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Methods and Measures used in Primary Care Patient Safety Research

Results of a literature review

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ABSTRACT

Background and Aims: As most patient safety research to date has focused on hospital-related issues, we aimed to determine the methods used in patient safety research conducted in primary care, their strengths and weaknesses, the measures they produced, and research gaps.

Methods: Review of MEDLINE, in-process and PubMed-not-MEDLINE, OLDMEDLINE, CINAHL and EMBASE records from 1966 to 2007. Bibliographies of selected articles were scanned for additional publications. MeSH terms relating to patient safety, primary care and incident reporting were used. We excluded studies that examined only one type of patient safety incident or only one primary care process, and studies based on hospital data only. We included research using both primary care and hospital data and research about community-based complementary or alternative medicine. We searched the internet

sites of national patient safety organizations and the English-language websites of 92 international, national or provincial general practice/family medicine organizations, and one international and one national physician insurance agency.

Results: We identified nine retrospective studies, 34 concurrent or prospective or single method studies and six mixed methods studies. The most common method was analysis of reports of patient safety incidents made by primary care clinicians, practice staffs, or patients (22 papers).

We identified no primary care patient safety research from developing countries. No studies comparable to hospital-based retrospective record reviews or autopsy research were found. Patients' perspectives were poorly represented.

Estimates of patient safety incidents in primary care were 0.004-240.0 per

1000 primary care consultations and 45%-76% of all “errors” were preventable. Many studies included measures of the relative frequency of different types of patient safety incident: 26%-57% of incidents involved diagnostic “errors”; 7%-52% involved treatment; 13%-47% involved investigations; 9%-56% involved office administration; 5%-72% were communication errors. Harm from safety incidents ranged from 1.3 significant minor incidents

per 1000 treatments to 4% of incidents resulting in death, 17%–39% resulting in harm, and 70%–76% had potential for harm.

Conclusions:

Much useful work has been done but the study of patient safety in primary care is still in its infancy. More rigorous methods need to be used and clearer and more consistent definitions of common terms would assist comparability of results.

INTRODUCTION

The internationally agreed definition of primary health care is provided in point VI of the Declaration of Alma-Ata.¹ Although each country interprets the concept slightly differently, overall, *primary health care* describes the activity of health care providers who are the first point of health system contact for patients and who are based in a community, rather than in a hospital.²

The purpose of this paper is to critically appraise the methods used to research patient safety in primary health care studies and the metrics (measures) this research uses and produces. This document has been developed as part of a series of reviews proposed by the World Health Organisation (WHO) World Alliance for Patient Safety aiming at understanding the tools available for conducting research on patient safety in various settings.³ Companion papers review methods and measures used for patient

research in acute hospital settings (focusing on higher income countries),⁴ and in transitional and developing countries.⁵ In addition there are papers on the ontology,⁶ epistemology,⁷ and scope of patient safety research⁸ that set the context for these three reviews.

To date concern about the safety of patients in hospital settings has driven most research in the field. The seminal reports about patient safety in the US⁹ and the UK¹⁰ excluded primary care from their discussions. The UK report was specific about this exclusion and it was implicit in the US report. Hospitals were the focus of attention and have remained so to date.

A stronger emphasis on primary care patient safety research is important because the overwhelming majority of healthcare is delivered outside hospitals, in primary care settings.¹¹ Many safety incidents identified in

hospitals originate elsewhere, often in primary care¹²⁻¹⁴ and most burden on health systems arises not from rare mistakes with drastic consequences, but from the more mundane incidents that have effects that are magnified by frequent repetitions and exposure of a large number of people.¹⁵

Primary care may hold different threats to patient safety from hospital settings due to both the health care delivery environment and the type of health services provided. Primary care providers often have less control over care management and delivery than in the more continuously monitored hospital admissions, and more than one site is often required for an episode of care (having implications for patient and information transfer). Primary care sites are not necessarily designed for this purpose (for example: patients' homes, providers' cars, or on roads). As well, episodes of primary care may extend over very long time frames – sometimes years. There is an argument that incidents

with immediate or close observable consequences should be defined within the *safety* paradigm but incidents with delayed effects should be regarded as primarily a *quality* issue.⁶ From a primary care perspective this distinction based on time is problematic, but there remain challenges in identifying and measuring patient safety incidents that are associated with lengthy latency, and where incomplete records may mask complete understanding of contributing factors.

Further complicating patient safety research in primary care are the characteristics of patients who commonly present in primary care with undifferentiated problems, uncertain diagnoses and multiple co-morbidities.¹⁶ Appropriate and inappropriate delays in protecting their safety by making a correct diagnosis must be subjectively assessed. There are also substantial challenges in protecting patients' safety where the systems to support safe care may be poorly defined and idiosyncratic.

There is one notable exception to the overall dearth of patient safety research in primary care. Because of the need to test the safety of pharmaceutical products before they are released onto the market, and to regulate their use after release, the pharmacovigilance literature has generated a great deal of knowledge about drug safety and much of this is primary care-based (see, for example¹⁷⁻²⁵). This paper reviews the methods and measures used for patient safety research conducted in, about, and for primary care patients and providers. We excluded papers concentrating on one particular primary care process or function (such as prescribing) and we focus instead on research aimed at investigating the full spectrum of patient safety issues in primary care.

METHODS

A review of the published scientific literature was undertaken using OVID Medline from 1966 to December 2007. This database includes "In-Process and Other Non-

Indexed Citations", Ovid's collection of non-indexed National Library of Medicine records, both the in-process and PubMed-not-MEDLINE records, and OLDMEDLINE (the National Library of Medicine's online database of approximately 1,700,000 citations to articles from international biomedical journals covering the fields of medicine, preclinical sciences and allied health sciences). The same Medical Subject Headings (MeSH terms) relating to patient safety, primary care and incident reporting (shown in Table 1) were also used to search the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Excerpta Medica (EMBASE). The reference lists of selected articles were scanned for any additional relevant publications.

We excluded articles that did not report original research, studies that examined only one type of patient safety incident or only one primary care process, and studies based on hospital data only. We included research about patient safety

incidents where both primary care and hospital data were used and we included research about community-based complementary or alternative medicine that met other review criteria.

We also searched the internet sites of national patient safety organizations in Australia, Europe and North America and the English-

language websites of 92 international, national or provincial general practice or family medicine organizations, and one international and one national physician insurance agency. The search strategy for Medline (repeated for searches of the CINAHL and EMBASE databases) is shown in Table 1.

Table 1. Search strategy used for OVID Medline

Search	
#1	Family practice OR primary care OR primary health care OR general practice
#2	Medical error* OR medication error* OR diagnostic error* OR iatrogenic disease OR malpractice OR safety culture OR near failure OR near miss OR patient safety method* OR patient safety indicator* OR patient safety measure* OR patient safety report* OR safety event report* OR safety manage* OR risk manage* OR adverse drug reaction
#3	#1 AND #2
#4	LIMIT: Abstracts
#5	LIMIT: English language
#6	LIMIT: clinical trial OR meta-analysis OR randomized controlled trial OR review OR case report OR classical article OR comparative study OR evaluation studies OR controlled clinical trial

RESULTS

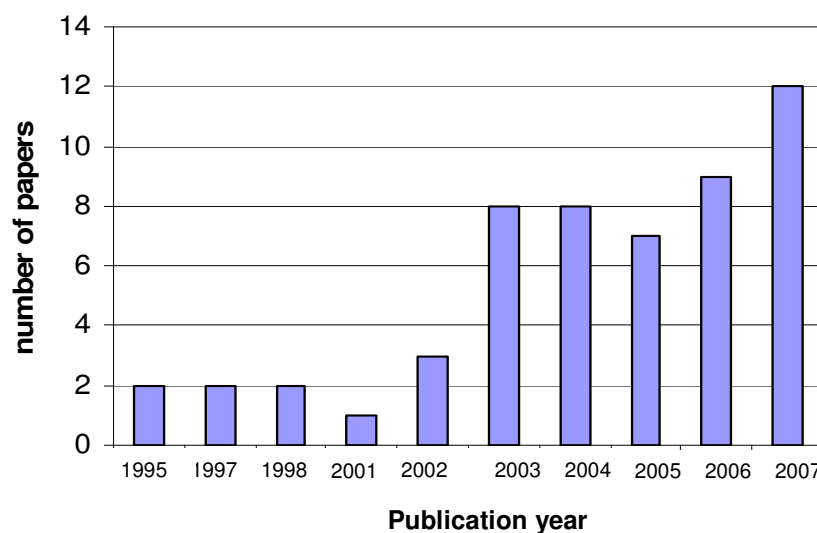
Search results

The Ovid Medline search returned 1057 titles and abstracts and the CINAHL and EMBASE searches returned 773 potentially relevant papers.

We reviewed the titles of all papers and if the title suggested eligibility we also reviewed the abstract. Titles and abstracts suggested the eligibility of 126 papers and we read the full text of these. Eliminating duplicates, discussion papers and letters, we found 49 articles reporting original research of direct relevance to the objectives of this paper, and 29 that were peripherally related. We

excluded the peripherally related papers because their data were derived hospitals only (8 papers), their subject matter was not directly related to patient safety (8 papers), or they were focused on individual types of safety incident or care process (13 papers).

The number of papers reporting patient safety research in primary care increased rapidly over the period of the review. Figure 1 shows the publication year of the 49 research reports included in this review and Table 2 shows the research methods used in each of the three general types of research approach.

Figure 1: Review-eligible papers by publication year

Methods used in primary care patient safety research

The 49 articles directly related to patient safety research in primary care were of three main types:

1. Retrospective studies, including literature reviews and studies using medical records and malpractice databases as their data sources.²⁶⁻³⁴ We included studies of significant event audits in the retrospective category because although the audits themselves were

reported in real-time, the research involving databases of audits was completed retrospectively.

2. Concurrent or prospective or single method studies using data analyzed either qualitatively or quantitatively.³⁵⁻⁶⁸ We included reporting systems studies in this category because, although reported incidents may have happened in the past (retrospectively), reports used in these studies

were made especially for the research, or in “real-time”.

3. Mixed methods studies reporting research that used two or more different methods.⁶⁹⁻⁷⁴

Within these three main research approaches, 10 different methods were used. Forty-eight studies used only one main method but the six remaining studies used two^{69-72, 74} and four⁷³ different methods. The most common method was analysis of reports of patient safety incidents made by primary care clinicians, practice staffs, or patients^{36, 37, 39-42, 45, 48-50, 53, 54, 57-61, 63-66, 68} and the research question most often addressed was: “what types of

patient safety incident happen in primary care?”^{29, 30, 32, 33, 36-39, 41, 42, 46, 48-54, 58-63, 65, 66, 68, 70, 71}

Reported research was grouped according to the following generic reasons for the study:

1. To establish the types (and sometimes frequency) of patient safety incidents happening in primary care.
2. To propose and/or test interventions to make primary care safer for patients.
3. To propose and/or test methods for patient safety research in primary care settings.

Table 2: Generic research questions addressed in studies using different designs/methods

	Research Design		
Research Aim	Retrospective	Concurrent or Prospective	Mixed methods
To establish the types (and/or frequency) of patient safety events happening in primary care	Systematic literature reviews ^{29, 33} Studies of malpractice claims and risk management databases ^{30, 34}	Interview studies ^{38, 51} Surveys ^{46, 52, 62} Reporting systems ^{36, 37, 39-42, 48-50, 53, 54, 57-61, 63-66, 68}	Survey + Interview study ⁷¹ Survey + Systematic literature review ⁷⁰
To propose and/or test methods for patient safety research in primary care settings	Systematic literature reviews ²⁶ Studies of Significant Event Audit databases ³¹ Studies of malpractice claims and risk management databases ³²	Surveys ^{47, 56} Reporting systems ⁴⁵	Systematic literature review + Focus group study ⁷² Study of Significant Event Audit database + Survey ⁷⁴
To propose and/or test interventions to make primary care safer for patients	Studies of significant event audit databases ^{27, 28}	Interview studies ^{35, 44} Focus group ^{43, 55} Reporting systems ^{40, 44, 57, 58, 64, 67}	Delphi study + Interview study ⁶⁹ Systematic literature review + Interview study + Focus group study ⁷³

A. Strengths and weaknesses of retrospective research methods

Retrospective research methods are generally used to find out what has happened in the past in order to plan improvements for the future.

Systematic reviews of the literature have been published both as a stand-alone research method^{26, 29, 33} and in combination with other methods.^{70, 72, 73} The first literature review appeared in 2002²⁹ aimed at developing a way to describe primary

care patient incidents, followed by another in 2003³³ that aimed to both describe incidents and estimate their frequency. In 2006^{70, 72} and 2007^{26, 73} four more literature review papers were published. Where a literature review is reported in combination with other research methods, it was used in advance of other methods to develop a tentative definition,⁷⁰ proposal,⁷² or method⁷³ that was then tested by the other methods.

The strengths of literature reviews lie in their being able to summarize existing knowledge and identify knowledge gaps. Results of a literature review crucially depend on the literature being reviewed, the means by which it is identified, and how it is interpreted. Medline was accessed for all primary care patient safety literature reviews although one paper was silent on their search strategy.⁷⁰ Medline excludes many journals that publish primary care research so used alone it is unlikely to provide a complete picture. Most searches were limited to English language reports and this would also limit their comprehensiveness.

Most literature reviews used more than one citation database, and included searches of EMBASE,^{26, 29, 73} CINAHL,^{26, 73} the Cochrane Library,²⁹ E-PIC (Pharmacy information),⁷³ the Health Management Information Circular (HMIC)⁷³ and the websites or bibliography collections of WHO,⁷⁰ the Joint Commission for the Accreditation of Healthcare

Organizations,⁷⁰ the National Patient Safety Foundation,^{29, 33} the Institute for Healthcare Improvement,²⁹ the American Academy of Family Physicians,²⁹ the American College of Physicians-American Society of Internal Medicine,²⁹ the Institute of Medicine,²⁹ and the Medical Protection Society.³³

Measures of primary care patient safety incidents from literature reviews:

All literature reviews concentrated on qualitative analyses of prior research, producing definitions of “medical error”^{29, 70} and “preventable adverse events”,²⁹ identification of factors impeding or facilitating disclosure of “medical errors”,⁷² ways that mortality data are used in general practice,²⁶ and a measure of patient safety culture in primary care organizations.⁷³

One review found 25 different definitions of “medical error”.⁷⁰

Another derived quantitative measures of “medical errors” in primary care (5-80 per 100,000 consultations), “errors in diagnosis”

(26-78% of all “errors”), and “treatment errors” (11-42% of all “errors”).³³ This study also estimated that 60-83% of all “errors” were preventable.

Studies of significant event audits

are limited to the United Kingdom, where since 2004 the Quality and Outcomes Framework has rewarded general practices for carrying out analyses of significant occurrences (not necessarily involving negative patient outcomes) in an effort to improve care. One paper was published shortly before conducting such audits was associated with payment.³¹ Three studies used significant event audits alone^{27, 28, 31} and in one study a significant event audit was used in combination with a survey.⁷⁴ The former three studies aimed to describe the content of general practices’ significant event audits while the latter study used the quality of significant event audits as an outcome measure for an intervention aiming to improve risk management in general practice.

These studies were descriptive, small, and not designed for epidemiological generalizability: the 2003 study reviewed only 56 significant event reports³¹ although 337²⁷ and 662²⁸ reports were included in the later studies.

Significant events described in these studies tended to be serious, with events that may threaten patient safety but not pose an immediate risk to life regarded as not significant enough to warrant inclusion. A limitation of significant event audit as a method for researching patient safety in primary care is that so far it has been reported only in the UK.

We could find no evidence of its having been used for research in other countries. However, in the UK it is now a compulsory activity for general practices and in the future, outcome measures for patient safety research may possibly be derived from significant event reports.

Furthermore, if other countries adopt the same technique, it may provide a means of making international comparisons.

Measures of primary care patient safety incidents from significant event audits: The main measures produced by three studies were descriptions of the significant events reported in general practice.^{27, 28, 31}

These descriptions grouped events according to classifications derived from reporting system studies.^{39, 53,}

⁶⁰ Other measures used in significant event audit research were reasons for significant event reports being “unsatisfactory”^{27, 28} and severity of patient safety event outcomes. Serious or life-threatening events were 6.5% of reports in one study²⁸ and 22% of reports in another.³¹

Studies of malpractice claims and risk management databases are currently not a mainstream approach in primary care patient safety research. We identified three relevant studies.^{30, 32, 34} One was a study of incidents reported to a risk management database at one US academic medical centre,³⁰ one was a case series (N = 94) of criminal cases in Hungary that involved

health care providers,³⁴ and the third analyzed 49,345 US primary care malpractice claims.³² This method was not used in any mixed-method studies.

The study by Fischer et al³⁰ is the earliest quantitative study of patient safety incidents in primary care we found. Quantitative analyses make an important contribution to the field of patient safety because they highlight common problems that can then be used to prioritize interventions. The main weakness of studies involving malpractice claims or risk management databases is that they provide a limited view of patients’ experiences with patient safety incidents. Most incidents do not prompt a malpractice claim and many claims do not arise from preventable incidents.⁷⁵ However, they do give access to data about incidents that patients have found unsatisfactory and, as in two of the studies we identified, data can be found for entire countries.^{32, 34}

Another strength, demonstrated in the study by Phillips et al,³² is that by

linking malpractice and other databases, additional information can be derived about the characteristics of these incidents.

Measures of primary care patient safety incidents from malpractice databases: The main measures were the prevalence of incidents that resulted in an injury, potential injury, or financial liability (5.4 per 100,000 clinic visits³⁰) and the distributions of incidents of different types. Patient safety incidents described in these malpractice and risk management databases were due to treatment (31%³⁰) or medication errors (8%³²), diagnostic mishaps (26%,³⁰ 29%³⁴ and 34%³²), failure to supervise or monitor (16%³²), improper performance (15%³²), failure or delay in referral (4%³²), 'other' errors (26%³⁰) or no error, such as known complications (17%³⁰).

Severity of outcome was measured as death (3.4%³⁰ and 37%³² of "errors"), severe or permanent disability (13.8%³⁰ and 19%³² of "errors"), moderate or temporary

disability (34.5%³⁰ and 26%³² of "errors"), and low severity or emotional outcome only (48.3%³⁰ and 18%³² of "errors").

B. Strengths and weaknesses of concurrent and prospective research

Concurrent and prospective primary care patient safety research methods are generally used to find out what is currently happening and the qualitative methods often used in concurrent and prospective primary care patient safety research are particularly important for providing in-depth analyses of why patient safety incidents happen.

Interview studies have been used as a method for studying patient safety in primary care for more than a decade. They have been used as both a stand-alone method^{35, 38, 44, 51} and in mixed-methods studies.^{69, 71, 73} They have been used to describe patient safety incidents in primary care^{38, 51, 71} and to develop ways to make primary care safer.^{35, 44, 69}

They have involved primary care

clinicians^{35, 44, 69, 71, 73} and trainees,³⁸ academics,³⁵ managers,^{69, 73} support personnel,^{35, 69} policy-makers,^{35, 69} hospital staff⁶⁹ and patients.^{35, 51, 69}

Methods used to enroll study participants included “snowballing”,³⁵ purposive sampling of physicians, patients, practices, or organizations,^{38, 69, 71, 73} and random sampling from physician⁴⁴ and general⁵¹ populations. These studies used interviews lasting between 25 minutes⁴⁴ and 2 hours.³⁵ Most interviews were conducted according to an interview guide and recorded,^{35, 51, 69, 71, 73} and the verbatim transcripts were analyzed together with field notes.^{35, 73}

Interview studies and other qualitative research techniques are especially valuable for their ability to derive new information that have not been anticipated by researchers.⁷⁶ Data from individual interviews provides information on non-factual data that is difficult to obtain by other means. One study highlighted difficulties with classifying errors,

assessing severity of harm, and estimating incidence that are not assessable from other studies producing these measures. The privacy of the interview allows exploration of topics such as anxiety and guilt about incidents. Interview studies can be economical because participants are ideally purposively sampled, ensuring that every interview makes a meaningful contribution to the study’s goals. Random sampling, used in two of the identified studies,^{44, 51} is often considered wasteful in qualitative research because it may cause some unnecessary interviews to be conducted at the cost of potentially useful interviews not being carried out.

Conversely, interview studies (and other qualitative research approaches) are sometimes considered uneconomical, because they are labour-intensive and time-consuming. They are difficult to integrate into regular routines for patient safety research, although some reporting systems include

capacity for interviews in their confidential reporting processes.⁷⁷ Some participants may also be reluctant to fully disclose some issues as there is no anonymity of participants from investigators. Recall bias also plays an important part in colouring the discussions held during interviews. Interview studies tend to be less familiar to healthcare planners and providers than quantitative or epidemiological research and may sometimes be less valued because of the inevitably small numbers of study participants (relative to the large numbers of participants possible in some study designs – especially database studies), the usual lack of random sampling and the contextual specificity of study groups.

Measures of primary care patient safety incidents from interview studies: Measures produced by interview studies included the type of safety incident primary care physicians notice while seeing patients in their offices (office administration errors (17%),

physician-related errors (8%), patient communication errors (5%), and preventable adverse events (4%))⁷¹ or encountered by trainee doctors (shortfalls in interpersonal skills, diagnostic skills, and management skills).³⁸ Prevalence of observed “errors” was 24% of consultations in primary care office practice (3% to 60% of encounters per physician).⁷¹ Two studies identified the type of safety incident patients are concerned about.^{51, 69} These were access restriction (29% of “problem incidents”), communication breakdown, relationship failure (37%), technical error and inefficiency (24%)⁵¹ and issues relating to the interface between primary and hospital care.⁶⁹

Consequences of observed “errors” in office practice included “harm” (24% of consultations) and “potential harm” (70% of consultations).⁷¹

Patients spoke of anger, frustration, belittlement, and loss of relationship with and trust in their physician as consequences of safety events.⁵¹

Consequences of patient safety

events that were memorable to family physicians included patient death (47% of memorable events), no adverse outcome (26%) and malpractice suits (4 of 53 “errors”).⁴⁴ One study identified deficiencies in computer systems, focusing on drug alerts, and proposed ways to rectify these deficiencies³⁵ and another used interviews to test theories about patient safety culture in the process of developing an instrument to measure safety culture in general practices.⁷³

Focus group studies were reported in two studies as a stand-alone method^{43, 55} and in another two alongside other methods.^{72, 73} The studies reported on three⁴³ to fourteen⁷³ focus groups involving 21⁴³ to 38⁵⁵ participants. In both mixed methods studies the focus group component was the final part, carried out to determine whether the tool developed by other methods would be useful. All studies analyzed recorded discussions and field notes.

The strengths and weaknesses of focus group studies are similar to those of interview studies. Personally sensitive data are less likely to be divulged in focus groups than in personal interviews, but focus groups take advantage of group dynamics to spark new ideas that may be less likely to arise from individual interviews. They are therefore an ideal method for exploring factors contributing to patient safety incidents because they promote discussion among group members, who are usually chosen because they share common experiences.

Measures of primary care patient safety incidents from focus group studies: Patients identified issues in primary care that were classified as relating to both quality (access to care, coordination of care, system resources, and ability to pay) and safety (“errors”).⁴³ “Errors” were classified as medication errors, errors of inattention, or technical errors. One multi-method study produced a tool describing factors facilitating physician disclosure of

patient safety incidents (responsibilities to patients, the profession, self, and to the community) and barriers to disclosure (attitudinal barriers, helplessness, uncertainty, and fears and anxieties).⁷² No new measures came from the other two focus group investigations although the overall product of one study was the Manchester Patient Safety Assessment Framework,⁷⁸ a framework for exploring ways of improving patient safety culture in primary care teams.

A Delphi study was reported in one paper as part of a mixed-method study aimed at testing a method to research patient safety events occurring at the hospital-primary care interface.⁶⁹ The Delphi component followed an interview study phase that identified quality of care and patient safety issues associated with the total healthcare of patients with Chronic Obstructive Pulmonary Disease (COPD). A two-stage process was used to identify specific

patient safety risks to patients with COPD. A Failure Modes and Effects Analysis (FMEA)⁷⁹ was tested.

Measures of primary care patient safety incidents from the Delphi study: Patient safety risks ranked most important were “routine difficulties with access to patient records post-discharge leads to decisions being made without adequate background information” and “information about discharged patients sometimes does not reach relevant primary care staff”.⁶⁹

Surveys were used as the only research method in six papers^{46, 47, 52, 56, 62, 67} and as a complementary method in a further three papers.^{70, 71, 74} Participants in these studies included random⁴⁷ and non-random^{56, 62, 70, 71} samples of primary care clinicians^{46, 47, 52, 56, 62} and staff,^{46, 52, 62} and complementary care providers.⁵³ Response rates were reported in five papers and ranged from 29%⁷⁰ to 76%.⁵⁶ Only one⁵⁶ had a response rate greater than 50%. Surveys were used to describe

patient safety events in primary care,^{46, 52, 62, 70, 71} and they contributed to the development of both interventions to improve safety,⁶⁷ and research tools.^{47, 56, 74}

Surveys are a strong research design for estimating prevalence (for example, prevalence of safety events in primary care) but to be effective in this function survey participants must be a randomly selected sample of sufficient size to produce results that are generalizeable to the population from which the sample was drawn. Only one of the studies in this group used a random sample,⁴⁷ although this design strategy appears to have been possible for at least two others.^{52, 56} Response rates were also very low (compromising generalizeability of results) and only one study reported efforts to improve response rates by follow-up of initial non-responders.⁵⁶

One of these surveys was used to develop an FMEA.⁶² Although this is a relatively common approach to use on safety data collected in hospitals,

it has rarely been used in primary care settings because it is a labour-intensive process that provides information specific to the institution in which it is conducted. Primary care practices are in general too small to support the infrastructure needed to conduct FMEAs. The technique involves studying one task in detail, identifying steps where failure might occur and designing interventions to avoid failure at these points.

Measures of primary care patient safety incidents from survey studies:

Despite the above design concerns, the surveys reviewed produced measures of factors contributing to deaths among primary care patients (patient behaviors (40% of deaths), general practice teams (5%), hospitals (6%), and the environment (3%)),^{46, 52, 62} the type and frequency of adverse events encountered by patients of acupuncturists,⁵³ factors influencing clinical educators' responses to "medical errors" (trainees' prior history, clinical knowledge levels, receptivity to

feedback, training level, emotional reaction, and whether they apologized or offered an excuse),^{55, 67} and attitudes to reporting significant patient safety events (18% favored mandatory reporting,^{47, 56} 6%⁷⁰-41%^{47, 56} had difficulty defining a significant patient safety event). Other surveys did not aim to produce any outcome measures other than a contribution to a larger research study.^{47, 56 46, 52, 62}

Patient Safety Incident Reporting

System studies dominate the research on patient safety in primary care settings. We defined surveys as restricted pieces of research, in contrast to reporting systems studies, where the method of data collection was intended to generate research data to address a number of different questions. Sometimes more than one included study was produced by a single patient safety event reporting system. Reporting systems have also been used to study individual processes used in

primary care, but we excluded these studies from the current review.

Participants in reporting system studies included primary care doctors,^{36, 37, 39, 41, 42, 45, 48-50, 53, 54, 57-61, 63-66, 68} practice staff^{57, 58, 60, 61, 63, 65, 66} and patients.⁵⁸ Reporting systems have been designed for anonymity (where reporters can never be identified),^{39, 53, 58} and confidentiality (where reporters can be identified for as long as it takes to correctly record the event)^{45, 50, 65} and have used (alone or in combination) paper,^{36, 37, 39, 58, 60} electronic,^{39, 58, 59, 65, 68} and telephone reporting.⁶⁶ They have involved regional,^{54, 57, 60, 65, 66} national,^{39, 58, 61} and international^{53, 59, 64, 68} participants.

The earliest patient safety event reporting study was the Australian study of Incident Monitoring in General Practice, involving data collected between 1993 and 1995.^{36, 37} In 2004 the UK government-sponsored National Patient Safety Agency opened an anonymous on-line web-based reporting route for

any healthcare staff. This system can be viewed at:

<http://www.npsa.nhs.uk/health/reporting/reportanincident>.

Shaw et al⁶² reported an analysis of 28,998 safety incidents reported to this system from 18 NHS Trusts (including one primary care Trust). One study was designed as a randomized controlled trial that aimed to compare paper and computer reporting of patient safety events but has only ever been published as a reporting system study.⁴⁰ Along with many other reporting system studies^{36, 37, 54, 58, 60, 61, 63} it aimed to develop a way to describe the patient safety events encountered in primary care. There was one international study that involved participation from primary care doctors in Australia, Canada, Germany, the Netherlands, New Zealand, the United Kingdom and the United States. Only the English-language papers from this reporting system study are included in this review^{48, 53, 59, 64, 68} but an additional

paper has been published in German.⁸⁰

The main strengths of reporting systems studies are that they give a robust indication of the types of patient safety incidents observed by healthcare providers and they are a well-established method in the patient safety literature, as reporting systems are embedded in the institutional processes of many hospital systems. The problem with patient safety incident reporting systems for primary care research is that many primary care providers work outside the organized systems with established incident reporting. In many hospitals reporting systems are part of continuous quality improvement processes and data are routinely collected that can later be used to address specific research questions. Primary care practices are usually much smaller institutions and unable to support either the routine collection of patient safety data or the infrastructure to use these data for research. Therefore, most of the studies we found related to reporting

systems set up in universities, specifically for research. Report providers contributed their data on the understanding that they were participating in a time-limited research project, rather than engaging in an ongoing quality improvement programme. This means that most studies were relatively small and the reporting systems had no long-term life expectancy. The exception is the UK's national reporting system, which is available to all healthcare providers, including those working in primary care. To date, contributions to the system from primary care have been very small relative to the contribution from hospitals but this may change now that the patient safety agenda is moving to incorporate primary care.

A well-recognised, important, and inevitable limitation of reporting systems is under-reporting.^{81, 82} Runciman et al have estimated that as few as 5% of incidents are notified to reporting systems.⁸³ They cannot, in general, be treated as databases

suited for calculating epidemiological statistics (such as incident prevalence). As well, data from reporting systems are difficult to generalize because contributors are seldom statistically representative. We identified only one study where representativeness was a concern and a random selection of doctors contributed to the study.⁵⁵ A further limitation of reporting systems is that over time they accumulate massive amounts of complex data that can be very difficult to extract meaningful information from. So far this has not been a problem for primary care reporting systems because they have been specifically designed for research. As incident reporting becomes a routine activity for primary care providers this issue is likely to become increasingly relevant.

Measures of primary care patient safety incidents from reporting system studies: Most reporting system studies developed a way to describe the patient safety incidents reported, often in an hierarchical

taxonomy and according to categories such as: office administration (between 15%⁶³ and 31%³⁹ of reports) including appointments (2%⁶³ to 14%⁵⁸ of reports), investigations (6%⁵⁸ to 33%⁶⁷ of reports), treatments (including medication (8%⁶¹ to 52%^{36, 37} of reports), communication (4%⁵⁸ to 80%⁶⁸ of reports), payment mistakes, clinical mistakes (3%⁶⁰ to 10%⁶³ of reports), wrong diagnosis (4%³⁹ to 34%³⁶ of reports), wrong treatment decisions, and equipment (5%^{36, 37} to 16%⁶¹ of reports). Causes or contributing factors (work organization, excessive task demands, and fragmentation), prevention strategies and consequences (harm (17%⁵⁰ to 43%⁶⁸ of reports) and potential for serious harm (27%³⁶ to 76%⁵⁰ of reports)) and other consequences and contributing factors³⁷ are sometimes also classified. Some of these descriptions have been published electronically: www.errorsinmedicine.net/taxonomy/aafp and

www.cudfm.org/carenet/asips/taxonomy. Other ways of classifying reported events were: adverse events (21%⁵¹ of reports) and near misses (64%⁵¹). One paper reported remedial strategies.⁶⁴

The “error” report rate was calculated at 75.6 per 1000 appointments⁶⁰ and 2 per 1000 patients seen per year.⁵⁵

Strengths and weaknesses of mixed-methods research

Mixed-methods studies are where a single main research aim is addressed progressively using different research methods to either develop the tools to answer the research question definitively, or to build different perspectives to a research issue by approaching it in different ways. This latter approach is sometimes called “triangulation”. We identified six mixed-methods studies in this review. They methods they used included combinations of surveys,^{70, 71, 74} interview studies,^{69, 71, 73} systematic literature reviews,^{70, 72, 73} focus group studies,^{72, 73} significant event audits,⁷⁴

and a Delphi study.⁶⁹ Four studies took the approach of successive tool development^{69,70,72,73} and the other two adopted a triangulation approach.^{71,74}

Each mixed-method study incorporates the strengths and weaknesses of their individual methods (as above). Additionally, however, they develop the science of patient safety research by creating new multi-faceted processes, such as “care process mapping”.⁶⁹ Care process mapping identified key care decisions on the care pathway (from primary care to hospital and back to primary care), aiming to identify and remedy processes and problems that adversely affected patient safety. This analytic method was applied to

DISCUSSION

Compared to hospital-based research, qualitative *methods* for researching safety incidents in primary care are relatively common, the body of quantitative research is immature, and few robust *measures*

data collected from interviews and a Delphi process⁶⁹ and concentrated on in-depth analyses that produced outcomes with practical application.

Measures of primary care patient safety incidents derived from mixed-method studies are reported above, as part of the review of their individual methods.

Overview

Table 3 in the Appendix summarizes the retrospective, concurrent or prospective, and mixed-method primary care patient safety studies included in this review. Their aims, methods, measures, and high-level conclusions are shown with a note of the design limitations of the study.

of patient safety events in primary care have been developed.

Methods used in primary care patient safety research:

We identified research that used one of three general methodological approaches: retrospective,

concurrent or prospective, and mixed-methods. Retrospective methods included systematic literature reviews^{26, 29, 33} and retrospective analyses of significant incident,^{27, 28, 31} risk management, and malpractice claims^{30, 32, 34} databases. Concurrent and prospective methods included the qualitative approaches of interviews,^{35, 38, 44, 51} focus groups,^{43, 55} and safety incident reporting^{36, 37, 39-42, 45, 48-50, 53, 54, 57-61, 63-68} and the quantitative approach of surveys.^{46, 47, 52, 56, 62} Mixed-method studies used combinations of two,^{69-72, 74} or three⁷³ of these methods.

Although almost all of the methods employed in hospital-based research have also been used in primary care, some are missing from the primary care literature. No studies were found that were directly comparable to the retrospective record reviews used in hospital-based patient safety studies^{84, 85} and the measures that might arise from such reviews. Numerous barriers to using this method could apply in primary care settings, where a record of the breakdown in care that leads to a

safety incident might be spread over several different health care providers in different locations - unlike a hospital record, where multiple providers contribute to a single set of patient notes. However, a study of this type has the potential to draw some comparisons with hospital-based studies using this method and may warrant further exploration. We also found no primary care research comparable to the hospital-based research that uses autopsy reports,⁸⁶⁻⁸⁸ although mortality databases have been identified as a potentially important source of safety information and one that primary care researchers are prepared to use.²⁶

There is a dearth of research on the types of methods that may better engage patients in safety research in primary care, and the value of their input in addressing different aspects of patient safety is poorly understood. Patients have engaged successfully in qualitative research in community settings about perceived harm,⁵¹ but not in other types of patient safety research.⁵⁸ This should

be considered in future research planning.

Measures used in primary care patient safety research:

The terms most often used to describe patient safety incidents in primary care settings were “error”, “medical error” and “preventable adverse events”. There was no standard definition of these terms. One literature review found 25 different definitions of “medical error”.⁷⁰

Estimates of the rate of patient safety incidents occurring in primary care varied enormously, ranging from 0.004³⁰ to 240⁷¹ per 1000 primary care consultations. Estimates of preventability ranged from 45%⁷¹-76%^{36, 37} of all “errors”.

The types of participants involved in primary care patient safety incidents were primary care physicians and trainees^{29, 30, 32, 34-42, 44-46, 48, 50, 53-62, 64-66, 68-73, 89, 90} patients,^{43, 51} nurses and other practice staff,^{45, 47, 57, 58, 65, 66, 69, 73} paramedics,³⁴ pharmacists,³⁴ computer suppliers,³⁵ academics,³⁵ acupuncturists,⁵² optometrists,⁶³ and managers.^{35, 69} Many studies

included measures of the relative frequency of different types of patient safety incident. Most commonly these were “errors” in: diagnosis (26%³⁰-57%⁴⁴ of all incidents), treatment (7%⁴³-52%³⁷ of all incidents), investigating (13%⁵³-47%⁴⁵ of incidents), office administration (9%⁶⁴-56%⁵⁸), and communication (5%⁷¹-72%⁶⁵ of incidents). Two studies^{43, 51} investigated the type of safety incident patients are concerned about. These were mainly relationship (37%⁴³-77%⁵¹ of concerns) and access problems (29%⁵¹ of concerns).

Causes or contributing factors to patient safety incidents included: environmental hazards (3%⁴⁶-14%³⁰) including work organization, physician factors (5%⁴⁶-91%⁴⁴) including excessive task demands and fragmentation, patient factors (40%⁴⁶-72%⁴⁴), and hospital factors (6%⁴⁶).

Reported harm arising from patient safety incidents ranged from 1.3 significant minor incidents per 1000 treatments⁵² to 4% of incidents resulting in death,^{36, 37} 17%⁵⁰-39%⁴²

of incidents resulting in harm, and 70%⁷¹–76%⁵⁰ of incidents having potential for harm. Patients spoke of anger, frustration, belittlement, and loss of relationship with and trust in their physician as consequences of safety incidents. Consequences of patient safety incidents that were memorable to family physicians⁴⁴ included patient death (47% of memorable incidents), no adverse outcome (26%) and malpractice suits (8%).

Factors influencing clinical educators' responses to "medical errors" were trainees' prior history, clinical knowledge levels, receptivity to feedback, training level, emotional reaction, apologizing, and offering an excuse.⁵⁵ A taxonomy of factors enabling and inhibiting voluntary disclosure of "errors" was also developed.⁷² Attitudes to reporting significant patient safety incidents were measured in one study:⁵⁶ 18% favored mandatory reporting.

Other studies did not aim to produce any outcome measures other than a contribution to a larger research study.^{47, 73} They contributed to products such as the Manchester

Patient Safety Assessment Framework,⁷⁸ a tool for developing improvements in patient safety culture in primary care teams.

Limitations of this review:

The primary care patient safety research in this review generally spans little more than a decade, although there is an older and more extensive literature interpretable as relevant to patient safety in bounded areas such as medications use and diagnosis. The scope of the current research did not include an analysis of these specific safety topics, which may provide further insight into methods and measures of relevance to patient safety incidents in community settings. We included only research publications investigating a wide view of primary healthcare activity and its risks for patient safety. We excluded studies focused on a single bounded activity or cluster of activities, such as medications use or diagnosis. There are many studies in both of these general areas, usually focusing on particular drugs or drug classes and particular diagnoses. Because of the

broad scope of primary care, it was not possible to review this literature. We included patient safety research at the interface between hospital and primary care only if it involved data derived from both settings. We included only English-language papers. For these reasons it is unlikely that we have identified all relevant literature but our search methods have likely captured the essence of the literature as a whole.

This review appraised research conducted mainly in the USA, the UK, and Australia. We caution that because the overwhelming body of published research about patient safety in primary care comes from this limited set of countries, it is unlikely to address issues of importance to many other countries – especially in the developing world. More appropriate methods and measures need to be found for patient safety research in a wider range of countries.

Recommendations for further research:

It is becoming clear that patient safety research in all settings needs

to develop new methods and this process is already starting. We included in this review some papers that used the approaches of hazards or Failure Modes and Effects Analysis in primary care.^{62, 66, 69}

These new methods have recently started to be reported in the literature. However, there is also a need to use older methods (such as survey research) with greater attention to designing in research elements to enhance scientific robustness. Greater use of random samples and more attention to increasing response rates are obvious early targets for improving this type of research. All measures of primary care safety incidents identified in this review require further refinement in other primary care settings to test their reliability and validity.

In the absence of a definitive and internationally understood set of terms and definitions the need to create classification systems, descriptions, and definitions has been compelling for researchers of patient safety in primary care settings. Point estimates were

calculated for many types of safety incident but the difficulty with measurement is reflected in the fact that these estimates varied by more than 1000-fold between studies. This may be due to different research data and methods, or different interpretations of the same terms (in two studies 6%⁷⁰ and 41%⁵⁶ of participants had difficulty defining a “significant patient safety event”). Several studies grouped safety incidents according to classifications derived from incident reporting systems.^{39, 53, 60} The WHO’s International Classification for Patient Safety (beta version released July 2007)⁹¹ is an international tool designed to facilitate understanding about patient safety across health sectors and between countries. Refinement and use of this classification system may obviate the need for further development of taxonomies in primary care patient safety research.

While Australia, the US, and the UK have started to build research programs about patient safety in primary care settings, most countries have not yet engaged in primary care

patient safety research. We recommend that such research should be on the agendas of all countries because of the likely opportunities for improvement of patient safety in the most widely used sector of any health system.

Conclusions:

Primary care patient safety research is at an early stage of development, with research efforts concentrating on describing the safety environment rather than intervening to improve it. As recently as five years ago, primary health care providers were more or less exempt from considerations about patient safety and they were excluded from the seminal patient safety reports from the US⁹ and the UK.¹⁰ Since that time there has been a growing recognition of the increasingly urgent need to reduce patient safety threats in primary care settings.

The methods of primary care patient safety research are well recognized and replicable so it is likely that they will become more widely used, refined, and ultimately deliver more useful knowledge than is currently

available. The methods tend to be mainly pragmatic, dominated by studies using reporting systems that have been set up specifically for research purposes. These studies have not yet resulted in national patient safety strategies appropriate for primary care. However, they provide a form of anticipatory testing and show that primary health care providers are generally receptive to the idea of identifying and rectifying risks to patient safety. An integrated information and incident management system is probably ideal for managing threats to patient safety in both primary and other health care settings.⁹² To develop the study, measurement, and improvement of patient safety in primary care settings, there is a pressing need to address the rigor with which research is designed in order to make their results generalizeable. Researchers need to consider methods that will address the internal validity of the measures produced by their research, as well as maintaining the current concern for external validity.

Only a small amount of research has investigated patient safety in primary care from the perspective of patients. To date patients' views have been heard only through small-scale qualitative studies or in the analysis of complaints and risk management systems. An early challenge to address is how to incorporate patients' perspectives on patient safety using valid methods that are devoid of medico-legal threats to clinicians. The sustainable methods of reporting that have identified threats to patient safety from providers' perspectives have been far less successful in eliciting patients' experiences of patient safety threats. There is a need to develop methods that allow patients more voice in researching the patient safety agenda in primary care (and other) settings. Involving patients in this type of research is likely to result in measures of patient safety that are different from the current metrics, all of which are focused on the provider perspective.

Measures of primary care patient safety are still under development and there are no agreed outcome

measures of “safer” care. Identifying and measuring harms related to primary care patient safety incidents is a research gap. Some harms such as death may be applicable across health care settings but others, such as wrong side surgery, are not relevant to primary care research.

Barriers to healthcare access, extended waiting times and emotional disaffection, generally not considered serious harms in hospital-based research, may turn out to be important outcomes of patient safety incidents in primary care because of their long-term consequences in terms of reducing trust in the health system, consequent low use of preventive care and resultant higher need for emergency and acute care. The debate currently is whether these outcomes relate to quality or safety. More research is needed.

Relatively few countries appear to be engaged in primary care patient safety research. This review shows the dominantly western nature of the published scientific literature. Attempts to increase the efforts at an international level should ideally

consider ways to engage a broader range of communities and health care settings, including developing countries and different cultural groups.

Much useful work has been done but the study of patient safety in primary care is still in its infancy.

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Appendix: Table 3: Studies measuring patient safety events in primary care settings identified in the literature

Systematic Literature Reviews					
Study	Research aim	Research methods	Research measures	Design limitations	Overall conclusions
Elder and Dovey (2002) ²⁹	Describe and classify process errors and preventable adverse events	Searches of Medline and the Cochrane Library	Preventable adverse events (diagnostic, treatment, preventive care incidents); Process errors (clinician, communication, administration, "blunt end" factors)	English language only	Little is known about primary patient safety in care. Most studies focus on physician perspectives.
Sandars and Esmail (2003) ³³	Identify frequency and nature of error in primary care; consider causes for diversity in reported error rates	Searches of Medline, Embase and NPSF database	5-80 "medical errors" per 100,000 consultations: 26-78% of "errors" relate to diagnosis 11-42% of "errors" relate to treatment <1-11% of prescriptions have "errors" 60-83% of "errors" are preventable	English language only	Nature and frequency of "error" in primary care is poorly understood because of diversity in definitions and approaches.
Baker et al (2007) ²⁶	Review how mortality data are used in primary care	Searches of Medline, Embase and CINAHL	Impact of primary care on mortality, methods of monitoring mortality, role of audit and death registers in quality and safety improvement.	English language only	Mortality data are not used systematically in primary care to improve quality and safety.
Studies of Significant Event Audits					
Murie and McGhee (2003) ³¹	Describe significant events	Content analysis of 56 significant event reports from one Scottish Primary Care Trust	Ratio of near-miss to adverse events = 1:6 44% of reports relate to operational risk 36% of reports relate to clinical risk 16% of reports relate to strategic risk 4% of reports relate to human resources 2% of reports relate to political incidents 2% of reports relate to legislative incidents 56% had no or minimal harm 40% resulted in a disabling injury or death	Regionally limited	General practitioners can work in a national framework for risk assessment. There is a need for consistency in definitions and coding.
Bowie et al (2005) ²⁷	Identify satisfactory and unsatisfactory significant event reports	Content analysis of 662 significant event reports from the west of Scotland	25% involved a learning issue 11% of reports were judged unsatisfactory 17% of reports relate to prescribing 16% of reports relate to diagnosis 13% of reports relate to communication	Regionally limited	If significant event reporting is to be effective in improving quality and safety, there must be a valid way to check reports.
Cox and Holden (2007) ²⁸	Describe significant events	Content analysis of 337 significant event reports from one English Primary Care Trust	19% of reports involved a learning issue 29% of reports relate to prescribing 27% of reports were patient safety incidents 7% were serious or life-threatening 20% were potentially serious	Regionally limited	Significant event audits valuable for education and clinical governance that highlight patient safety issues.

Studies of malpractice claims and risk management databases					
Fischer et al (1997) ³⁰	Describe the prevalence of adverse events	Review of 51 incident reports to a risk-management database over .55 year period	3.7 "adverse events" per 100,000 clinic visits 14% of injuries due to environmental hazard 69% of injuries due to medical mismanagement: 31% relate to treatment 26% relate to diagnosis	Regionally limited Limited to an academic health center	Serious adverse events are probably infrequent in primary care. Better systems are needed to track events.
Phillips et al (2004) ³²	Describe negligent adverse events from primary care; assess condition-specific rates of claims	Review of 49,345 claims in a national US malpractice database over a 15 year period	68% of claims were for negligent events in primary care 34% of negligent claims relate to diagnosis 16% of negligent claims relate to failure to monitor 15% of negligent claims relate to improper performance 8% of negligent claims relate to prescribing 4% of negligent claims relate to delay in referral	Data definitions may not be robust Limited to the US	The total burden of high severity outcomes and death is higher when negligent events occur in primary care than when they occur in hospitals.
Varga et al (2006) ³⁴	Describe criminal liability of healthcare providers in Hungary	Review of 94 criminal cases involving physicians and other healthcare providers, over a 4 year period	82% of criminal cases involved physicians 29% of physicians were primary care physicians and the main reason for their case was failing to examine the patient or diagnostic error 10% of criminal cases involved nurses 5% of criminal cases involved paramedics 3% of criminal cases involved pharmacists	Limited to Hungary	Primary care physicians are at the centre of more criminal cases than any other healthcare professional group.
Interview studies					
Diamond et al (1995) ³⁸	Describe GP trainee experiences with positive and negative incidents	Qualitative analysis of open-ended interviews with 39 GP trainees	180 critical incidents (4.6 per doctor) 50% of critical incidents involved difficult patients, children, counseling skills, the doctor-patient relationship, obstetrics and gynaecology, relationships with other health professionals and practice staff, and cardiovascular disorders.	Purposive sampling from one training program	Analysis of critical incidents can accelerate learning and help plan curricula.
Ely et al (1995) ⁴⁴	Determine perceived causes of family physician error	In-depth interviews with a random sample of 70 family physicians	76% response rate (53 physicians/errors) 57% of errors related to missed diagnosis 21% of errors related to surgical mishaps 25% of errors related to treatment Mean of 8 causes for each error case 91% of errors caused by physician stressors 91% of errors caused by care processes 72% of errors caused by patient factors 62% of errors caused by physician factors	No sample size justification	Physicians remembered errors with often serious consequences that they attributed to a variety of causes.
Kuzel et al	Develop patient-	Structured interviews	38 interviews analysed	No sample size	Medical errors related by

(2004) ⁵¹	focused typologies of medical errors and harms in primary care	with 40 people recruited by random digit dialling	Mean of 5.8 problematic incidents per interview 37% of incidents involved breakdown in doctor-patient relationship 77% involved disrespect or insensitivity 29% of incidents involved breakdown in access 27% involved excessive office waiting times 16% involved difficulty in contacting the office 16% involved delay in obtaining appointments Mean of 4.5 harms per interview (170 harms) 70% of harms were psychological	justification	patients contrast sharply with errors reported by family physicians.
Avery et al (2006) ³⁵	Define ways computer systems can be improved to enhance safety in primary care	Semi-structured interviews with 31 clinicians, computer system suppliers, academics, and policymakers	4 main themes Designing systems for safety Accurate and relevant information Taking human ergonomics into account Audit trails Electronic information transfer Optimizing computer safety features Recording data accurately Call and recall reminders Training for safe and effective computer use Regulations and guidelines Safety culture	Limited to stakeholders with computer expertise Excluded non-medical team members and patients	Primary care computer systems could be improved and this would enhance patient safety.
Focus group studies					
Dowell et al (2005) ⁴³	Describe patients' experiences of quality and safety in primary care	3 focus groups including 21 patients from 3 urban clinics	187 comments 44% of comments were about system issues 37% of comments were about interpersonal skills 9% of comments were about knowledge 7% of comments were about medication and technical errors and errors of inattention	Limited to English language-proficient patients	Patients provide important insights into complex systems issues.
Mazor et al (2005) ⁵⁵	Describe how and why preceptors respond to trainees when medical errors occur	7 focus groups involving 38 primary care preceptors from north-west USA	Preceptors provided corrective and supportive responses to trainees' errors Factors influencing preceptors' responses were error type, clinical outcome, and their connection, and the learner's response	Analysis may be influenced by researcher bias	Future research should focus on faculty development to optimize learning from errors and reduce future recurrence
Surveys					
Holden et al (1998) ⁴⁶	Determine pattern of deaths and preventable factors in 4 general practices	Audit of all 1263 deaths occurring over 40 months, using a standard data collection form	679 avoidable factors contributed to deaths 40% were patient factors (eg smoking, suicide) 6% were hospital factors (eg delayed diagnosis) 5% were GP factors (eg delayed referral) 3% were environmental factors (eg falls)	Limited practice participation	An audit of deaths has educational value for GPs and is a source of ideas for service improvement and further study.

MacPherson et al (2001) ⁵²	Describe the type and frequency of adverse events and transient reactions after consultations with acupuncturists	Postal survey of 1848 professional acupuncturists	31% response rate (574) 34,407 treatment reports No serious adverse events 1.3 significant minor adverse events per 1000 treatments (eg nausea, fainting) 15% of treatments had mild transient reactions 3 avoidable errors (2 forgotten needles, 1 moxibustion burn)	Low response rate Non-random sampling	Acupuncture is a relatively safe treatment.
McKay et al (2004) ⁵⁶	Describe GPs' attitudes to mandatory significant event reporting	Census of 617 GP principals in south-west Scotland	76% response rate 73% would not report all significant events 75% favoured anonymous reporting 41% had difficulty defining a significant event	Non-random sampling	The success of the NPSA system will be hindered by mandatory reporting.
Singh et al (2005) ⁶²	Develop and test a method to form learning teams that can prioritize patient safety problems	2 practices with 45 respondents	Each site identified its own hazards, with little overlap	No denominator reported Non-random sampling	The method empowered practice teams to develop a common vision of their practice microcosm.
Hutchison et al (2006) ⁴⁷	Develop a patient safety climate questionnaire (the MaPSaF)	Census of 3650 staff of 4 acute hospital trusts and 9 primary care trusts in England. Factor and reliability analyses	Response rate 33% for primary care Trusts Removing 5 items from the questionnaire improved the internal reliability of the questionnaire's two domains of teamwork and safety climate	Low response rate Non-random sampling	A 22-item version of the questionnaire is usable as a research instrument in primary care and acute hospital settings.
Patient Safety Event Reporting Systems					
Britt et al ³⁷ Bhasale et al ³⁶ (1997-98)	Describe safety incidents in General Practice	Modified critical incident technique, with 297-324 GPs anonymously submitting 500-805 paper incident reports	51-52/100 mishaps involved drug treatments 37-42/100 mishaps involved non-drug treatments 28-34/100 mishaps involved diagnosis 5/100 mishaps involved equipment 76 % of incidents were preventable 17% of incidents resulted in major harm 4% of incidents resulted in death Poor communication was the most common contributing factor Early intervention was the most common mitigating factor	Participation limited to one sentinel practice research network and additional volunteers	The incident monitoring technique can be used in general practice.
Dovey et al ³⁹⁻⁴² (2002-03)	Describe the types of errors reported	344-416 errors reported by 42 family	31% were reports of administrative errors 25% were reports of investigation failures	Participation limited to one	Family physicians will report errors and their

	by family physicians and develop an error taxonomy	physicians using both paper and computer based questionnaires	23% were reports of treatment errors 6% were reports of communication errors 337 reports of consequences 38% were health consequences 35% were care consequences 22% were financial and time consequences 288 ideas about solutions to medical errors 34% of solutions were "don't make mistakes" 30% of solutions were "better communication" 26% of solutions were "provide care differently"	sentinel practice research network	consequences and propose solutions.
Makeham et al, ⁵³ Woolf et al, ⁶⁸ Rosser et al, ⁵⁹ Jacobs et al, ⁴⁸ Tilyard et al, ⁶⁴ (2002-05) The PCISME project	To describe the types of errors reported by GPs and family physicians in 7 countries and develop an international error taxonomy	Paper and computer based questionnaires submitted by 100 GPs and family physicians over a four month period	437 error reports: 132 from Australia, 81 from Canada, 63 from England, 14 from Holland, 66 from New Zealand, 75 from the US. 9-25% of reports related to office processes 14-30% of reports related to treatment 14-22% of reports related to investigations 7-19% of reports related to communication 2-3% of reports related to workforce 1-2% of reports related to finances 77% of reports documented a chain of errors 29-39% of reported incidents resulted in harm 66 different prevention strategies 70% of reports related to more diligence 23% of reports related to providing care differently 20% of reports related to communication	Small number of reports per country Limited time frame for data collection	Errors are common and similar in nature in general practice and family medicine settings around the world.
Wilf-Miron et al (2003) ⁶⁶	Apply aviation safety principles to reporting errors in a large ambulatory healthcare setting	Root cause analysis of 2000 adverse event reports over 5 years reported by telephone hotline to a specialized risk management unit	1300 events were accidents and near misses 21% involved family medicine 33% of errors related to processes of care 21% of errors related to treatment 18% of errors related to judgment 15% of errors related to auxiliary tests 13% of errors related to poor communication 470 recommendations made to improve care	Regionally limited Multidisciplinary study did not report primary care results separately	Aviation safety concepts and tools were successfully adapted to ambulatory care.
Fernald et al, ⁴⁵ Parnes et al, ⁵⁷ Westfall et al ⁶⁵ (2003-04) The ASIPS	Develop a system for confidential error reporting, describe types of error and differences	128-754 confidential or anonymous reports submitted by phone, electronically, or on paper from 14-33 practices with 150-	97- reports of patient safety events 71-72% of reports involved communication 33% of reports involved delay in care 20-35% of reports involved medication events 17-47% of reports involved diagnostic testing 209 reports of harm from patient safety events	Participation limited to two sentinel practice research networks Regionally	Confidential reports afford greater analysis of cause than anonymous reports.

project	between confidential and anonymous reports	475 clinicians and staff	68% were no known harm 6% were unstable 7% were non-clinical harm 9% were increased risk of clinical harm 10% were clinical harm now	limited	
Rubin et al, ⁶⁰ Steele et al ⁶³ (2003-06)	Classify errors in general practice and community optometric clinics in north-east England	540 events reported using an anonymous paper form, reporters coded events using a descriptive classification	136 reports of 940 errors from general practice and 439 from optometric practice 18-42% of errors related to prescriptions 30-36% of errors related to communication 12-16% of errors related to equipment 2-7% of errors related to appointments 10-35% of errors related to clinical care 75.6 "errors" per 1000 GP consultations	Regionally limited Limited time frame for data collection	Medical error descriptions generated in primary care are applicable to different types of provider.
Shaw et al (2005) ⁶¹	Describe the implementation of a national incident reporting system	Electronic patient safety incident reports from 1 Primary Care and 17 other Trusts in England and Wales	28,988 safety incident reports were made 32 (0.1%) came from the primary care Trust	No data reported for primary care specifically	Majority of reported incidents from all sources were slips, trips and falls. Primary care engages poorly in the system.
Makeham et al (2006) ⁵⁴	Determine the incidence of reported errors in general practice	418 anonymous web-based error reports from a random sample of 320 New South Wales (Australia) GPs over 12 months	26% (84) of the random sample of 320 agreed to participate in the study 1-25 reports per participating GP 5.3 reports on average, per participating GP 1 error per 1000 GP encounters per year 2 errors per 1000 patients seen per year Incidence of reported errors per patient = 0.24%	Regionally limited Low response rate	Incidence of GP-reported errors can be calculated when a secure anonymous reporting system is provided.
Phillips et al (2006) ⁵⁸	Compare the types of medical error reports made by primary care clinicians, administrative staff, and patients.	126 reports from patients and 717 reports from 401 clinicians and staff reporting electronically, in paper reports, or by telephone.	108/126 patient reports expressed satisfaction 6/18 patient error reports were about waiting 2/18 patient error reports were about mistaken identity 717/726 provider reports included 935 errors 56% of errors related to office administration 15% of errors related to treatments 14% of errors related to investigations 9% of errors related to communication 4% of errors related to knowledge and skills 3% of errors related to payment	Study design unsuitable for learning of patients' views of patient safety	Clinicians and administrative staff perceived errors differently (through different "lenses"). Patients did not engage well with the study's processes.
Kostopoulou (2007) ⁵⁰	Describe patient safety incidents in general practice based on cognitive psychological	78 reports from 5 general practices with follow up interviews from investigators	21 adverse events and 50 near misses 47 reports had information about the active failure leading to the patient safety incident 45% involved situation assessment errors 23% involved response execution errors	Small number of reports limits description breadth	Cognitive and system factors both contribute to patient safety incidents in primary care.

	theory		17% involved memory errors 15% involved perception errors 17% had fairly or very serious patient harm 76% had potential for patient harm		
Mixed Method studies					
Elder et al (2004) ⁷¹	Describe errors identified by family physicians and determine physician's perception of resulting harm	15 family physicians in 17 practices identified errors during 351 patient visits. Interviews at the end of consulting sessions collected data about harm.	117 errors reported in 83 (24%) consultations 17% of error visits were administration error 8% of error visits were physician related error 5% of error visits were communication error 45% of error visits were preventable adverse events 24% of error visits harmed patients 70% of error consultations involved potential harm	Regionally limited	There is variation between doctors in how harm is defined and how different error categories are interpreted.
Dean et al (2007) ⁶⁹	Evaluate feasibility of prospective hazard analysis of care pathways crossing primary and secondary care interface	Observation of care processes for patients with COPD, interviews with 16 patients and 7 staff, two-round modified Delphi study	Themes from interviews were mainly about communication problems The Delphi study ranked difficulties in accessing hospital records, information transfer to primary care, and failure to communicate medication changes as the most important events	Limited to one chronic disease	Mixed methods study delivered a clear picture of the quality and safety of care in a care pathway.
Elder et al (2006) ⁷⁰	Define what physicians consider an "error"	Systematic review followed by census of active members of the American Academy of Family Physicians	25 different definitions of "error" found in the literature The most common definition is Reason's ⁹ 29% response rate to the survey Family physicians' definition of error depends on event outcomes, whether the event was rare or common, and whether it was related to the system of care or an individual mistake.	English language literature only Low response rate to survey Survey sample size not justified	Definition of "error" is an area of confusion
Kaldjian et al (2006) ⁷²	Describe factors affecting voluntary disclosure of medical errors by physicians	Literature review; 5 focus groups	Literature review revealed 53 factors impeding disclosure and 38 factors facilitating disclosure Focus groups added 27 factors The final taxonomy had 4 facilitating factors: Responsibility to patient; Responsibility to profession; Responsibility to self; Responsibility to community and 4 factors impeding error disclosure: Attitudinal barriers; Helplessness; Uncertainty; Fears and anxieties	English language literature only MEDLINE database search only	A conceptual framework describing factors facilitating and impeding disclosure of medical errors was developed.
Kirk et al	Test a framework	Literature review,	9 dimensions of organization safety culture were:	Regionally	Provides a way of

(2007) ⁷³	for making the concept of a safety culture meaningful to primary care providers	survey,33 semi-structured interviews, 14 focus groups	Overall commitment to quality; priority given to patient safety; perceiving the causes of patient safety incidents; investigating patient safety incidents; organizational learning following a patient safety incident; communication about patient safety; personnel management; staff education; team-working 5 levels of safety culture maturity were: Pathological; reactive; calculative; proactive; generative	limited	understanding why and how the shared values of staff can together create a safety culture in practice
Wallace et al (2007) ⁷⁴	To examine the effect on practice safety culture of a health authority's promotion of risk management	Survey of 75 practice managers to derive a risk management competence score before and after an intervention of a training package to improve risk management skills	Risk management competence scores of practices after the intervention did not change significantly from before. 6 general measures of competence: Scope: before = 11, after = 13 Staff involved in risk management: before = 12, after = 15 Documenting risk management activity: before = 6, after = 13 Access to records: before = 15, after = 15 Written practice policies: before=9, after=11 Written procedures: before = 8, after = 8	Non-random sample Before-and-after study without controls	There was evidence that risk management improved over the period of the study but little evidence that this was caused by organizational culture