culture within their teams. These include: Safety Culture: improving patient safety through the use of trigger tools (structured case note reviews) and safety climate surveys; Safer Medicines: including the prescribing and monitoring of high risk medications, such as warfarin and disease-modifying anti-rheumatic drugs (DMARDs), and developing |

| | |
|---|---|
| | reliable systems for medication reconciliation in the community; and Medicine Sick Day Rules Card – to complement the publication of the updated Polypharmacy Guidance (March 2015), NHS Scotland and the Scottish Patient Safety Programme are making the card available nationally. Safety Across the Interface by focusing on developing reliable systems for handling written and electronic communication and implementing measures to ensure reliable care for patients. |
| **Results** | The resources provided include a summary booklet (Patient safety in Primary Care 2013–2014: It's no trouble at all) and a training pack. These resources are provided to influence patient safety within the primary healthcare setting. They are for individual practices to use and contain trigger tools, patient safety culture surveys and other information. They are not designed for linked data collection with other practices or a national database of incidents. |
| **Key findings** | Tools, resources and patient safety information to improve safety practice and culture in general practice |
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | Canadian Patient Safety Institute[142]<br><br>*Patient safety and incident management toolkit*<br>Not stated |
| **Resource description** | Website – incident management online toolkit |
| **URL and access date** | www.patientsafetyinstitute.ca/English/toolsResources/PatientSafetyIncidentManagementToolkit/Pages/default.aspx<br>Accessed 25/06/15 |
| **Aim** | To provide a resource for the establishment of a patient safety culture in primary healthcare units and family practices in analysing patient safety incidents as they occur. |
| **Methods** | The online Toolkit provides those responsible for patient safety and incident management with an integrated set of practical strategies and resources for recognising, responding to and learning from patient safety incidents which ultimately aims to improve the safety of patient care. This practical, yet comprehensive resource provides tools that can be used to help strengthen quality, risk management and patient safety endeavours. |
| **Results** | The Toolkit provides an inventory of relevant information in one place, including the Canadian Incident Management Framework, the Canadian Disclosure Guidelines, the Guidelines for Informing the Media after an Adverse Event, and Global Patient Safety Alerts. The Incident Management Continuum from the Canadian Incident Analysis Framework formed the foundation for the Toolkit. New content, guidance and resources were added to better support actions to understand and prevent incidents as well as to understand and leverage system factors. The World Health Organization (WHO) classification language has also been adopted throughout the Toolkit. |
| **Key findings** | The Toolkit takes into account the entire life cycle of a patient safety incident from end-to-end and provides organisations with different tools and considerations to look at as they improve their processes around patient safety. |

| | |
|---|---|
| **Author (Organisation)**<br>**Title**<br>**Publication Date** | Conway J, Federico F, Stewart K, Campbell MJ [170]<br>Institute for healthcare improvement<br>*Respectful management of serious clinical adverse events*<br>2011 |
| **Resource description** | Report – white paper |
| **URL and access date** | www.ihi.org/resources/Pages/IHIWhitePapers/RespectfulManagementSeriousClinicalAEsWhitePaper.aspx<br>Accessed 25/06/15 |
| **Aim** | To introduce an overall approach and tools designed to support two processes: the proactive preparation of a plan for managing serious clinical adverse events, and the reactive emergency response of an organisation that has no such plan. |
| **Methods** | The white paper covers three areas:<br>1. Encourage and help every organisation to develop a clinical crisis management plan before they need to use it<br>2. Provide an approach to integrating this plan into the organisational culture of quality and safety, with a particular focus on patient- and family-centred care and fair and just treatment for staff<br>3. Provide organisations with a concise, practical resource to inform their efforts when a serious adverse event occurs in the absence of a clinical crisis management plan and/or culture of quality and safety. |
| **Results** | The paper includes three tools for leaders (as appendices) – a Checklist, a Work Plan, and a Disclosure Culture Assessment Tool – and numerous resources to guide practice. The three tools are also included below as individual documents for ease of use. |
| **Key findings** | A guide to the management of serious adverse events for health care organisations. |

## Appendix 5: Data extraction and quality scoring template



| | | | |
|---|---|---|---|
| Describe the study population | | | |
| Sample size: | | | |
| Country: | | Location other | |
| Professional setting: | | Setting_other | |
| Intervention type: | | Intervention_other | |
| Describe the study: (Methods, interventions, outcome measures etc) | | | |
| Describe any definitions used | | | |
| Describe any tools or resources developed or used: | | | |

| | | | |
|---|---|---|---|
| What is the topic? | | Other: | |
| Datasource | | Other: | |
| Results:<br>Describe the main findings. Include patient demogrpahics and primary and secondary outcomes | | | |
| Key finding: | | | |
| Comments | | | |

| | |
|---|---|
| Are the individuals selected to participate representative of the target population? | |
| What percentage of selected indivudals agreed to participate? | |
| Selection bias rating | |
| Study design: | |
| Was the study described as randomised? | |
| Was the method of randomisation described? | |
| Was the method of randomisation appropriate? | |
| Study design rating | |
| Were there important differences between groups? | |
| What percentage of confounding was controled via design, matching or stratification? | |
| Confounder rating: | |
| Were the outcome assessors aware of the intervention or control status? | |
| Were the participants aware of the research question? | |
| Blinding rating: | |
| Were the data collection tools shown to be valid? | |
| Were the data collection tools shown to be reliable? | |
| Datacollection rating: | |

| | |
|---|---|
| Were withdrawals and drop outs reported in terms of numbers and/or reasons? | |
| What percentage of subjects completed the study? | |
| Withdrawal rating | |
| What percentage of participants were exposed to the intervention? | |
| Was the consistency of the intervention measured? | |
| Is it likely that subjects recived an unintended intervention (contamination)? | |
| What was the unit of allocation? | |
| What was the unit of analysis? | |
| Is the analysis (including statistics) appropriate for the study design? | |
| Is the analysis performed by intervention allocation (ie intention to treat)? | |

| | |
|---|---|
| What is the NHMRC level of evidence for the study? | |
| Which National Safety and Quality Standard does the study align to? | |
| Other: | |
| Which research question is the study relevant to? | |

## Appendix 6: Quality scoring template for quantitative studies

# QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES


### COMPONENT RATINGS

### A) SELECTION BIAS

**(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?**

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

**(Q2) What percentage of selected individuals agreed to participate?**

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| See dictionary | 1 | 2 | 3 |

### B) STUDY DESIGN

**Indicate the study design**

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

**Was the study described as randomized? If NO, go to Component C.**

No Yes

**If Yes, was the method of randomization described? (See dictionary)**

No Yes

**If Yes, was the method appropriate? (See dictionary)**

No Yes

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| **See dictionary** | 1 | 2 | 3 |

## C) CONFOUNDERS

**(Q1) Were there important differences between groups prior to the intervention?**

1 Yes
2 No
3 Can't tell

**The following are examples of confounders:**

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

**(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?**

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| See dictionary | 1 | 2 | 3 |

## D) BLINDING

**(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?**

1 Yes
2 No
3 Can't tell

**(Q2) Were the study participants aware of the research question?**

1 Yes
2 No
3 Can't tell

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| See dictionary | 1 | 2 | 3 |

## E) DATA COLLECTION METHODS

**(Q1) Were data collection tools shown to be valid?**

1 Yes
2 No
3 Can't tell

**(Q2) Were data collection tools shown to be reliable?**

1 Yes
2 No
3 Can't tell

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| See dictionary | 1 | 2 | 3 |

## F) WITHDRAWALS AND DROP-OUTS

**(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?**

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

**(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).**

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

| RATE THIS SECTION | STRONG | MODERATE | WEAK | |
|---|---|---|---|---|
| See dictionary | 1 | 2 | 3 | Not Applicable |

## G) INTERVENTION INTEGRITY

**(Q1) What percentage of participants received the allocated intervention or exposure of interest?**

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

**(Q2) Was the consistency of the intervention measured?**

1 Yes
2 No
3 Can't tell

**(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?**

4 Yes
5 No
6 Can't tell

## H) ANALYSES

**(Q1) Indicate the unit of allocation (circle one)**

community organization/institution practice/office individual

**(Q2) Indicate the unit of analysis (circle one)**

community organization/institution practice/office individual

**(Q3) Are the statistical methods appropriate for the study design?**

1 Yes
2 No
3 Can't tell

**(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?**

1 Yes
2 No
3 Can't tell

**GLOBAL RATING**

**COMPONENT RATINGS**

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

| | | | | | |
|---|---|---|---|---|---|
| **A** | **SELECTION BIAS** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **B** | **STUDY DESIGN** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **C** | **CONFOUNDERS** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **D** | **BLINDING** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **E** | **DATA COLLECTION METHOD** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **F** | **WITHDRAWALS AND DROPOUTS** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | Not Applicable |

**GLOBAL RATING FOR THIS PAPER (circle one):**

| | | |
|---|---|---|
| 1 | STRONG | (no WEAK ratings) |
| 2 | MODERATE | (one WEAK rating) |
| 3 | WEAK | (two or more WEAK ratings) |

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

| | |
|---|---|
| 1 | Oversight |
| 2 | Differences in interpretation of criteria |
| 3 | Differences in interpretation of study |

**Final decision of both reviewers (circle one):**

| | |
|---|---|
| **1** | **STRONG** |
| **2** | **MODERATE** |
| **3** | **WEAK** |

## Appendix 7: AMSTAR tool to assess the quality of systematic reviews

AMSTAR – a measurement tool to assess the methodological quality of systematic reviews[16-18]

| | |
|---|---|
| **1. Was an 'a priori' design provided?**<br>The research question and inclusion criteria should be established before the conduct of the review.<br><br>*Note: Need to refer to a protocol, ethics approval, or pre-determined/a priori published research objectives to score a "yes".* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |
| **2. Was there duplicate study selection and data extraction?**<br>There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.<br><br>*Note: Two people do study selection, two people do data extraction, consensus process or one person checks the other's work.* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |
| **3. Was a comprehensive literature search performed?**<br>At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialised registers, or experts in the particular field of study, and by reviewing the references in the studies found.<br><br>*Note: If at least two sources + one supplementary strategy used, select "yes" (Cochrane register/Central counts as two sources; a grey literature search counts as supplementary).* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |
| **4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?**<br>The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.<br><br>*Note: If review indicates that there was a search for "grey literature" or "unpublished literature," indicate "yes". SIGLE database, dissertations, conference proceedings, and trial registries are all considered grey for this purpose. If searching a source that contains both grey and non-grey, must specify that they were searching for grey/unpublished literature.* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |
| **5. Was a list of studies (included and excluded) provided?**<br>A list of included and excluded studies should be provided.<br><br>*Note: Acceptable if the excluded studies are referenced. If there is an electronic link to the list but the link is dead, select "no".* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |
| **6. Were the characteristics of the included studies provided?**<br>In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of | □ Yes<br>□ No |

| | |
|---|---|
| characteristics in all the studies analysed, e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.<br><br>*Note: Acceptable if not in table format as long as they are described as above.* | □ Can't answer<br>□ Not applicable |
| **7. Was the scientific quality of the included studies assessed and documented?**<br>'A priori' methods of assessment should be provided (e.g. for effectiveness studies if the author(s) chose to include only randomised, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.<br><br>*Note: Can include use of a quality scoring tool or checklist, e.g. Jadad scale, risk of bias, sensitivity analysis, etc., or a description of quality items, with some kind of result for EACH study ("low" or "high" is fine, as long as it is clear which studies scored "low" and which scored "high"; a summary score/range for all studies is not acceptable).* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |
| **8. Was the scientific quality of the included studies used appropriately in formulating conclusions?**<br>The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.<br><br>*Note: Might say something such as "the results should be interpreted with caution due to poor quality of included studies." Cannot score "yes" for this question if scored "no" for question 7.* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |
| **9. Were the methods used to combine the findings of studies appropriate?**<br>For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. chi-squared test for homogeneity, I2) if heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).<br><br>*Note: Indicate "yes" if they mention or describe heterogeneity, i.e. if they explain that they cannot pool because of heterogeneity/variability between interventions.* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |
| **10. Was the likelihood of publication bias assessed?**<br>An assessment of publication bias should include a combination of graphical aids (e.g. funnel plot, other available tests) and/or statistical tests (e.g. Egger regression test, Hedges-Olken).<br><br>*Note: If no test values or funnel plot included, score "no". Score "yes" if mentions that publication bias could not be assessed because there were fewer than 10 included studies.* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |

| | |
|---|---|
| **11. Was the conflict of interest included?**<br>Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.<br><br>*Note: To get a "yes", must indicate source of funding or support for the systematic review AND for each of the included studies.* | □ Yes<br>□ No<br>□ Can't answer<br>□ Not applicable |

## Appendix 8: The World Health Organization International Classification for Patient Safety – definitions of key concepts[8]

1. Classification: an arrangement of **concepts** into **classes** and their subdivisions, linked so as to express **semantic relationships** between them.
2. **Concept**: a bearer or embodiment of meaning.
3. **Class**: a group or set of like things.
4. **Semantic relationship**: the way in which things (such as **classes** or **concepts**) are associated with each other on the basis of their meaning.
5. **Patient**: a person who is a recipient of **healthcare.**
6. **Healthcare**: services received by individuals or communities to promote, maintain, monitor or restore **health**.
7. **Health**: a state of complete physical, mental and social wellbeing and not merely the absence of **disease** or infirmity
8. **Safety**: the reduction of risk of unnecessary **harm** to an acceptable minimum.
9. **Hazard**: a **circumstance**, **agent** or action with the potential to cause harm.
10. **Circumstance**: a situation or factor that may influence an **event**, **agent** or person(s).
11. **Event**: something that happens to or involves a **patient**
12. **Agent**: a substance, object or system which acts to produce change.
13. **Patient Safety**: the reduction of risk of unnecessary **harm** associated with **healthcare** to an acceptable minimum.
14. **Healthcare-associated harm: harm** arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying **disease** or **injury**.
15. **Patient safety incident**: an **event** or **circumstance** which could have resulted, or did result, in unnecessary **harm** to a **patient**.
16. **Error**: failure to carry out a planned action as intended or application of an incorrect plan.
17. **Violation**: deliberate deviation from an operating procedure, standard or rule
18. **Risk**: the probability that an **incident** will occur.
19. **Reportable circumstance**: a situation in which there was significant potential for harm, but no incident occurred.
20. **Near miss**: an **incident** which did not reach the patient.
22. **No harm incident**: an **incident** which reached a patient but no discernible harm resulted.
23. **Harmful incident (adverse event)**: an **incident** which resulted in **harm** to a patient.
24. **Harm**: impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes **disease**, **injury**, **suffering**, **disability** and death.
25. **Disease**: a physiological or psychological dysfunction.

26. **Injury**: damage to tissues caused by an **agent** or **event**.
27. **Suffering**: the experience of anything subjectively unpleasant.
28. **Disability**: any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present **harm**.
29. **Contributing Factor**: a **circumstance**, action or influence which is thought to have played a part in the origin or development of an **incident** or to increase the **risk** of an **incident**.
30. **Incident type**: a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.
31. **Patient characteristics**: selected **attributes** of a **patient**.
32. **Attributes**: qualities, properties or features of someone or something.
33. **Incident characteristics**: selected **attributes** of an **incident**.
34. **Adverse reaction**: unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
35. **Side effect**: a known effect, other than that primarily intended, related to the pharmacological properties of a medication.
36. **Preventable**: accepted by the community as avoidable in the particular set of circumstances.
37. **Detection**: an action or **circumstance** that results in the discovery of an **incident**.
38. **Mitigating factor**: an action or **circumstance** which prevents or moderates the progression of an **incident** towards harming a **patient**.
39. **Patient outcome**: the impact upon a patient which is wholly or partially attributable to an **incident**.
40. **Degree of harm**: the severity and duration of harm, and any treatment implications, that result from an **incident**.
41. **Organisational outcome**: the impact upon an organisation which is wholly or partially attributable to an **incident**.
42. **Ameliorating action**: an action taken or **circumstances** altered to make better or compensate any **harm** after an **incident**.
43. **Actions taken to reduce risk**: actions taken to reduce, manage or control any future harm, or probability of **harm**, associated with an **incident**.
44. **Resilience**: The degree to which a system continuously prevents, detects, mitigates or ameliorates **hazards** or **incidents**.
45. **Accountable**: being held responsible.
46. **Quality**: the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
47. **System failure**: a fault, breakdown or dysfunction within an organisation's operational methods, processes or infrastructure.

48. **System improvement**: the result or outcome of the culture, processes, and structures that are directed toward the prevention of **system failure** and the improvement of **safety** and **quality**.

49. **Root cause analysis**: a systematic iterative process whereby the factors which contribute to an **incident** are identified by reconstructing the sequence of events and repeatedly asking why? Until the underlying root causes have been elucidated.

## Appendix 9: World Health Organization International Classification for Patient Safety Definitions of Harm[8]

| | |
|---|---|
| **No Harm** | Patient outcome is not symptomatic or no symptoms detected and no treatment is required |
| **Low Harm 1** | Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g. extra observation, investigation, review or minor treatment) is required. |
| **Moderate Harm** | Patient outcome is symptomatic, requiring intervention (e.g. additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function. |
| **Major/Severe Harm** | Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function. |
| **Death/Serious** | On balance of probabilities, death was caused or brought forward in the short term by the incident. |

## Appendix 10: Items included in the SCOPE-PC Questionnaire

Adapted from Verbakel et al.[30]

| Item | Description |
|---|---|
| **Open communication and learning from error** | |
| C1 | We are given feedback about changes put into place based on event reports |
| C2 | Staff will freely speak up if they see something that may negatively affect patient care |
| C3 | We are informed about errors that happen in this practice |
| C4 | Staff feel free to question the decisions or actions of those with more authority |
| C5 | In this practice, we discuss ways to prevent errors from happening again |
| C7 | Professionals discuss errors that occurred with each other |
| C9 | We are given personal feedback about our own event reports |
| B4n | My supervisor/manager overlooks patient safety problems that happen over and over |
| **Handover and teamwork** | |
| F1n | Problems often occur in the exchange of information across disciplines in our practice |
| F2n | The fact that patients are treated by different professionals in our practice is causing problems |
| F3n | Disciplines in the practice that we co work with do not coordinate well with each other |
| F4 | There is a good exchange of information between professionals in this practice |
| F5 | There is a good exchange of information between supporting staff in this practice |
| F7n | Things "fall between the cracks" when transferring patients between different disciplines in this practice |
| F8n | Important patient care information is often lost because patients see different professionals |
| **Adequate procedures and working conditions** | |
| A5n | It is just by chance that more serious mistakes don't happen around here |
| A7n | We use more agency/temporary staff than is best for patient care |
| A8n | Staff feel like their mistakes are held against them |
| A10n | In this practice we work longer hours than is best for patient care |
| A12n | When an event is reported, it feels like the person is being written up, not the problem |
| A13n | We work in "crisis mode" trying to do too much, too quickly |
| A14n | Staff worry that mistakes they make are kept in their personnel file |
| A15n | We have patient safety problems in this practice |
| B3n | Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts |
| **Patient safety and management** | |
| B1 | My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures |
| B2 | My supervisor/manager seriously considers staff suggestions for improving patient safety |
| B5 | My supervisor/manager provides a work climate that promotes patient safety |
| B6 | The actions of my supervisor/manager show that patient safety is top priority |
| B7n | My supervisor/manager seems interested in patient safety only after an adverse event happens |

| Item | Description |
|---|---|
| **Support and fellowship** | |
| A1 | People support one another in this practice |
| A2 | We have enough staff to handle the workload |
| A3 | When a lot of work needs to be done quickly, we work together as a team to get the work done |
| A4 | In this practice, people treat each other with respect |
| A11 | When someone in this practice gets really busy, others help out |
| **Intention to report events** | |
| D2 | When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? |
| D3 | When a mistake is made, but has no potential to harm the patient, how often is this reported? |
| D4 | When a mistake is made that could harm the patient, but does not, how often is this reported? |
| **Organisational learning** | |
| A6 | We are actively doing things to improve patient safety |
| A9 | Mistakes have led to positive changes here |
| A16 | Our procedures and systems are good at preventing errors from happening |
| The letter "n" in an item-code means that it concerns an item in negative wording | |

## Appendix 11: Developing a preliminary 'never event' list for general practice using consensus-building methods – criteria and included items

Adapted from De Wet et al.[29]

### 11.1: Never event criteria for general practice settings

A never event….

1. Is known to cause severe harm to a patient, or has the potential to do so AND
2. Is preventable by the healthcare professional, team, or organisation AND
3. Can be clearly and precisely defined AND
4. Can be detected AND
5. Is not the result of an unlawful act.

### 11.2: Preliminary list of never events for UK general medical practice

| Never event | Overall CVI Score |
|---|---|
| 1. Prescribing a drug to a patient that is recorded in the practice system as having previously caused her/him a severe adverse reaction | 100 |
| 2. A planned referral of a patient, prompted by clinical suspicion of cancer, is not sent | 100 |
| 3. Prescribing a teratogenic drug to a patient known to be pregnant (unless initiated by a clinical specialist) | 100 |
| 4. Emergency transport is not discussed or arranged when admitting a patient as an emergency | 94 |
| 5. An abnormal investigation result is received by a practice but is not reviewed by a clinician | 94 |
| 6. Prescribing aspirin for a patient <12 years old (unless recommended by a specialist for specific clinical conditions for example, Kawasaki's disease) | 94 |
| 7. Prescribing systemic oestrogen-only hormone replacement therapy for a patient with an intact uterus | 94 |
| 8. Prescribing methotrexate daily rather than weekly (unless initiated by a specialist for a specific clinical condition, for example, leukaemia) | 88 |
| 9. A needle-stick injury caused by a failure to dispose of 'sharps' in compliance with national guidance and regulations | 88 |
| 10. Adrenaline (or equivalent) is NOT available when clinically indicated for a medical emergency in the practice or GP home visit. | 88 |