QUIP Quest for Quality and Improved Performance

Safety and risk management in hospitals

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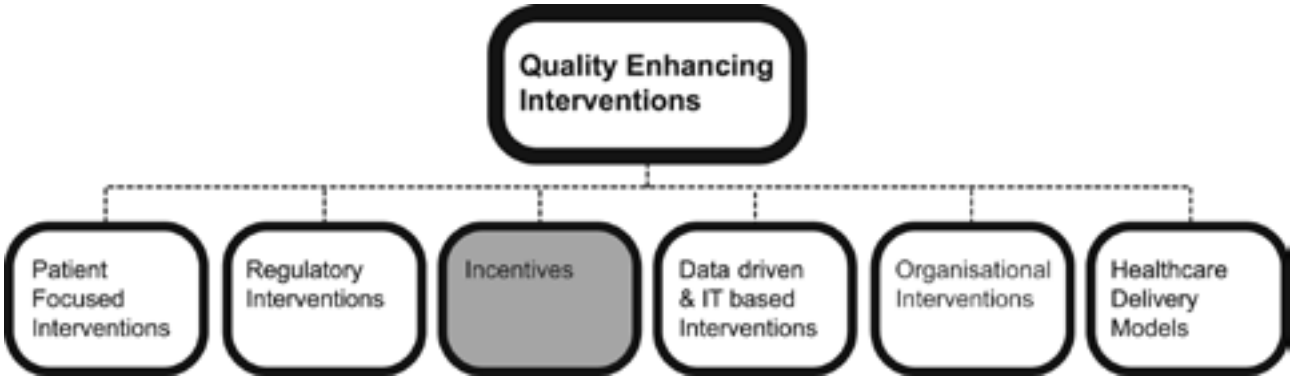
QQUIP and the Quality Enhancing Interventions project

QQUIP (Quest for Quality and Improved Performance) is a five-year research initiative of the Health Foundation. QQUIP provides independent reports on a wide range of data about the quality of healthcare in the UK. It draws on the international evidence base to produce information on where healthcare resources are currently being spent, whether they provide value for money and how interventions in the UK and around the world have been used to improve healthcare quality.

The Quality Enhancing Interventions component of the QQUIP initiative provides a series of structured evidence-based reviews of the effectiveness of a wide range of interventions designed to improve the quality of healthcare. The six main categories of Quality Enhancing Interventions for which evidence will be reviewed are shown below.



For more information visit www.health.org.uk/qquip

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Contents

Glossary of acronyms

ADE – adverse drug event

AE – adverse event

AIMS – Australian Incident Monitoring System

ARIMA – autoregressive integrated moving average

CBA – controlled before-after study

CI – criticality indices

CIT – critical incident technique

CPOE – computerised physician order entry

CWS – comparison with standards

EPOC – Effective Practice and Organisation of Care Group

FMEA – failure mode and effect analysis

MeSH – Medical Subject Heading

ICPS – International Classification for Patient Safety

IOM – Institute of Medicine

ITS – interrupted time series study

IV – intravenous

NICU – neonatal intensive care unit

OACM – organisational accident causation model

PDA – personal digital assistant

QEI – Quality Enhancing Interventions

QQUIP – Quest for Quality and Improved Performance

RCA – root cause analysis

RCT – randomised controlled trial

SEA – significant event auditing

SRM – safety and risk management

UBA – uncontrolled before-after study

WHO – World Health Organization

Executive summary

Introduction

Patient safety has become a matter of interest to healthcare professionals, governments and researchers worldwide. During the last decade, many studies have been conducted to assess the prevalence, severity and causes of a large variety of different types of adverse events in hospitals, as well as the effectiveness of various approaches to enhance safety.

Objectives

The objectives of this systematic review were:

1. to synthesise the evidence on the effectiveness of detection, mitigation and actions to reduce risks in hospitals; and
2. to identify and describe the components of interventions that are responsible for effectiveness.

Methods

Thirteen literature databases were examined in May and June 2008 following a predefined search strategy. We included studies of sufficient methodological quality if these dealt with the effects of safety and risk management (SRM) in a hospital setting. At least two reviewers assessed the title and abstracts of unique studies. Two reviewers, working independently, studied the retrieved full-text articles and extracted information on their methods and results.

Results

Thirty-eight studies were included in the final review:

- three systematic reviews
- six randomised controlled trials (RCTs)
- four controlled before-after studies (CBAs)
- nine interrupted time series studies (ITSs)
- sixteen uncontrolled before-after studies (UBAs).

The types of interventions and outcomes were classified into three categories (two studies fitted in more than one category):

1. detection (nine studies)
2. mitigating factors (no studies)
3. actions to reduce risks (thirty-one studies).

Detection

Studies could be divided into two categories: incident reports and analysis techniques.

Incident reports

All studies showed positive effects on the quality and/or quantity of reports. Specific findings were*:*

- The total error rate was higher in studies using voluntary reporting than in a study using mandatory reporting.
- Voluntary incident reporting may be associated with under-reporting in specific professions and in specific types of incidents.
- Nurses reported considerably more often than doctors.
- Incidents involving medication are reported most frequently.
- Feedback to the reporter is seen as an important way of encouraging staff to continue reporting incidents.
- Multi-institutional reporting, where information is gathered about adverse events in different hospitals and analysed centrally, identified rare but important problems.
- Paper-based reporting sometimes helps to increase reporting rates rather than a web-based tool.

Analysis techniques

Many publications were found relating to analysis techniques in industry and healthcare, although these did not focus on effects or effectiveness. Only two evaluations were identified; both showed positive results. However, systematic evidence on the effectiveness of safety analysis remains limited.

Mitigating factors

Mitigating factors are actions or circumstances that prevent or moderate the progression of an incident towards harming a patient. We did not identify any studies that fitted in this category.

Actions to reduce risks

The majority of the studies we examined dealt with this topic.

Actions taken to reduce risk concentrate on preventing the reoccurrence of the same or similar safety incidents, and on improving system resilience. The main patient outcome categories were:

- medication errors (for example, computerised physician order entry [CPOE]; pharmacist participation in rounds; education tools; clinical decision support systems; bar coding; organisation-wide safety programmes; smart-pump technology – an infusion system that checks that medication programming is within pre-established institutional limits before infusion can begin; structured order sheets – a standardised order sheet containing a number of pre-structured information categories; the Breakthrough Series, which uses a collaborative approach to enhance learning and reduce medication errors; failure mode and effect analysis [FMEA]
- fall incidents (for example, multi-component falls prevention programmes; flooring types; types of physiotherapy)

- diagnostic errors (for example, computerised decision support and web-based reminder systems)
- adverse events and risks (for example, reporting systems; computerised clinical information systems; retrospective medical-record screening and review; or a combination of interventions, including multidisciplinary rounds led by doctors, and culture interventions)
- simulated survival (for example, human simulation training).

Conclusion

Research evidence for safety interventions in hospitals has remained limited. Published studies predominantly report on positive effects; however, the methodological quality of the studies is generally weak. The diversity of the collected material made it problematic to combine studies quantitatively. SRM interventions applied in a hospital setting are multifaceted and therefore it was difficult to disentangle the effects from the context in which they were implemented. This makes it challenging to formulate recommendations for future implementation to professionals and policy-makers. There is therefore a pressing need for high-quality evaluations of the effectiveness – and cost-effectiveness – of SRM interventions.

1. Introduction

This study is part of the Health Foundation's QQUIP (Quest for Quality and Improved Performance) research initiative. One of the three main focuses of QQUIP is the Quality Enhancing Interventions (QEI) programme, which includes a series of structured, evidence-based reviews of the effectiveness of a wide range of interventions designed to improve the quality of healthcare. The programme aims to answer the question: 'What works to improve quality and performance?' There are six categories in the QEI programme, and this study falls within the category of 'organisational interventions' and focuses on safety and risk management (SRM).

Patient safety has increasingly become a matter of interest to governments, health professionals and scholars internationally. Over the last decade a great deal of research has been conducted to assess the prevalence, severity and causes of many different types of adverse events, as well as the effectiveness of efforts and approaches to enhance safety, and reduce risks and adverse events. SRM interventions relate to a wide variety of organisational aspects linked to safety and risks, ranging from co-ordination, resource allocation and standardisation in healthcare organisations, to issues of human resource management, communication, information technology, and inter-institutional improvement initiatives.

Safety and risk management concepts and definitions

The MeSH is the US National Library of Medicine's controlled vocabulary thesaurus. It consists of sets of terms that name descriptors in a hierarchical structure. This allows users to search at various levels of specificity. The Medical Subject Heading (MeSH) of 'safety management' was introduced in 1994. It encompasses:

> the development of systems to prevent accidents, injuries, and other adverse occurrences in an institutional setting. The concept includes prevention or reduction in adverse events or incidents involving employees, patients, or facilities. Examples include plans to reduce injuries from falls or plans for fire safety to promote a safe institutional environment.
>
> (MeSH 2009)

Safety management belongs to the MeSH tree of 'risk management', a heading that was introduced in 1990. Risk management involves:

> the process of minimizing risk to an organization by developing systems to identify and analyze potential hazards to prevent accidents, injuries, and other adverse occurrences, and by attempting to handle events and incidents which do occur in such a manner that their effect and cost are minimized. Effective risk management has its greatest benefits in application to insurance in order to avert or minimize financial liability.
>
> (MeSH 2009)

The World Health Organization (WHO) Conceptual Framework for the International Classification for Patient Safety (ICPS) offers a definition of SRM, restricted to a healthcare setting:

> activities or measures taken by an individual or a health care organization to prevent, remedy or mitigate the occurrence or reoccurrence of a real or potential (patient) safety event.
>
> (WHO, World Alliance for Patient Safety 2009)

The ICPS aims to define, harmonise and group a standardised set of patient safety concepts – with agreed definitions, and labelled with preferred terms – into an internationally acceptable classification in a way that is conducive to learning and to improving patient safety over time and across borders (Sherman et al 2009).

A widely accepted definition of 'patient safety' comes from the Institute of Medicine (IOM). In *To err is human* patient safety is described 'as the freedom from accidental injury due to medical care or from medical error' (IOM 2000). The ICPS provides another definition:

> the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.
>
> (WHO, World Alliance for Patient Safety 2009)

None of the definitions presented so far conflict with each other. They all refer to intentional actions, activities and measures: part of an organisational improvement or learning process in a healthcare setting. Other relevant phrases relating to patient safety are 'medical error', 'near miss' and 'adverse event'. Again a leading definition comes from the ICPS:

> An error is a failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase.
>
> (WHO, World Alliance for Patient Safety 2009)

Fallowfield and Fleissig (2004) suggest that medical errors should be distinguished from negligence or malpractice, insofar as the first is accidental while the second two are deliberate violations of a rule or standard of behaviour. Furthermore, medical errors do not lead to observable injury to the patient in all cases. The situations that did not cause harm to patients, but could have done, are described as 'near miss' (Wilson et al 1996). The term 'adverse event' is used for incidents in which the person receiving healthcare was harmed (Leape et al 1993). In their study, Leape et al identified a range of factors that contribute to adverse patient events, categorising them as diagnostic, treatment, preventive and other.

A continuous process

In its simplest form, SRM in healthcare can be conceptualised as a continuous process in which healthcare providers respond to safety incidents, medical errors and expected risks. A logical starting point for an attempt to collect and synthesise the evidence on effective SRM interventions is to make an inventory of key concepts. An understanding of the patient safety literature, however, has been compromised by the inconsistent use of language (Runciman et al 2009). Similar patient safety concepts use different terms (for example 'near miss', 'close call'), and identical terms are used to embrace several concepts (for example 'medical error' for errors, violations and system failures – see also Runciman et al 2006; Elder, Pallerla and Regan 2006. To meet the need for clarification and standardisation, the WHO's World Alliance for Patient Safety has undertaken a project to develop an ICPS.

The current conceptual framework for the ICPS consists of three categories that are linked in several ways semantically (see Box 1). Two of the categories relate to the 'clinically meaningful' categorisation of an incident (based on incident types and patient outcomes) and 'descriptive information' about the context of the incident, including patient characteristics, incident characteristics, contributing factors/ hazards and organisational outcomes. The third category, 'proactive and reactive system resilience', affects the activities and measures relating to SRM, and is the focus of this study. Within the ICPS, a distinction is made between detection, mitigating factors, ameliorating actions and actions taken to reduce risk (see Figure 1).

Box 1: Ten classes within the conceptual framework for the ICPS

Clinically meaningful incident categorization

- *Incident type* is a descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features, such as 'clinical process/procedure', 'resources/ organizational management' or 'medication/IV fluid' incident.
- *Patient outcome* is the impact upon a patient, which is wholly or partially attributable to an incident. Patient outcomes can be classified according to type of harm, degree of harm and any social and/or economic impact.

Descriptive information providing context for the incident

- *Patient characteristics* categorize patient demographics, the original reason for seeking care and the primary diagnosis.
- *Incident characteristics* classify the information about the circumstances surrounding the incident, such as where and when in the patient's journey through the healthcare system the incident occurred, who was involved and who reported it.
- *Contributing factors*/*hazards* are the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident. Examples are human factors such as behaviour, performance or communication; system factors, such as work environment and external factors beyond the control of the organization, such as the natural environment or legislative policy. More than one contributing factor and/or hazard is typically involved in a single patient safety incident.
- *Organizational outcomes* refer to the impact upon an organization which is wholly or partially attributable to an incident such as an increased use of resources to care for the patient, media attention or legal ramifications.

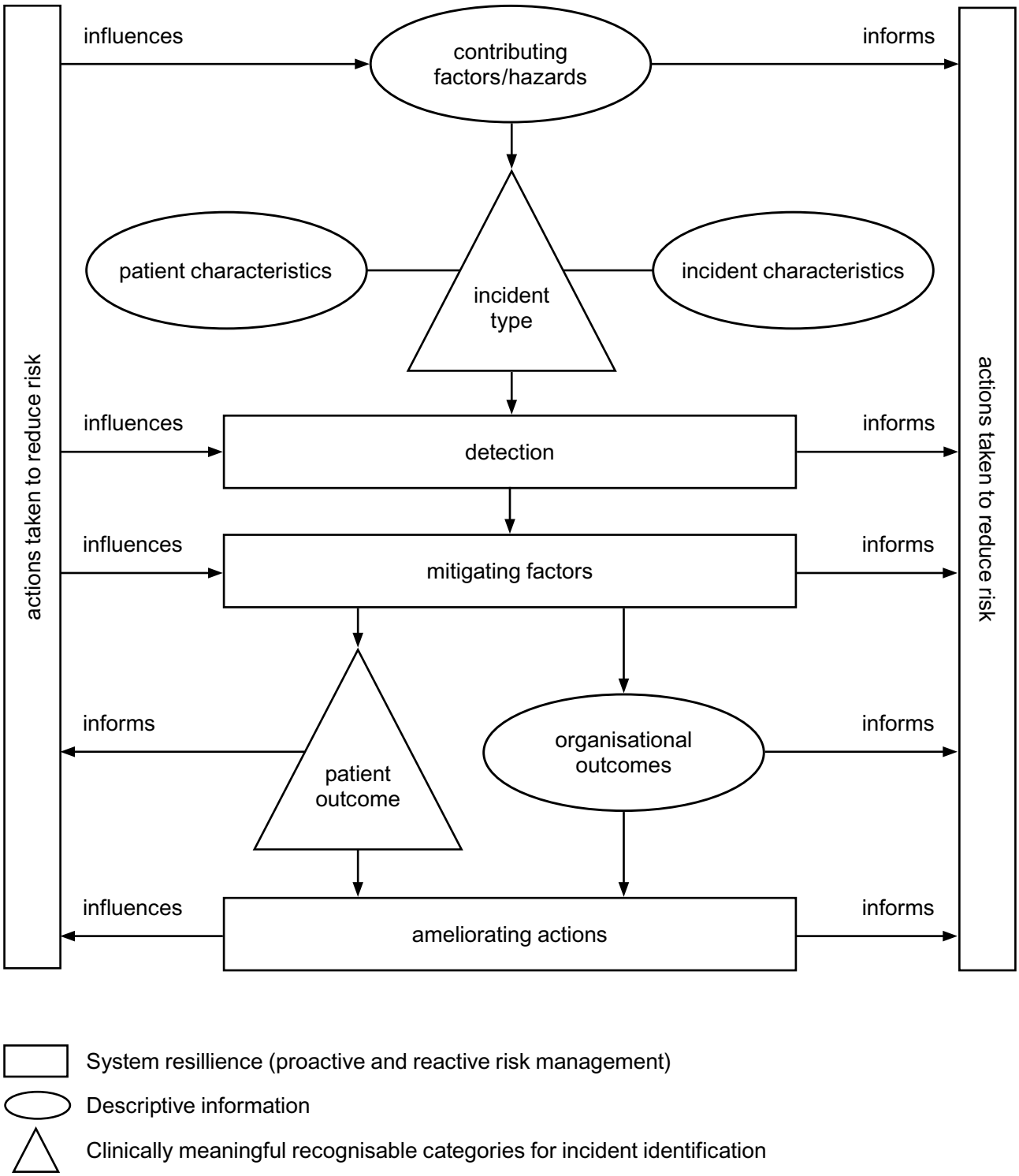
System resilience (proactive and reactive risk management)

The concept of 'resilience' in the context of the ICPS is defined as the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents so that an organization can 'bounce back' to its original ability to provide core functions.

- *Actions taken to reduce risk* concentrate on steps taken to prevent the reoccurrence of the same or similar patient safety incident and on improving system resilience. Actions taken to reduce risk are those actions taken to reduce, manage or control any future harm, or probability of harm, associated with an incident. These actions may be directed toward the patient (provision of adequate care, decision support), toward staff (training, availability of policies/protocols), toward the organization (improved leadership/guidance, proactive risk assessment), and toward therapeutic agents and equipment (regular audits, forcing functions). Detection, mitigating factors and ameliorating actions both influence and inform the actions taken to reduce risk.
- *Detection* is defined as an action or circumstance that results in the discovery of an incident. For example, an incident could be detected by a change in the patient's status, or via a monitor, alarm, audit, review or risk assessment. Detection mechanisms may be built into the system as official barriers or informally developed.
- *Mitigating factors* are actions or circumstances that prevent or moderate the progression of an incident toward harming the patient. Mitigating factors are designed to minimize the harm to the patient after the error has occurred and triggered damage control mechanisms.
- If the incident does result in harm, ameliorating actions can be introduced. *Ameliorating actions* are those actions taken or circumstances altered to make better or to compensate any harm after an incident. Ameliorating actions apply to the patient (clinical management of an injury, apologizing) and to the organization (staff debriefing, culture change and claims management).

Source: Sherman H, Castro G, Fletcher M et al (2009). 'Towards an International Classification for Patient Safety: the conceptual framework'. *International Journal for Quality in Health Care*, vol 21, pp 4–7, by permission of Oxford University Press

Figure 1: Conceptual framework for the ICPS



Source: Sherman H, Castro G, Fletcher M et al (2009). 'Towards an International Classification for Patient Safety: the conceptual framework'. *International Journal for Quality in Health Care*, vol 21, p 4, by permission of Oxford University Press

Safety and risk management in hospitals

This review focuses on SRM in hospitals. Most research on the effectiveness of SRM strategies has been carried out in hospital settings, with little in primary and community settings or in people's homes (Øvretveit 2008). In terms of risk, hospitals are a relatively hazardous working environment for both patients and staff. Hospital staff must continuously deal with adverse events and numerous potential risks relating to surgery, anaesthetics and patient transfers: for example, wound infections, medication errors, wrong-site surgery. The relatively high risk of unsafe situations makes the hospital sector an important setting for an assessment of various approaches to SRM.

A new research contribution

There is a substantial body of research in the area of patient safety. It is an ongoing challenge to keep track of the growing literature base and to categorise study findings and their implications in an orderly way. In their systematic review, Hoff et al (2004) examined the relationship between system features and safety outcomes. They considered the evidence available on associations between organisational dynamics, medical errors and patient safety. Their contribution involved an exploration of the relevance of, among others, culture, organisational structure, teams, feedback, opinion leaders, board leadership, educational programmes and information technology. Only a small number of studies confirmed a relationship between system components and errors or safety. This is an important finding. A possible explanation might be that the distance between system features and medical errors and safety events as investigated by Hoff et al (2004) is too large. A complementary perspective is that the field of organisational dynamics covers important conditions but that the association between conditions and safety outcomes depends on the successful implementation of specific SRM interventions. In other words, interventions – and not the organisational features – are linked more directly to patient safety. The effectiveness of such interventions, implemented within hospital organisations, is the main focus of our systematic review.

Given the gradual progress that is being made in the development of an international taxonomy and conceptual framework (see Figure 1), we apply our review on the effectiveness of SRM interventions from a system resilience perspective. The concept of resilience as defined by the ICPS is 'the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents' so that an organisation can 'bounce back' to its original ability to provide core functions (Sherman et al 2009). Resilience is, in that sense, closely linked to actions to reduce risk. We underline the notion that, together, detection and mitigation can impede the progression of an incident from reaching and/or harming a patient. However, we refrain from placing undue emphasis on the effectiveness of ameliorating actions (that is, responses to harm), unless a direct influence is assessed of reactive 'damage control' actions on the dependent variable. Variables may include the number and severity of medical errors, adverse events, events reported, or hazards/root causes identified.

2. Objectives and methods

Objectives

The objectives of this study were to synthesise the evidence on the effectiveness of detection, mitigation and actions to reduce risks in hospitals, and to identify and describe the components of interventions that are responsible for effectiveness.

Methods

Data sources and searches

A search for all relevant articles published before May 2008 was conducted in May and June 2008 of the following databases:

- PubMed
- PsycINFO
- Embase
- Cochrane Database of Systematic Reviews
- Database of Abstracts of Reviews of Effects (DARE)
- Cochrane Central Register of Controlled Trials
- Health Technology Assessment (HTA)
- NHS Economic Evaluation Database (NHS EED)
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- King's Fund
- World Health Organization Library and Information System (WHOLIS)
- CSA Sociological Abstracts
- Web of Science.

Search strategy

When searching for SRM literature, it became apparent at an early stage that we would need to apply additional limits, rather than just combining SRM with hospital terms as sector restrictors. Hospitals – together with risk and safety management (both as text words and MeSH headings) – resulted in almost 16,000 hits in PubMed, even when we applied a design filter from the Cochrane Effective Practice and Organisation of Care Group (EPOC). We therefore added a number of patient safety-related phrases to the search strategy. The final search strategy was based on SRM in relation to medical errors, adverse events, incidents and near misses, restricted to the hospital sector (see Box 2). An example of a search strategy from one database can be found in Appendix A.

Box 2: Search strategy

	Search term
#1	'risk management' (all fields, if possible MeSH)
#2	'safety management' (all fields, if possible MeSH)
#3	2 OR 3
#4	'medical error(s)' (all fields, if possible MeSH)
#5	'incident(s)' (all fields)
#6	'adverse event(s)' (all fields)
#7	'near miss(es)'
#8	4 OR 5 OR 6 OR 7
#9	'hospital(s)' (all fields, if possible MeSH)
#10	3 AND 8 AND 9
#11	EPOC methodological filter
#12	10 AND 11

Study selection and data extraction

Types of studies

To determine which studies to include, we used a general hierarchy of evidence classification (from higher to lower validity):

- systematic reviews of reviews
- systematic reviews of studies
- individual randomised controlled trials
- quasi-experimental studies (for example, experimental studies without randomisation)
- controlled observational studies (for example, cohort or case-control studies)
- observational studies without a control group (for example, interrupted time series studies, uncontrolled before-after studies or case series).

Based on an exploration of available experimental studies, we considered all systematic reviews, randomised controlled trials (RCTs), controlled before-after studies (CBAs), interrupted time series studies (ITSs) and uncontrolled before-after studies (UBAs) as candidates for inclusion. To ensure that primarily studies with the preferred design were included in the study, we used a methodological filter (see Appendix B). We excluded studies that were not published in English, case studies or studies that did not include comparisons with a control group or pre-intervention episodes.

Types of interventions and setting

The review focused on three types of organisational interventions:

1. Detection: an action or circumstance that results in the discovery of an incident.
2. Mitigating factor: an action or circumstance that prevents or moderates the progression of an incident towards harming a patient.
3. Actions to reduce risks: actions taken to reduce, manage or control any future harm, or probability of harm, associated with an incident.

Types of outcome measures

SRM can influence different sorts of outcomes and this review focused on two types: the effects on safety and risk, and the effects on incident reporting and tracking. In the first case, outcomes were associated with changes in the safety and risk situation, so an SRM intervention was considered effective if it led to specific outcomes, such as the reduction in the number of (possible) incidents, errors, near misses and adverse events. In the second case, since an effective SRM cannot take place without adequate detection, it is likely that effective detection techniques will result in an increased quality or quantity of reported incidents (see Box 3).

Box 3: Types of outcome measures

Effects	Examples
Effects on safety and risks	Reducing the frequency or severity of: • fall incidents • wound infections • misuse • medication errors
Effects on incident reporting and tracking	• Frequency • Categories and severity/seriousness • Willingness to report • Differences between groups of practitioners (eg nursing staff or doctors)

Study selection procedure

Two reviewers, working independently, screened the papers found based on title and abstract, or, if necessary, the complete text. A third reviewer was consulted in those cases in which discrepancies were found.

We excluded studies from our review if they did not report any actual changes in the safety and risk situation, or any effect on monitored or reported incidents and risks. We also excluded studies if the intervention was not clearly defined.

Data extraction

One reviewer carried out the data extraction of full-text studies, and a second reviewer checked this using a pre-structured extraction form. The content of each paper included was summarised in descriptive texts. In the case of systematic reviews (of reviews), the topic, setting, search period, data sources, number of included studies, main outcomes (see Box 3) and conclusions were described. For non-review papers, the study setting and the nature of the intervention were described. For all included papers, an indication of the strength of the study was reported, based on the extent to which EPOC criteria for reviews, RCTs, CBAs and ITSs were met (as defined by The Cochrane Collaboration). The methodological quality of the reviews was determined by the quality of the studies they included, as well as the extent to which a systematic approach was followed. Criteria taken into account were:

- at least two authors scored eligibility
- authors used inclusion and exclusion criteria
- designs were judged using predefined criteria (EPOC, Jahad, etc)
- at least two authors scored findings
- authors used data extraction forms.

RCTs were assessed using seven criteria:

1. protection against selection bias
2. protection against contamination (for example, randomising organisations/professionals rather than individual patients)
3. protection against exclusion bias
4. follow-up of patients or episodes of care
5. comparability of baseline measurements
6. protection against detection bias (blinded assessment of primary outcomes)
7. reliability of primary outcome measures.

CBAs were judged using seven criteria:

1. protection against contamination
2. protection against exclusion bias
3. follow-up of patients or episodes of care
4. comparability of baseline measurements
5. protection against detection bias
6. characteristics for studies using second site as control
7. reliability of primary outcome measures.

The methodological quality of ITSs were determined using eight criteria:

1. intervention was independent of other changes
2. data analysed appropriately (autoregressive integrated moving average [ARIMA] or time series regression)
3. reason given for number of points pre and post intervention
4. shape of intervention effect was specified

5. intervention unlikely to affect data collection
6. protection against detection bias
7. completeness of data set
8. reliability of outcome measures.

UBAs were rated on one criteria only: the reliability of the primary outcome measure.

The summarising labelling of the methodological quality was based on two rules:

- Rule 1: if zero to two of the criteria were not fulfilled, for example, rated as ‘not done’ or ‘unclear’, in the case of an RCT, CBA or ITS, the study was considered strong. Studies were classed as moderate when three to maximally half of the criteria were not fulfilled. With weak studies, more than half of the criteria were not fulfilled.
- Rule 2: extra weight was given to fundamental characteristics of different studies, as critical aspects of the methodological quality had to be guaranteed. Strong RCTs and CBAs were rated as moderate if the comparability of control groups was not fulfilled. UBAs were rated as weak if the criterion on the reliability of the primary outcome measure was not fulfilled.

Synthesis of data

Our discussion of the evidence on SRM interventions has been organised into the activities described in the ICPS conceptual framework. We have described relevant characteristics for each activity, such as the study objectives and design, the nature of the intervention and the effects reported. Detailed information, for example, about the country, research setting and the statistical tests applied, can be found in Appendix E.

3. Results

About the studies found

Number of studies

Initially, we retrieved 3,772 references to studies from the various literature databases. Applying an EPOC design filter, in preparation for the first screening round, helped to reduce this to 1,872 studies. PubMed provided approximately 65 per cent of the studies. After checking the total number of studies for duplicates, we examined the abstracts of 1,645 unique studies using inclusion criteria (see Figure 2).

Two reviewers subsequently assessed 146 full-text articles and included 38 studies (see Appendix C for further details):

- three systematic reviews
- six randomised controlled trials (RCTs)
- four controlled before-after studies (CBAs)
- nine interrupted time series studies (ITSs)
- sixteen uncontrolled before-after studies (UBAs).

Methodological quality

We considered the design of four studies to be strong (Berner et al 2006; Paoletti et al 2007; Schneider et al 2006; Walsh et al 2008) and the design of seven studies to be moderate (Kozer et al 2005; Leape et al 1999; Lehmann et al 2007; Schwendimann et al 2006; Simon et al 2005; Snijders et al 2007; Voeffray et al 2006). The methodological quality of the remaining 27 studies was weak. (See Appendix D for further details.) Major limitations of these weak studies were the absence of studies with strong designs, and unclear descriptions of review procedures. In the case of RCTs, CBAs and ITSs, there was often uncertainty about the extent to which a perceived change was independent of other changes. The authors of most RCTs and CBAs could not guarantee the absence of contamination of interventions (that is, the possibility that the intervention reached the comparison group). ITSs were rarely examined with appropriate statistical techniques. The reliability of the outcome measure of many UBAs is unclear. In general, interventions were multifaceted or otherwise poorly specified.

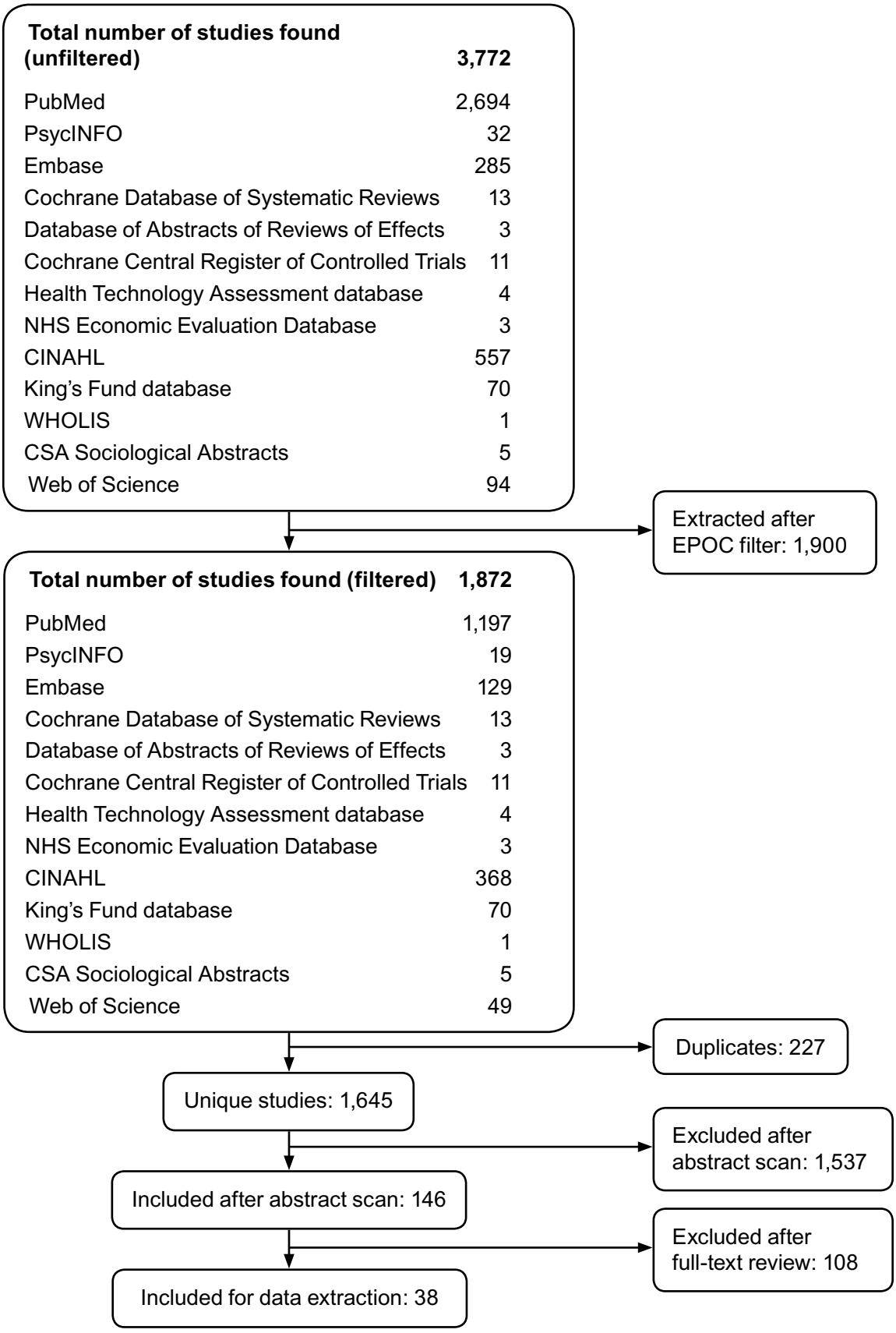
Research setting

More than half of the material relates to studies in the USA. The other studies described interventions implemented in the UK, Australia, Canada, Hong Kong, the Netherlands and Switzerland. A limited number of studies made no distinction in the specialty or the types of patients treated. Other studies focused on: acute care, medical wards, ambulatory care, general internal medicine, paediatrics, cardiology, surgery, geriatrics, intensive care, and chemotherapy.

Detection

Nine studies were identified on detection approaches. Studies could be divided into two categories: incident reports and analysis techniques. Two systematic reviews focused on incident reporting systems and their characteristics in relation to the size of effects (Simon et al 2005; Snijders et al 2007). Four empirical studies also described the effects of reporting systems, mainly voluntary or non-punitive

Figure 2: Changes in the number of studies included during the review process



systems (Harris et al 2007; Lehmann et al 2007; Plews-Ogan et al 2004; Stump 2000). The other studies addressed an intervention package (Evans et al 2007), the Breakthrough Series, which uses a collaborative learning approach (Silver and Antonow 2000), and a multidisciplinary team addressing medication-related patient safety (Sim and Joyner 2002).

Incident reports

Effectiveness of reporting systems

The methodological quality of the studies in this category was moderate or weak. All of the studies reported positive effects on the quality or quantity of reported medical errors and incidents. One of the reviews (Simon et al 2005) assessed the effectiveness of hospital incident reporting systems in improving hospital and clinic performance in terms of patient safety, clinical outcomes, costs and operations. The authors included 11 studies published between 1994 and 2004: four with control conditions and seven uncontrolled evaluations. The main findings were that incident reporting and chart-review detection were less reliable than direct observation. The conclusion of the second review (Snijders et al 2007) was similar. Here the scope was narrowed to characteristics of incident reporting systems in neonatal intensive care units (NICU) in relation to type, aetiology, outcome and preventability of incidents. The search period was restricted to January 1980 and January 2006 and resulted in the inclusion of uncontrolled studies: eight prospective and two retrospective. Medication incidents were most frequently reported. Available data in the NICU showed that the total error rate was much higher in studies using voluntary reporting than in a study using mandatory reporting. Multi-institutional reporting, where information is gathered about adverse events in different hospitals and analysed centrally, identified rare but important errors. A substantial number of incidents were potentially harmful.

Various studies showed that the number of reports can be increased significantly by different approaches. Harris et al (2007) presented an increase of reporting incidence in their study of patient-safety event reporting in three intensive care units (medical, surgical and cardiothoracic). The introduction of a new, voluntary, card-based event reporting system was compared to existing online tools. In both systems, nurses submitted the majority of the reports (nurses 67.1 per cent; doctors 23.1 per cent; other reporters 9.5 per cent). However, with the paper-based system, the greatest increase in reporting related to doctors.

In a study by Lehmann et al (2007) the significant increase in the number of reports per month (from 19 to 102), and a change in the type of errors, was attributed to a revised medication event reporting policy that was implemented throughout the hospital in 2005. This policy was preceded by strategy sessions with the senior management about non-punitive reporting in the autumn of 1999 and small-scale implementation in October 2000.

Plews-Ogan et al (2004) described a substantial increase in the reporting of adverse events and near misses after the implementation of clinician-based near miss/adverse event voluntary reporting, coupled with systems analysis and redesign as a model for continuous quality improvement. The study took place in the ambulatory setting.

In a study by Stump (2000) the number of reported events increased considerably within one year after the medication error reporting process was redesigned in one hospital. The new process differed from the old one in the following ways:

- It was non-punitive.
- The central pharmacy department received a report within 48 hours rather than two to three months.
- A unified database was used instead of a fragmented process.

- Near misses could be captured in every stage of the medication-use process and not only during the dispensing process.
- Structured check-box reports were used instead of handwritten free text.
- Staff at department level were involved in reviewing the data.

Effects of interventions other than reporting systems

Evans et al (2007) described a significant improvement in reporting in inpatient areas and in emergency departments after an intervention package was implemented. This included:

- a questionnaire and focus group to identify barriers for reporting
- a manual to improve knowledge
- education sessions
- the redesign of reporting processes to address concerns
- a one-page report form replacing the existing three-page form
- the introduction of a free-call telephone service
- the mailing of four feedback newsletters
- presentations being given at meetings.

Silver and Antonow (2000) reported how a Breakthrough Series model was applied to reduce the number of medication errors reported. Teams consisting of staff from quality improvement, pharmacy and medical departments attended seminars and acquired knowledge to enhance error reporting. Sim and Joyner (2002) linked an increase in reporting of medication variances to the introduction of a multidisciplinary team, formed to address medication-related patient safety initiatives. The team was set up in a community hospital that had a wide variety of acute care, critical care, emergency care and surgical and diagnostic services.

In summary, all studies, regardless of the quality of their design and the different interventions, described attempts to enhance incident and risk reporting. Nevertheless, incident reporting and chart review were found to be less reliable, complete and precise than observation. Nurses reported more often than doctors. There are also indications that the number of incidents reported was lower with mandatory rather than voluntary reporting.

Analysis techniques

Extensive literature is available on different analysis techniques. Woloshynowych et al (2005), for example, wrote an extensive and detailed publication on the nature and characteristics of different methods in industry and healthcare such as the Australian Incident Monitoring System (AIMS), the critical incident technique (CIT), comparison with standards (CWS), failure mode and effect analysis (FMEA), the organisational accident causation model (OACM), root cause analysis (RCA) and significant event auditing (SEA).

The study identified the following positive aspects of these methods:

- They contribute to priority setting.
- They emphasise the system and not the individual.
- They localise weak spots and risks.

Negative elements included the following:

- They can be time consuming or complex.
- Their outcomes depend on the level of available expertise.
- A comprehensive answer is not always guaranteed.

Although relevant, the above study and other studies addressing reactive (for example, critical incident technique) or proactive (for example, FMEA) analysis techniques could not be included in this review as they do not focus on effects or effectiveness.

Two examples of studies that address the results of FMEA show that it enables changes to be monitored. Bonnabry et al (2005) conducted an FMEA to compare risks associated with the old and new process, to quantify the improved safety of the new process, and to identify the major residual risks in paediatric parental nutrition. A multidisciplinary team carried out the FMEA by following a series of process steps:

1. prescription
2. transmission to pharmacy
3. pharmaceutical validation
4. label production
5. compounding
6. quality control.

Several changes were implemented:

- new prescription software
- direct recording on a server
- automatic printing of the labels
- the creation of a file used to pilot an automatic compounder.

In the new process, the sum of the criticality indices (CI) of all 18 identified failure modes was reduced by 59 per cent compared with the old process. In the new process, the CIs of the different failure modes were reduced by a mean factor of seven.

Robinson et al (2006) also used FMEA to identify the elements of risk in chemotherapy, with the aim of implementing appropriate improvement strategies. The results of the analysis helped them to implement strategies in three processes: prescribing, dispensing and administration. The study concluded that it was feasible to improve potential error rates for prescribing, dispensing and administration. Actual effects were addressed in a later section of the study.

The main conclusion to be drawn in relation to different analysis methods and techniques is that, despite an abundance of descriptive material, information on their reliability and accuracy is limited. We did not find any studies comparing the effectiveness of analysis techniques.

Mitigating factors

Mitigating factors are designed to minimise the harm to a patient after an error has occurred and has triggered damage-control mechanisms (see Box 1 on page 3). We did not identify any studies that fitted in this category.

Actions to reduce risk

The remaining studies included in this review address interventions aimed at reducing risks. Actions taken to reduce risk concentrate on preventing the reoccurrence of the same or similar safety incidents and on improving system resilience (see Box 1). The main patient outcome categories were medication errors, fall incidents, diagnostic errors, human simulation training, adverse events, and safety risks.

Reducing the number and severity of medication errors

Medication was by far the largest category of safety improvement and risk-reduction interventions. We identified ten different types of interventions:

- computerised physician order entry (CPOE)
- pharmacist participation in doctors'/post-admission rounds
- education tools
- a clinical decision support system on a personal digital assistant (PDA)
- bar-code technology
- an organisation-wide safety programme
- smart-pump technology
- structured order sheets
- the Breakthrough Series
- failure mode and effect analysis (FMEA).

Computerised physician order entry

Four studies evaluated the effectiveness of CPOE implementation. One of them was a systematic review conducted by Shamliyan et al (2008). The hypothesis was tested that medication errors and adverse clinical events decrease with CPOE compared with handwritten orders by doctors in paediatric and adult patients, independent of patient and provider characteristics. The search period ranged from 1995 to 2004, and 12 studies were included: one RCT, nine UBAs and two studies with an unclear design. The main conclusion was that CPOE implementation was associated with a significant reduction in medication errors in adult and paediatric populations. However, results should be interpreted with caution. Effects may have been overestimated due to the use of non-randomised uncontrolled interventions. Implementation of CPOE was not associated with a substantial improvement in patient safety, and the studies did not allow broad generalisability. Two other studies also reported positive effects of CPOE (King et al 2003; Voeffray et al 2006). The authors of a fourth study – about CPOE in paediatric inpatient care – did not consider it as effective in reducing medication errors as it is in adult inpatient care (Walsh et al 2008).

Pharmacist participation in doctors'/post-admission rounds

Two studies described how pharmacist participation in doctors'/post-admission rounds led to lower rates of preventable adverse drug events (Leape et al 1999) and enhanced accuracy of medication history (Fertleman et al 2005).

Education tools

Three studies examined the effectiveness of education tools. Simpson et al (2004) concluded that the impact of a combined risk-management/clinical pharmacist-led education programme on medication errors in an NICU was significantly positive. The results were similar to an assessment by Schneider et al (2006) of the influence of an interactive CD-ROM programme on the rate of medication administration errors made by nurses. However, this second approach did not contribute to a significantly reduced administration error rate. A study by Manning et al (2007) highlighted that a new web-based educational tool was not accompanied by a reduction in self-reported error rate either.

Clinical decision support system

Berner et al (2006) evaluated the effectiveness of a clinical decision support system on a PDA. The intervention group with the PDA decision support tool revealed a significantly lower mean proportion of cases per doctor with unsafe prescriptions for the intervention group than the control group, after adjustment for baseline rates.

Bar-code technology

Two studies dealt with the effectiveness of bar-code technology. Paoletti et al (2007) described the implementation of a multidisciplinary approach to systematically decrease medication errors by using observation methodology, electronic medication-administration records and bar-coded medication administration. The medication error rate decreased significantly in one of the two intervention groups and remained unchanged in the other. In the second study (Poon et al 2006) the implementation of bar-code technology resulted in a considerable reduction in dispensing errors and potential adverse drug events (ADEs).

Organisation-wide safety programme

Cohen et al (2005) focused on a possible reduction in adverse drug events as a result of an organisation-wide safety programme. The positive results – a significant reduction in ADE rate and the proportion of patients with ADEs – were attributed to a programme that included:

- the formation of a patient safety council
- assigning a full-time safety specialist
- the implementation of an event reporting system
- the introduction of drug protocols
- weekly medication-profile audits
- order standardisation.

Smart-pump technology

Smart-pump technology is an infusion system that checks that medication programming is within pre-established institutional limits before infusion can begin. Larsen et al (2005) conducted a study to determine whether combining standard drug concentrations with smart-pump technology reduced reported medication-infusion errors. They found that the significant reduction in the number of reported errors was associated with continuous medication infusions.

Structured order sheet

Kozer et al (2005) concluded that a structured order sheet (a standardised order sheet containing a number of pre-structured information categories) is effective in reducing the incidence of medication errors in paediatric emergency departments. The intervention group used a new structured order sheet instead of the regular blank order sheets, which resulted in a statistically significant reduction.

The Breakthrough Series

Silver and Antonow (2000) conducted an evaluation of the Breakthrough Series (described on page 14). Analysis of this model, which used a collaborative approach to increase knowledge among teams of staff, demonstrated a significant decrease in overall error frequency and a significant increase in error detection and prevention.

Failure mode and effect analysis

The FMEA conducted by Robinson et al (2006) has also been described earlier (see page 15). After the implementation of improvement strategies, which resulted from the analysis, improvements were achieved in the potential prescribing error rate, actual dispensing errors and actual administration errors. The use of pre-printed standard order sets increased.

Reducing the number and severity of fall incidents

Multi-component falls prevention programmes

Five of the seven studies addressing interventions to reduce the number and/or severity of fall incidents are multi-component falls prevention programmes. Dempsey (2004) and Donoghue et al (2005) both reported positive results. Dempsey tested a falls prevention programme in an acute medical area, which was re-evaluated five years later to determine if the effects had been sustained. The conclusion was that the number of falls reduced by 55 per cent between 1995 and 1996. In 2001, the rate of patient falls had exceeded pre-research levels. Donoghue et al carried out research to find out whether a companion observer programme helped to prevent high-risk inpatients on an acute aged care ward from falling. Patients at high risk were accompanied in a room staffed by volunteer companion observers. The 128 observers worked in two-hour shifts, on weekdays from 8.00am to 8.00pm. Their primary objective was to keep patients company and to notice if they became increasingly agitated or showed risky behaviour. If this was the case, then they gently reassured the patient and, if necessary, contacted a nurse. The fall rate decreased by 44 per cent.

Another programme proved partly effective. Williams et al (2007) evaluated a systematic, co-ordinated approach to limit the severity and minimise the number of falls in an acute care hospital. Patients were classified according to three levels of risk: low, medium and high. Appropriate interventions (environment, mobility, elimination) were developed for each risk level on a fall care plan for each patient. Analysis showed a significant reduction in the number of falls (9.5 per 1,000 occupied bed days before and 8.0 per 1,000 occupied bed days after), although not in the severity of falls.

In the remaining studies, the intended decrease was not detected. Schwendimann et al (2006) examined an interdisciplinary falls prevention programme based on:

1. screening of all patients at admission for risk of falls
2. examination of patients considered at risk of falling
3. interventions for all patients to provide safety in the hospital
4. interventions for patients considered at risk of falling
5. reassessment of those patients who fell.

After the implementation, a decrease in falls was observed, but this was not significant. There were no considerable differences over time in individual departments, and the annual proportion of minor and major injuries did not decrease. Lane (1999) evaluated the effectiveness of a falls prevention programme in reducing the patient fall rate. The programme also identified patients at risk of falling and established guidelines for interventions promoting patient safety. However, the study reported an insignificant change in patient fall rate per 1,000 patients days and an insignificant decrease in injuries.

Other interventions

In a falls prevention interventions review, Gillespie et al (2003) extracted two other studies, which did not deal with a falls prevention programme, but with different interventions. Donald et al (2000) compared two flooring types – carpet and vinyl – in hospital bed areas, and two types of physiotherapy – conventional therapy and additional leg strengthening exercises – in avoiding falls. No significant effect was found for either intervention. Tideiksaar et al (1993) examined the clinical efficacy of a bed alarm system in reducing falls from bed on a geriatric evaluation and treatment unit. The system functioned effectively, activating an alarm in all cases when patients were transferring from their bed and, with the exception of one case, nurses could respond quickly to help patients and prevent bed falls. Although there was a clinical trend towards reduced falls in the experimental group, this was not significant enough to make a statistical difference in bed falls between the experimental group with the bed alarm system and the four control groups.

Reducing diagnostic errors

A third category of outcomes was the reduction in diagnostic errors. Two studies about reminder systems were included, with both reporting significant improvements. Ramnarayan et al (2006a) examined the impact of a web-based diagnostic reminder system on clinicians' decisions in an acute paediatric setting during assessments that were characterised by diagnostic uncertainty. After the introduction of the diagnostic computerised decision support system, the percentage of unsafe diagnostic workups decreased significantly from 45.2 per cent to 32.7 per cent. Ramnarayan et al (2006b) assessed the impact of a diagnostic reminder system on the quality of clinical decisions made by various grades of clinicians during acute assessment. The mean count of diagnostic errors of omission decreased significantly, and the mean diagnostic quality score increased. The number of irrelevant diagnoses increased from 0.7 to 1.4, but did not result in a corresponding increase in the number of irrelevant or deleterious tests and treatments.

Reducing the number and severity of adverse events and risks

Four studies fit within this category. The review of institutional reporting systems by Simon et al (2005) has been discussed on page 13. In this review the authors also assessed the effectiveness of reporting systems as an SRM intervention to improve safety and reduce risks. The majority (7 out of 11) of the included studies reported no reduction in medical errors and adverse events after implementing incident reporting systems.

The three other studies mainly reported positive results. A wide variety of approaches has been studied in attempts to reduce the number and severity of adverse events and risks, using information and communication technology (ICT) programmes, FMEA or multi-component intervention packages.

Fraenkel et al (2003) described the effects of a computerised clinical information system, implemented in an intensive care unit. Significant reductions occurred in the following incidents: medication, intravenous, ventilation and other incidents.

Jain et al (2006) reported a variety of positive results. They evaluated a combination of different interventions that were implemented individually over a 12-month period, including:

- multidisciplinary rounds led by doctors
- daily bed-flow meetings to access bed availability
- evidence-based practices relating to three quality initiatives
- culture change, with a forum on team decision-making.

In a third study, the number of patient attendances associated with an adverse event decreased significantly between the first and last quarter of the study year (Wolff and Bourke 2002). Retrospective screening of patient files took place in two phases. After three months, several interventions were implemented:

- a variety of actions aimed at preventing events from recurring (changes in hospital policies, focused auditing, discussion with staff, implementation of guidelines)
- weekly adverse event reports/quarterly reports
- encouragement of staff to report clinical incidents.

In the light of the findings of the studies in this category, it is important to emphasise that the number of adverse events is generally an unreliable patient safety measure as the risk of under-reporting is substantial.

Other safety or risk effects

While most of the studies could be organised into the following categories: adverse events in general, medication errors, fall incidents, and diagnostic errors, one study could not be categorised in this way. DeVita et al (2005) found that simulated survival rates improved significantly after human simulation training in an educational environment to develop multidisciplinary team skills. The course components were:

- a web-based presentation and pre-test before the course
- a brief reinforcing training session on the day of the course
- three out of five different simulated scenarios, each followed by debriefing and analysis with the team.

4. Discussion

The primary study objectives of this review were:

1. to synthesise the evidence on the effectiveness of detection, mitigation and actions to reduce risks in hospitals; and
2. to identify and describe the components of interventions that are responsible for effectiveness.

The study covered a wide variety of conditions and interventions related to safety and risks. We categorised the collected studies within different safety and risk management (SRM) interventions, as part of the International Classification for Patient Safety (ICPS) framework (see Box 1and page 3 and Figure 1 on page 4).

Main findings

Detection

The first type of intervention is detection. All the studies we included that deal with incident reporting (incident reporting systems, intervention packages, the Breakthrough Series, and efforts by a multidisciplinary team) indicate a positive effect of the interventions on the quality and/or quantity of reports. Most of the research on detection addresses reporting systems. When identifying the effective components of these systems, one finding is that voluntary incident reporting may lead to under-reporting (Plews-Ogan et al 2004). The total error rate was higher in studies using voluntary reporting than in a study using mandatory reporting (Snijders et al 2007). In practice, nurses report considerably more events than do doctors (Simon et al 2005; Harris et al 2007). Feedback to the reporter is seen as an important factor in safeguarding the willingness of staff to continue to report incidents and near misses (Simon et al 2005). In the case of neonatology, Snijders et al (2007) found that multi-institutional reporting identified uncommon but relevant errors. Moreover, Harris et al (2007) concluded that paper-based reporting sometimes works better than a web-based tool. The effective components of the other interventions to advance reporting are part of a larger intervention package, which therefore makes it impossible to disentangle the effective components from the whole programme.

A second detection activity concerns analysis methods. Despite a large number of papers devoted to this subject, research addressing the effectiveness and efficiency of safety analysis is scarce (see also Vincent 2004). There are indications that analysis techniques are effective in identifying potential risks or root causes, and in monitoring changes. One study by Robinson et al (2006), which had a weak design, shows that applying an FMEA has positive results, although information about which method works best in which circumstances – in terms of effectiveness, efficiency, accuracy and reliability – was not provided.

Actions to reduce risk

No studies on mitigating factors were identified. The majority of the studies, which were also those with the strongest study designs, dealt with actions to reduce risk. The collected evidence contributes to the knowledge about what works in general in reducing the number and severity of medication errors, fall incidents, diagnostic errors and adverse events. Unfortunately, however, it often remains unclear what the effective component was and why it worked. This is because SRM interventions are embedded in the structure and process of healthcare organisations. Furthermore, the diversity of the collected material, combined with the limited evidence for each topic, makes it difficult to draw generic conclusions or to conduct a quantitative meta analysis.

Resilience

Resilience is the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents so that an organisation can 'bounce back' to its original ability to provide core functions (see Box 1 on page 3). Within the context of 'resilience', SRM is linked to implementation science and concepts such as continuous quality improvement, cyclical quality management systems, and organisational learning. Improving safety and risk reduction, based on collected information about incidents and risks, or analysis results, requires some sort of learning or feedback mechanism. The study by Robinson et al (2006) provides a case in which analysis results were used as input for improvement. However, Simon et al (2005) concluded that many of the studies in their review on institutional reporting systems suffered from a flaw: that they are based on the assumption that incident data will automatically improve safety performance by directing system or institutional interventions, and by affecting health provider knowledge and skills via feedback.

In many of the studies included in our review, the relationship between detection, mitigation and risk reduction actions could not be verified. A general conclusion is that the initiation of reporting systems is likely to contribute to an increase in the number of reports. The real challenge, however, relates not to the quantity or quality of reports but to the degree to which professionals or organisations use the collected information to generate improvement. Feedback is considered a *conditio sine qua non* for learning and, thus, for continuous SRM. Still, the practical feasibility of feedback must be considered with some reservations. There is limited evidence about effective forms of safety feedback within healthcare (Benn et al 2009), and a Cochrane review of audit and feedback, which included more than 100 trials, showed a very modest improvement in professional performance overall (Jamtvedt et al 2006).

Limitations

There are several reasons to view the findings of the studies we reviewed with caution and to question their usefulness in initiatives that translate them to new settings. These reasons are set out below:

- It seems highly probable that the published research on SRM has a substantial publication bias. Almost 90 per cent of the studies included in our review reported positive results.
- More than two-thirds of the included studies were of a low methodological quality. The available research is mainly comprised of uncontrolled observational evaluations. In many of the studies, the sample size was relatively small, and details were described poorly. This therefore limited the ability of the researchers to determine whether patients with particular characteristics – for example, age or morbidity – were more or less likely to respond to, for example, fall incident or medication safety interventions. In particular, the effects reported in the UBAs should be interpreted with caution.
- Interventions were often embedded in multifaceted intervention packages or programmes. In these cases, it was not possible to isolate the impact of specific components from other activities and conditions. This is not necessarily problematic, but it does make it challenging to determine what exactly caused an effect, or lack of effect.
- Most studies provided limited information on the costs relating to the intervention. Without this information, policy-makers, programme designers, managers and/or professionals cannot make informed decisions about the costs and benefits of improvement schemes.
- By taking 'safety and risk management' as a starting point, this review identified research linked to this term in the literature. Such an open approach allowed us to obtain a general sense of reference and guidance, instead of directly focusing on specific applications. This is an explorative approach, in which the term itself defines the scope. However, as a result, not all of the safety research performed in the context of quality improvement has been included.

We therefore recommend extending the search strategy of future literature studies by using key phrases from the evolving ICPS framework. Our decision to select studies with strong research designs follows from the study objectives, but this means that relevant information from studies not meeting this threshold was excluded. As a result, only a selection of safety items were presented in this review, while highly relevant items such as infection control were omitted.

Future research

Effectiveness detection

By linking our review to the ICPS framework, we have the opportunity to locate gaps in the international literature on SRM. Most of the evidence discussed in this review affects detection and risk reduction measures. Researchers need to feel encouraged to proceed with the evaluation of the effectiveness of these and other detection interventions. In particular, we recommend the further assessment and comparison of analysis techniques (and their role as a window on the system – see, for example, Vincent 2004). It is important to learn more about their effectiveness, efficiency and accuracy. One way of exploring this area tentatively is for experts with practical experience of particular analysis methods to analyse the same incident (in the case of causes) or process (in the case of failure modes) and study whether their findings are similar. If they are, research could identify whether differences found can be attributed to the method or way the analysis was conducted. In this way, it may be possible to decide whether the result of an applied risk analysis method depends on the type of analysis or on the presence of specific conditions during the implementation. Likewise, the impact of analysis techniques may be best studied in combination with safety improvement interventions.

Continuous safety and risk management and resilience

Although the poor availability of material on mitigation is interesting, it is in the area of continuous SRM and resilience where we perceive the greatest need for original and system-oriented evaluations of effectiveness. How do SRM interventions contribute to continuous learning? Testable hypotheses can be formulated in relation to positive influences of various SRM approaches and conditions within hospitals, such as:

- the application of integrated safety frameworks
- organisational culture
- safety culture
- leadership styles
- guidelines
- performance management
- continuous quality improvement techniques
- multidisciplinary teams joining a quality improvement collaborative.

Although high expectations are often raised, in the current review no evidence on these topics was found in relation to SRM outcomes. This finding reflects that of other studies: for example, the research evidence concerning collaboratives (Schouten et al 2008), as well as the low number of studies identified by Hoff et al (2004) that verify the relationship between organisational features and patient safety. Compared with the review by Hoff et al, which focused on conditions, our emphasis on interventions resulted in a relatively large number of studies describing positive effects on safety and risk outcomes. Nevertheless, the possibilities for future research are enormous.

Combined safety and risk management and implementation science

There is currently a substantial body of research on organisational changes in healthcare settings, but quality and safety systems have seldom been studied in rigorous evaluations, so their effectiveness remains unproven (Wensing et al 2006). Authors of studies identified in this review have highlighted the importance of follow-up measurements and the issue of sustainability (Dempsey 2004; Kozer et al 2005), and sustainability of implementation outcomes and changed practices is a highly relevant research area (Greenhalgh et al 2005; Grol et al 2007). We strongly recommend that research on the improvement of patient safety links to, and builds on, the extensive and rich world of quality improvement research and implementation science (Grol et al 2008). For example, it is not clear whether and how knowledge about the success and failure of the implementation of SRM interventions is used in dissemination decisions locally, nationally or internationally (in the case of effect studies published in international journals). Dissemination without a good understanding of the idiosyncrasies of a particular innovation may be a waste of time or may even be counterproductive.

Expanding and improving safety and risk management research

A conclusion that can be drawn from this review is that it is surprising – given the international attention focusing on patient safety – that the evidence base for SRM in a hospital setting is so limited. SRM needs to be approached like any intervention in healthcare in that it should prove its effectiveness – and cost effectiveness – before wide implementation is promoted. At this point, the number and quality of published studies on SRM interventions is too small to support conclusions about effectiveness in a systems perspective. Therefore, considerable expansion and improvement in research on SRM is much needed and would be of great value.

References

Benn J, Koutanji M, Wallace L et al (2009). 'Feedback from incident reporting: Information and action to improve patient safety' *Quality and Safety in Healthcare*, vol 18, pp 11–21.

Berner ES, Houston TK, Ray MN et al (2006). 'Improving ambulatory prescribing safety with a handheld decision support system: a randomized controlled trial'. *Journal of the American Medical Informatics Association (JAMIA),* vol 13*,* pp 171–179.

Bonnabry P, Cingria L, Sadeghipour F et al (2005). 'Use of a systematic risk analysis method to improve safety in the production of paediatric parenteral nutrition solutions'. *Quality and Safety in Health Care,* vol 14, pp 93–98.

Cohen MM, Kimmel NL, Benage MK et al (2005). 'Medication safety program reduces adverse drug events in a community hospital'. *Quality and Safety in Health Care,* vol 14, pp 169–174.

Dempsey J (2004). 'Falls prevention revisited: a call for a new approach'. *Journal of Clinical Nursing,* vol 13, pp 479–485.

DeVita MA, Schaefer J, Lutz J et al (2005). 'Improving medical emergency team (MET) performance using a novel curriculum and a computerized human patient simulator'. *Quality and Safety in Health Care,* vol 14, pp 326–331.

Donald IP, Pitt K, Armstrong E et al (2000). 'Preventing falls on an elderly care rehabilitation ward'. *Clinical Rehabilitation,* vol 14, pp 178–185.

Donoghue J, Graham J, Mitten-Lewis S et al (2005). 'A volunteer companion-observer intervention reduces falls on an acute aged care ward'. *International Journal of Health Care Quality Assurance Incorporating Leadership in Health Services,* vol 18, pp 24–31.

Elder NC, Pallerla H and Regan S (2006). 'What do family physicians consider an error? A comparison of definitions and physician perception'. *BMC Family Practice,* vol 7, p 73.

Evans SM, Smith BJ, Esterman A et al (2007). 'Evaluation of an intervention aimed at improving voluntary incident reporting in hospitals'. *Quality and Safety in Health Care,* vol 16, pp 169–175.

Fallowfield LJ and Fleissig A (2004). 'Communication with patients in the context of medical error'. *Health Care Risk Special Report,* vol 10, pp 12–14.

Fertleman M, Barnett N and Patel T (2005). 'Improving medication management for patients: the effect of a pharmacist on post-admission ward rounds'. *Quality and Safety in Health Care,* vol 14, pp 207–211.

Fraenkel DJ, Cowie M and Daley P (2003). 'Quality benefits of an intensive care clinical information system'. *Critical Care Medicine,* vol 31, pp 120–125.

Gillespie LD, Gillespie WJ, Robertson MC et al (2003). 'Interventions for preventing falls in elderly people. *Cochrane Database of Systematic Reviews*, Issue 4, Art no. CD000340.

Greenhalgh T, Robert G, Bate P et al (2005). *Diffusion of innovations in Health Service Organisations: a systematic literature review*. London: Blackwell Publishing.

Grol R, Berwick DM and Wensing M (2008). 'On the trail of quality and safety in health care'. *British Medical Journal,* vol 336, pp 74–76.

Grol R, Bosch MC, Hulscher MEJL et al (2007). 'Planning and studying improvement in patient care: the use of theoretical perspectives'. *Milbank Quarterly,* vol 85, pp 93–138.

Harris CB, Krauss MJ, Coopersmith CM et al (2007). 'Patient safety event reporting in critical care: a study of three intensive care units'*. Critical Care Medicine,* vol 35, pp 1,068–1,076.

Hoff T, Jameson L, Hannan E et al (2004). 'A review of the literature examining linkages between organizational factors, medical errors, and patient safety'. *Medical Care Research and Review,* vol 61, pp 3–37.

Institute of Medicine (2000). *To err is human: building a safer health system*. Washington DC: National Academy Press.

Jain M, Miller L, Belt D et al (2006). 'Decline in ICU adverse events, nosocomial infections and cost through a quality improvement initiative focusing on teamwork and culture change'. *Quality and Safety in Health Care,* vol 15, pp 235–239.

Jamtvedt G, Young JM, Kristoffersen DT et al (2006). 'Audit and feedback: effects on professional practice and health care outcomes'. *Cochrane Database of Systematic Review,* Issue 2, Art no. CD000259.

King WJ, Paice N, Rangrej J et al (2003). 'The effect of computerized physician order entry on medication errors and adverse drug events in pediatric inpatients'. *Pediatrics,* vol 112, pp 506–509.

Kozer E, Scolnik D, MacPherson A et al (2005). 'Using a preprinted order sheet to reduce prescription errors in a pediatric emergency department: a randomized, controlled trial'. *Pediatrics,* vol 116, pp 1,299–1,302.

Lane AJ (1999). 'Evaluation of the fall prevention program in an acute care setting'. *Orthopaedic Nursing,* vol 18, pp 37–43.

Larsen GY, Parker HB, Cash J et al (2005). 'Standard drug concentrations and smart-pump technology reduce continuous-medication-infusion errors in pediatric patients'. *Pediatrics,* vol 116, e21–e25.

Leape LL, Cullen DJ, Clapp MD et al (1999). 'Pharmacist participation on physician rounds and adverse drug events in the intensive care unit'. *Journal of the American Medical Association,* vol 282, pp 267–270.

Leape LL, Lawthers AG, Brennan TA et al (1993). 'Preventing medical injury'. *Quality Review Bulletin,* vol 19, pp 144–149.

Lehmann DF, Page N, Kirschman K et al (2007). 'Every error a treasure: improving medication use with a nonpunitive reporting system'. *Joint Commission Journal on Quality and Patient Safety,* vol 33, pp 401–407.

Manning DM, O'Meara JG, Williams AR et al (2007). '3D: a tool for medication discharge education'. *Quality and Safety in Health Care,* vol 16, pp 71–76.

MeSH (2009). Available at www.nlm.nih.gov/mesh/MBrowser.html. Accessed 29 August 2009.

Øvretveit J (2008). *Which interventions are effective for improving patient safety? A synthesis of research and policy issues*. Copenhagen/Stockholm: WHO HEN/MMC Karolinska.

Paoletti RD, Suess TM, Lesko MG et al (2007). 'Using bar-code technology and medication observation methodology for safer medication administration'. *American Journal of Health-System Pharmacy,* vol 64, pp 536–543.

Plews-Ogan ML, Nadkarni MM, Forren S et al (2004). 'Patient safety in the ambulatory setting. A clinician-based approach'. *Journal of General Internal Medicine,* vol 19, pp 719–725.

Poon EG, Cina JL, Churchill W et al (2006). 'Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy'. *Annals of Internal Medicine,* vol 145, pp 426–434.

Ramnarayan P, Roberts GC, Coren M et al (2006a). 'Assessment of the potential impact of a reminder system on the reduction of diagnostic errors: a quasi-experimental study'. *BMC Medical Informatics and Decision Making,* vol 6, p 22.

Ramnarayan P, Winrow A, Coren M et al (2006b). 'Diagnostic omission errors in acute paediatric practice: impact of a reminder system on decision-making'. *BMC Medical Informatics and Decision Making,* vol 6, p 37.

Robinson DL, Heigham M and Clark J (2006). 'Using Failure Mode and Effects Analysis for safe administration of chemotherapy to hospitalized children with cancer'. *Joint Commission Journal on Quality and Patient Safety,* vol 32, pp 161–166.

Runciman WB, Williamson JAH, Deakin A et al (2006). 'An integrated framework for safety, quality and risk management: an information and incident management system based on a universal patient safety classification'. *Quality and Safety in Health Care,* vol 15, i82–i90.

Runciman W, Hibbert P, Thomson R et al (2009). 'Towards an International Classification for Patient Safety: key concepts and terms'. *International Journal for Quality in Health Care,* vol 21, pp 18–26.

Schneider PJ, Pedersen CA, Montanya KR et al (2006). 'Improving the safety of medication administration using an interactive CD-ROM program'. *American Journal of Health-System Pharmacy,* vol 63, pp 59–64.

Schouten LMT, Hulscher MEJL, Van Everdingen JJE et al (2008). 'Evidence for the impact of quality improvement collaboratives: systematic review'. *British Medical Journal,* vol 336, pp 1,491–1,494.

Schwendimann R, Buhler H, De Geest S et al (2006). 'Falls and consequent injuries in hospitalized patients: effects of an interdisciplinary falls prevention program'. *BMC Health Services Research,* vol 6, p 69.

Shamliyan TA, Duval S, Du J et al (2008). 'Just what the doctor ordered. Review of the evidence of the impact of computerized physician order entry system on medication errors'. *Health Services Research,* vol 43, pp 32–53.

Sherman H, Castro G, Fletcher M et al (2009). 'Towards an International Classification for Patient Safety: the conceptual framework'. *International Journal for Quality in Health Care,* vol 21, pp 2–8.

Silver MP and Antonow JA (2000). 'Reducing medication errors in hospitals: a peer review organization collaboration'. *Joint Commission Journal on Quality and Patient Safety,* vol 26, pp 332–340.

Sim TA and Joyner J (2002). 'A multidisciplinary team approach to reducing medication variance'. *Joint Commission Journal on Quality and Patient Safety,* vol 28, pp 403–409.

Simon A, Lee RC, Cooke DL et al (2005). *Institutional medical incident reporting systems: a review*. Alberta: AHFMR, Health Technology Assessment Unit.

Simpson JH, Lynch R, Grant J et al (2004). 'Reducing medication errors in the neonatal intensive care unit'. *Archives of Disease in Childhood: Fetal and Neonatal Edition,* vol 89, F480–F482.

Snijders C, van Lingen RA, Molendijk A et al (2007). 'Incidents and errors in neonatal intensive care: a review of the literature'. *Archives of Disease in Childhood: Fetal and Neonatal Edition,* vol 92, F391–F398.

Stump LS (2000). 'Re-engineering the medication error-reporting process: removing the blame and improving the system'. *American Journal of Health-System Pharmacy,* vol 57, Suppl 4, S10–S17.

Thomson R, Lewalle P, Sherman H et al (2009). 'Towards an International Classification for Patient Safety: a Delphi survey'. *International Journal for Quality in Health Care,* vol 21*,* pp 9–17.

Tideiksaar R, Feiner CF and Maby J (1993). 'Falls prevention – the efficacy of a bed alarm system in an acute-care setting'. *Mount Sinai Journal of Medicine,* vol 60, pp 522–527.

Voeffray M, Pannatier A, Stupp R et al (2006). 'Effect of computerisation on the quality and safety of chemotherapy prescription'. *Quality and Safety in Health Care,* vol 15, pp 418–421.

Vincent C (2004). 'Analysis of clinical incidents: a window on the system not a search for root causes'. *Quality and Safety in Health Care,* vol 13, pp 242–243.

Walsh KE, Landrigan CP, Adams WG et al (2008). 'Effect of computer order entry on prevention of serious medication errors in hospitalized children'. *Pediatrics,* vol 121, e421–e427.

Wensing M, Wollersheim H and Grol R (2006). 'Organisational interventions to implement improvements in patient care: a structured review of reviews'. *BMC Implementation Science*, vol 1, p 2.

Williams TA, King G, Hill AM et al (2007). ‘Evaluation of a falls prevention programme in an acute tertiary care hospital’. *Journal of Clinical Nursing,* vol 16, pp 316–324.

Wilson RM, Runciman WB, Gibberd RW et al (1996). ‘Quality in Australian health care study’. *Medical Journal of Australia,* vol 164, p 754.

Wolff AM and Bourke J (2002). ‘Detecting and reducing adverse events in an Australian rural base hospital emergency department using medical record screening and review’. *Emergency Medical Journal,* vol 19, pp 35–40.

Woloshynowych M, Rogers S, Taylor-Adams S et al (2005). ‘The investigation and analysis of critical incidents and adverse events in healthcare’. *Health Technology Assessment,* vol 9, pp 1–143.

World Health Organization, World Alliance for Patient Safety (2009). *The conceptual framework for the International Classification for Patient Safety*. Geneva: World Health Organization.

Appendix A: Example of a search strategy and results

	Search term	No. of hits
#1	‘medical error’ [text word]	517
#2	‘medical errors’ [text word]	7,480
#3	‘medical errors’ [MeSH]	57,441
#4	1 OR 2 OR 3	57,871
#5	‘incident’ [text word]	22,827
#6	‘incidents’ [text word]	7,670
#7	5 OR 6	29,138
#8	‘adverse event’ [text word]	6,182
#9	‘adverse events’ [text word]	31,743
#10	8 OR 9	35,427
#11	‘near miss’ [text word]	468
#12	‘near misses’ [text word]	237
#13	11 OR 12	653
#14	4 OR 7 OR 10 OR 13	121,257
#15	‘risk management’ [text word]	12,602
#16	‘risk management’ [MeSH]	107,835
#17	15 OR 16	109,272
#18	‘safety management’ [text word]	8,952
#19	‘safety management’ [MeSH]	8,788
#20	18 OR 19	8,952
#21	17 OR 20	109,398
#22	‘hospital’ [text word]	610,365
#23	‘hospitals’ [text word]	224,372
#24	‘hospitals’ [MeSH]	156,732
#25	22 OR 23 OR 24	714,103
#26	14 AND 21 AND 25	2,694
#27	EPOC filter (see Appendix B)	7,422,048
#28	26 AND 27	1,197

Search results: PubMed, 29 May 2008

Appendix B: EPOC methodological filter

Randomized Controlled Trial [publication type] OR Controlled Clinical Trial [publication type] OR Comparative Study OR Evaluation Studies OR ‘comparative study’ OR ‘effects’ OR ‘effect’ OR ‘evaluations’ OR ‘evaluating’ OR ‘evaluation’ OR ‘evaluates’ OR ‘changing’ OR ‘changes’ OR ‘change’ OR ‘interventions’ OR ‘intervention’ OR ‘impact’ OR ‘random allocation’ OR ‘post test’ OR ‘posttest’ OR ‘pre test’ OR ‘pretest’ OR ‘time series’ OR ‘experimental’ OR ‘experiments’ OR ‘experiment’ OR ‘intervention studies’ OR ‘intervention study’ OR ‘controlled clinical trial’ OR ‘randomised controlled trial’ OR ‘randomized controlled trial’

Source: The Cochrane Effective Practice and Organisation of Care (EPOC) Group

Appendix C: Study topics and interventions per SRM activity, sorted by design

Activity	SRM topic	Review	RCT	CBA	ITS	UBA	Intervention
1	**Detection**	2	0	1	3	3	
	Quantity and quality of reports	+	-	-	-	-	Institutional medical incident reporting systems (Simon et al 2005)*
		+	-	-	-	-	Characteristics of incident reporting systems (Snijders et al 2007)
	Number of reports	-	-	+	-	-	Intervention package: education, a range of reporting options, enhanced report management and feedback (Evans et al 2007)
		-	-	-	+	-	New, voluntary, card-based event reporting system (Harris et al 2007)
		-	-	-	+	-	Revised, non-punitive medication event reporting policy (Lehmann et al 2007)
		-	-	-	+	-	Changing the traditional, multi-tiered incident reporting system for medication errors to a standardised, non-punitive medication-use variance process (Stump 2000)
		-	-	-	-	+	Voluntary near miss/adverse event reporting, combined with system analysis and redesign (Plews-Ogan et al 2004)
		-	-	-	-	+	Breakthrough Series to reduce medication errors (Silver and Antonow 2000)*
		-	-	-	-	+	Multidisciplinary team addressing medication-related patient safety initiatives: number of variance reports (Sim and Joyner 2002)
2	**Mitigating factors**	0	0	0	0	0	
3	**Actions to reduce risk**	2	6	3	6	14	
	Adverse events (unspecified)	+	-	-	-	-	Institutional medical incident reporting systems (Simon et al 2005)*
		-	-	-	+	-	Clinical information system (Fraenkel et al 2003)
		-	-	-	-	+	Teamwork and culture change (Jain et al 2006)
		-	-	-	-	+	Use of FMEA to identify risk, and for implementing strategies (Robinson et al 2006)
		-	-	-	-	+	Retrospective medical-record screening and clinical review followed by appropriate quality improvement actions (Wolff and Bourke 2002)
	Medication errors/adverse drug events	+	-	-	-		Computerisation of physician orders: prescription (Shamliyan et al 2008)
		-	+	-	-	-	Decision support tool on personal digital assistant (Berner et al 2006)
		-	+	-	-	-	Structured order sheet (Kozer et al 2005)
		-	+	-	-	-	New web-based education tool compared with a standard education tool (Manning et al 2007)

		-	+	-	-	-	Interactive CD-ROM programme (Schneider et al 2006)
		-	-	+	-	-	Computerised physician order entry system without clinical decision support (King et al 2003)
		-	-	+	-	-	Pharmacist participation in the ICU at the time of drug prescribing (Leape et al 1999)
		-	-	+	-	-	Observation methodology and electronic medication records: bar-code technology (Paoletti et al 2007)
		-	-	-	+	-	Organisation-wide safety programme (Cohen et al 2005)
		-	-	-	+	-	Combined risk management/clinical pharmacist-led education programme (Simpson et al 2004)
		-	-	-	+	-	Computerised physician order entry system (Voeffray et al 2006)
		-	-	-	+	-	Computerised physician order entry system, check dosage with alert function (Walsh et al 2008)
		-	-	-	-	+	Pharmacist participation on post-admission ward rounds (Fertleman et al 2005)
		-	-	-	-	+	Combining standard drug concentrations with smart-pump technology: infusion (Larsen et al 2005)
		-	-	-	-	+	Bar-code technology (dispensing errors and potential ADEs (Poon et al 2006)
		-	-	-	-	+	Breakthrough Series to reduce medication errors (Silver and Antonow 2000)*
	Severity and/or number of fall incidents	-	+	-	-	-	Comparison of carpet and vinyl flooring types in bed areas and two types of physiotherapy (Donald et al 2000)
		-	+	-	-	-	Bed alarm system (Tideiksaar et al 1993)
		-	-	-	+	-	Interdisciplinary falls prevention programme (Schwendimann et al 2006)
		-	-	-	-	+	Companion observer programme, based on 128 volunteer observers (Donoghue et al 2005)
		-	-	-	-	+	Fall risk assessment and prevention programme (Dempsey 2004)
		-	-	-	-	+	Falls prevention programme (Lane 1999)
		-	-	-	-	+	Systematic, co-ordinated approach (Williams et al 2007)
	Diagnostic errors	-	-	-	-	+	Web-based diagnostic reminder system on clinicians' decisions (Ramnarayan et al 2006a)
		-	-	-	-	+	Computerised decision support (a diagnostic reminder system) ((Ramnarayan et al 2006b)
	Simulated survival rates	-	-	-	-	+	Human simulation training/educational environment to develop team skills (DeVita et al 2005)

* Included more than once in this table

ADE = adverse drug event

FMEA = failure mode and effects analysis

ICU = intensive care unit.

Appendix D: Quality of study design

Design	First author	A1	A2	A3	A4	A5	B1	B2	C	D1	D2	E	F	G1	G2	H	I	J	K	L	M	N	O	P	Q	Overall quality
Review (3)	Shamliyan 2008	12	1	0	0	11	?	-	?	?	+															Weak
	Simon 2005	11	0	4	0	7	?	+	+	?	?															Moderate
	Snijders 2007	10	?	?	?	?	+	+	-	?	?															Moderate
RCT (6)	Berner 2006											+	-	+	NA	+	+								?	Strong
	Donald 2000											?	?	NA	+	+	?								?	Weak
	Kozer 2005											+	+	NA	+	-	+								?	Moderate
	Manning 2007											+	?	NA	-	NA	+								?	Weak
	Schneider 2006											+	+	+	NA	+	+								?	Strong
	Tideiksaar 1993											?	?	NA	+	+	?								?	Weak
CBA (4)	Evans 2007												+	?	?	+	?	-							?	Weak
	King 2003												?	NA	NA	+	?	-							-	Weak
	Leape 1999												?	NA	NA	+	+	-							+	Moderate
	Paoletti 2007												-	NA	NA	+	+	+							+	Strong
ITS (9)	Cohen 2005																?		?	-	?	+	-	+	?	Weak
	Fraenkel 2003																?		?	-	-	-	?	?	?	Weak
	Harris 2007																?		?	-	-	-	?	?	?	Weak
	Lehmann 2007																+		?	-	+	+	?	?	+	Moderate
	Schwendimann 2006																?		?	+	-	+	+	+	+	Moderate
	Simpson 2004																-		+	-	-	-	-	-	?	Weak
	Stump 2000																-		?	-	-	-	+	?	?	Weak
	Voeffray 2006																?		+	-	+	+	+	?	?	Moderate

	Walsh 2008																?		+	+	+	+	+	+	-	Strong
UBA (16)	Dempsey 2004																								?	Weak
	DeVita 2005																								+	Weak
	Donoghue 2005																								+	Weak
	Fertleman 2005																								?	Weak
	Jain 2006																								?	Weak
	Lane 1999																								+	Weak
	Larsen 2005																								?	Weak
	Plews-Ogan 2004																								?	Weak
	Poon 2006																								+	Weak
	Ramnarayan 2006a																								?	Weak
	Ramnarayan 2006b																								+	Weak
	Robinson 2006																								?	Weak
	Silver 2000																								?	Weak
	Sim 2002																								?	Weak
	Williams 2007																								+	Weak
	Wolff 2002																								?	Weak

A1: number of studies included. A2: number of RCTs included. A3: number of CBAs included. A4: number of ITSs included. A5: number of UBAs included

B1: scoring of eligibility by at least two authors. B2: authors used inclusion and exclusion criteria

C: designs were judged using predefined criteria (EPOC, Jahad, etc)

D1: scoring of findings by at least two authors. D2: authors used data extraction forms

E: concealment of allocation (protection against selection bias)

F: protection against contamination (eg randomising organisation/professionals rather than individual patients)

G1: follow-up of professionals (protection against exclusion bias). G2: follow-up of patients or episodes of care

H: baseline measurement (no differences)

I: blinded assessment of primary outcome(s) (protection against detection bias)

J: characteristics for studies using second site as control

K: the intervention is independent of other changes

L: data were analysed appropriately (ARIMA or time series regression)

M: reason for the number of points pre and post intervention given

N: shape of the intervention effect was specified

O: intervention unlikely to affect data collection

P: completeness of data set

Q: reliable primary outcome measure(s)

+ = done

- = not done

? = unclear

NA = not available

Appendix E: Included studies, sorted by alphabetical order

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Berner, 2006 USA	RCT Ambulatory/outpatient care, general internal medicine Intervention group: N = 34 (pre-intervention) N = 31 (post-intervention) Control group: N = 34 (pre-intervention) N = 28 (post-intervention) Period = NC (8-month follow-up)	**Aim** To evaluate the effectiveness of a PDA-based CDSS on NSAID prescribing safety by internal medicine residents in the outpatient setting **Intervention** PDA with CDSS **Control** PDA without CDSS	**Primary outcome** Proportion of cases per doctor with unsafe NSAID prescriptions	ANCOVA Significant reduction (0.23 versus 0.45 unsafe prescription cases per doctor [I versus C], F = 4.24, $p < 0.05$, effect size = 0.54)	Residents provided with a PDA-based CDSS for NSAID prescribing made fewer unsafe treatment decisions than participants using a PDA without the CDSS
Cohen, 2005 USA	ITS Hospital care N = 10–20 chart reviews of discharged patients per month Period = 2001–2003 (6 months baseline, 9 months implementation, 21-month follow-up)	**Aim** To assess the impact of a wide ranging safety programme on patient harm **Intervention** Combined intervention, including: • formation of a patient safety council • assigning a full-time safety specialist • implementation of event reporting system • introduction of drug protocols • weekly medication profile audits • order standardisation **Control** NA	1. ADE rate per 1,000 doses delivered 2. ADE rate per 1,000 patient days 3. Proportion of patients with an ADE 4. Number of ADEs associated with patient harm per total doses delivered 5. Cost saving	Chi-square test for trends 1. Significant reduction (median = 2.04 [1.79–2.70, IQR] in baseline versus 0.65 [0.41–0.87] post-intervention, $p = 0.001$) 2. Significant reduction (median = 5.07 [3.79–6.02] in baseline versus 1.30 [0.87–1.71] post-intervention, $p = 0.001$) 3. Significant decline (27% at baseline versus 9% post-intervention, RR = 0.33, $p < 0.001$) 4. Significant reduction (RR = 0.12 [0.04–0.38, 95% CI], $p < 0.001$) 5. With 4,400 ADEs prevented each year, annual cost savings are approximately $10,000,000	Highly effective, inexpensive programme

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Dempsey, 2004 Australia	UBA Acute medical area Period = January – June 1995 (pre-intervention), January – June 1996 (post-intervention), 2001 (re-evaluation 5 years post-intervention)	**Aim** To test the effectiveness of a falls prevention programme in an acute medical ward **Intervention** Falls prevention programme, consisting of an assessment tool, an alert graphic, and education for patient and staff **Control** NA	Fall rate (per 1,000 OBD)	Non-paired t-test Significant reduction in fall rate (3.63 pre-intervention versus 2.29 post-intervention [$p = 0.05$]) Five years post-intervention, fall rate has doubled (6.8, significance not presented)	Marginally effective falls prevention programme, but results were not sustainable after 5 years
DeVita, 2005 USA	UBA Advance cardiac life support/medical emergency team N = 10 courses and 138 individuals Period = March 2002 – May 2003	**Aim** To develop multidisciplinary team skills and improve MET performance **Intervention** Human simulation training in an educational environment to develop multidisciplinary team skills. Course components: 1. Web-based presentation and pre-test before the course 2. Brief reinforcing training session on the day of the course 3. Three of five different simulated scenarios each followed by 4. Debriefing and analysis with the team **Control** NA	**Primary outcome** 1. Successful crisis management resulting in mannequin 'survival' **Secondary outcome** 2. Completion of organisational and patient care tasks	Non-parametric tests: Cochran's Q and Kendall's W 1. Significant improved overall simulator 'survival' from 0% to 90% across the three sessions in a day's course (Cochran's Q = 12.6, $p = 0.002$). Most improvement between the first and the second sessions ($p = 0.014$) rather than between the second and third sessions ($p = 0.180$) (post-hoc analysis) 2. Significantly improved overall task completion rate from 31% to 89%, and each simulator role improved from 10 to 45% during the first session to 80 to 95% during the third session (Kendall's W = 0.91, $p < 0.001$). Improvement first and second sessions ($p = 0.002$) and between second and third ($p = 0.011$) (post-hoc analysis)	Training multidisciplinary teams using simulation technology is feasible and effective in improving team performance

ADE = adverse drug event; AE = adverse event; ANCOVA = analysis of covariance; ANOVA = analysis of variance; C = control group; CDSS = clinical decision support system; CI = confidence interval; CPOE = computerised physician order entry; CMI = continuous medication infusion; CO = companion observers; ED = emergency department; I = intervention group; ICU = intensive care unit; IQR = inter quartile range; ITS = interrupted time series; LOS = length of stay; MDW = medication discharge sheet; MET = medical emergency team; N = number; NA = not applicable; NC = not clear; NSAID = non-steroidal anti-inflammatory drug; OBD = occupied bed day; OR = odds ratio; PDA = personal digital assistant; QI = quality improvement; RCT = randomised controlled trial; RR = relative risk; SD = standard deviation; UBA = uncontrolled before-after.

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Donald, 2000 United Kingdom	RCT Elderly care rehabilitation ward in a community hospital N = 54 Period = February – September 1996 (9 months)	**Aim** Comparison of two flooring types – carpet and vinyl – in the bed areas, and two types of physiotherapy – conventional therapy and additional leg strengthening exercises – in avoiding falls **Intervention 1** 1a. Assigned to ward area with vinyl floor covering and conventional physiotherapy, once or twice daily 1b. As 1a plus seated leg strengthening exercises (hip flexors and ankle dorsiflexors) **Intervention 2** 2a. Assigned to ward area with carpet and conventional physiotherapy 2b. As 2a plus seated leg strengthening exercises (hip flexors and ankle dorsiflexors)	1. Number of fallers during admission 2. Number of fracture falls	Mann-Whitney U-test and Chi-square with Fisher's exact test 1. No difference in number of fallers: • additional exercise group versus conventional physiotherapy = 4 falls versus 7 falls, RR = 0.21, 95% CI = 0.04–1.2 (p = 0.12) • carpet versus vinyl = 10 falls versus 1 fall, RR = 8.30, 95% CI = 0.95–73 (p = 0.05) 2. No fall resulted in a fracture	There is no evidence to support either intervention in preventing falls on a rehabilitation ward

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Donoghue, 2005 Australia	UBA Acute aged care/elder care ward N = 3,972 OBD (2001), 3,455 OBD (2002), numbers not presented for 2003/2004 Period = January 2001 – August 2002 (pre-intervention 19 months), August 2002 – April 2004 (post-intervention 15 months)	**Aim** To prevent high-risk inpatients on an acute aged care ward from falling **Intervention** Patients at high risk of falling are accompanied by volunteer COs on weekdays 8.00am–8.00pm. Their primary objective was to observe patients for signs of increasing agitation or risky behaviour and, if needed, to reassure the patient or contact a nurse. The COs were also involved in other activities, such as conversations, playing cards, reading out loud, playing music, practical help in finding belonging sand setting up meals **Control** NA	Fall rate (per 1,000 OBD)	Chi-square test Significantly decreased fall rate. 15.6 falls/1,000 OBD (SD = 6.5) (before) versus 8.8 falls/1,000 OBD (SD = 3.0) (after), OR = 0.56 [95% CI = 0.45–0.68], $p < 0.0001$	Significant positive effect of intervention on fall rate

ADE = adverse drug event; AE = adverse event; ANCOVA = analysis of covariance; ANOVA = analysis of variance; C = control group; CDSS = clinical decision support system; CI = confidence interval; CPOE = computerised physician order entry; CMI = continuous medication infusion; CO = companion observers; ED = emergency department; I = intervention group; ICU = intensive care unit; IQR = inter quartile range; ITS = interrupted time series; LOS = length of stay; MDW = medication discharge sheet; MET = medical emergency team; N = number; NA = not applicable; NC = not clear; NSAID = non-steroidal anti-inflammatory drug; OBD = occupied bed day; OR = odds ratio; PDA = personal digital assistant; QI = quality improvement; RCT = randomised controlled trial; RR = relative risk; SD = standard deviation; UBA = uncontrolled before-after.

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Evans, 2007 Australia	CBA Inpatient care on ICUs, surgical units, medical units and EDs Intervention (I) units: N = 10 Control (C) units: N = 10 In each arm: 35,000 OBDs at baseline and during study period Intervention rollout was staggered, from June – August 2003, with units implementing the intervention over a 40-week period	**Aim** To assess the effectiveness of an intervention package in order to improve voluntary incident reporting **Intervention** • Questionnaire and focus group to identify barriers for incident reporting • Manual to improve knowledge • Education sessions • Redesign of reporting processes to address concerns • One-page report form replacing the existing three-page form and a free-call telephone service • Four feedback newsletters and presentations at meetings **Control** No intervention, ie usual error reporting procedures	1. Incident reporting rates per 10,000 OBD or per 10,000 ED attendances 2. Reporter designation 3. Reporting format 4. Types of incidents reported	Fisher's exact test, binomial regression analysis and Poisson regression analysis 1. Significant increase in reporting rates in inpatient care (additional 60.3 reports/10,000 OBD [95% CI = 23.8–96.8], $p < 0.001$) and in EDs (additional 39.5 reports/10,000 ED attendances [95% = CI 17.0– 62.0], $p < 0.001$) 2. More reports were generated: • by doctors in EDs (additional 9.5 reports/10,000 ED attendances [95% CI = 2.2–16.8], $p = 0.001$) • by nurses in inpatient areas (additional 59.0 reports/10,000 OBDs [95% CI = 23.9–94.1], $p < 0.001$) • anonymously (additional 20.2 reports/10,000 OBDs and ED attendances combined [95% CI = 12.6–27.8], $p < 0.001$) 3. Majority (79%) of reports in I-units were reported using one-page form, with 21% submitted through the call centre 4. Relative number of fall-related reports decreased in I-units (36.1% before versus 23.8% after, RR = 2.01 [95% CI = 1.7–2.3], $p < 0.001$). I-units had more documentation-related, clinical management and aggression-related incidents compared with C-units	The intervention units reported a greater variety and number of incidents during the study, with improved reporting by doctors from a low baseline. There was considerable heterogeneity between reporting rates in different types of units

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Fertleman, 2005 United Kingdom	UBA Acute medical services – general hospital N = 62 patients (pre-intervention) N = 57 patients (intervention) Period = April – July 2003	**Aim** To reduce medication errors and prescribing costs **Intervention** Addition of a pharmacist to the post-take medical team **Control** NA	1. Accuracy of medication history 2. Prescribing costs 3. Medication-associated risks	Chi-square test 1. Detected discrepancies between the admission and the pharmacist-derived drug history increased from 53% to 98% (pre-intervention versus intervention period) 2. Mean saving from drugs stopped during admission was £88.60 per patient per year during intervention period versus £5.52 in pre-intervention period 3. Majority of recommendations by pharmacist were of minor or moderate significance (53% and 53% respectively) and 5% were classified as preventing a potentially major incident	The presence of a pharmacist on a post-take ward round improved the accuracy of drug-history documentation, reduced prescribing costs and decreased the potential risk to patients
Fraenkel, 2003 Australia	ITS (but analysed as UBA) ICU in one hospital N = 12 beds Period = January 1995 – December 1998 (23 months pre-intervention and 25 months post-intervention)	**Aim** To quantify the quality benefits and staff perceptions of a computerised clinical information system implementation in an ICU **Intervention** Clinical information system, replacing paper-based charts of patient observations, clinical records, results reporting and drug prescribing **Control** NA	1. Frequency of clinical AEs 2. Perception of time taken in nursing documentation	Chi-square test 1. Number of clinical AEs by category: • Medication incidents decreased from 85 to 55 ($p < 0.05$) • Intravenous incidents decreased from 140 to 46 ($p < 0.001$) • Ventilation incidents decreased from 51 to 10 ($p < 0.001$) • Pressure ulcers remained stable (changed from 71 to 51, $p = 0.152$) • Other incidents increased from 201 to 323 ($p < 0.001$) 2. Significant decrease in percentage of nurses spending less than 10 minutes documenting notes (22% before versus 82% after, $p < 0.001$)	Significant reduction in number of key AEs, alongside positive nursing staff perceptions about time investment

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First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Harris, 2007 USA	ITS (but analysed as UBA) Medical ICU, surgical ICU and cardiothoracic ICU Pre-intervention: 16,089 patient days Post-intervention: 17,126 patient days Period = January 2002 – May 2004 (10 months pre-intervention, 14 months intervention and 5 months post-intervention)	**Aim** To increase patient-safety event reporting in three ICUs using a new, voluntary, card-based event reporting system and to compare and evaluate observed differences in reporting among healthcare workers across ICUs **Intervention** Implementation of an anonymous paper-based error report tool (as opposed to existing online tools) **Control** NA	1. Reported patient-safety events/1,000 patient days 2. Reporter designation 3. Severity of reported incidents	Chi-square test 1. Significant increase in reporting rates (pre-intervention = 20.4 events/1,000 patient days versus 41.7 reported events/1,000 patient days post-intervention; rate ratio = 2.05 [95% CI = 1.79–2.34]) 2. Nurses submitted the majority of reports (post-intervention: nurses = 67.1%, doctors = 23.1%, other reporters = 9.5%). Doctors experienced the greatest increase in reporting rate (doctors: 43-fold, nurses: 1.7-fold, other reporters: 4.3-fold) relative to pre-intervention rates 3. Significant differences in the reporting of harm by job description: 31.1% of reports from nurses, 36.2% from other staff and 17.0% from doctors described events that did not reach/affect the patient ($p < 0.001$); 33.9% of reports from doctors, 27.2% from nurses and 13.0% from other staff described events that caused harm ($p < 0.005$)	Reporting rates increased significantly, with significant differences in reporting behaviour by type of healthcare worker and ICU type

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Jain, 2006 USA	UBA Medical surgical ICU (28 beds) N = random review of at least 20 charts per month (± 20% sampling) Period = October 2000 – October 2002 (baseline), October 2002 – October 2003 (intervention)	**Aim** Reduction in AEs in ICUs by QI focusing on teamwork and culture change **Intervention** Combined intervention, including: 1. doctor-led multidisciplinary rounds 2. daily bed-flow meetings to access bed availability 3. implementation of evidence-based practices related to three quality initiatives 4. culture change with a forum on team decision-making The interventions were implemented one-by-one over a 12-month period **Control** NA	1. AEs per ICU day 2. Ventilator-associated pneumonia rate per 1,000 ventilation days 3. Bloodstream infection rate per 1,000 line days 4. Nosocomial urinary tract infection rate per 1,000 catheter days 5. LOS per episode 6. Mortality rate 7. Costs per ICU episode	Chi-square test 1. Strong downward trend (significance not provided) 2. Significantly lower infection rate (7.5 at baseline versus 3.2 at follow-up, $p = 0.040$) 3. Significantly lower infection rate (5.9 at baseline versus 3.1 at follow-up, $p = 0.031$) 4. No significant change 5. Downward trend (significance not provided by the authors) 6. No significant change 7. Decreased by 21% (from $3,406 to $2,973, significance not provided)	QI may have contributed to improvements
King, 2003 Canada	CBA Paediatric inpatient care N = 2 medical inpatient units (intervention) and 1 medical and 2 surgical units (control) Period = April 1993 – March 1996 (baseline 36 months), April 1996 – December 1996 (implementation 9 months), January 1997 – December 1999 (post-intervention 36 months)	**Aim** To assess the impact of a CPOE system on medication errors and ADEs in paediatric inpatients **Intervention** CPOE without clinical decision support, interfaced with the laboratory system, but not with the pharmacy computer **Control** Handwritten medication orders	1. Medication error rate (per 1,000 patient days) 2. Potential ADEs rate 3. ADEs rate	Poisson analysis of rate ratios 1. Significant reduction (RR = 1.54 [95% CI = 1.27–1.88], $p < 0.001$) 2. Significant increase (RR = 0.24 [95% CI = 0.09–0.68], $p < 0.001$) 3. No change (RR = 1.30 [95% CI = 0.47–3.52], $p = 0.60$)	The overall medication error rate and potential ADEs decreased, without an effect on ADEs

ADE = adverse drug event; AE = adverse event; ANCOVA = analysis of covariance; ANOVA = analysis of variance; C = control group; CDSS = clinical decision support system; CI = confidence interval; CPOE = computerised physician order entry; CMI = continuous medication infusion; CO = companion observers; ED = emergency department; I = intervention group; ICU = intensive care unit; IQR = inter quartile range; ITS = interrupted time series; LOS = length of stay; MDW = medication discharge sheet; MET = medical emergency team; N = number; NA = not applicable; NC = not clear; NSAID = non-steroidal anti-inflammatory drug; OBD = occupied bed day; OR = odds ratio; PDA = personal digital assistant; QI = quality improvement; RCT = randomised controlled trial; RR = relative risk; SD = standard deviation; UBA = uncontrolled before-after.

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Kozer, 2005 Canada	RCT Paediatric ED N = 376 order sheets (intervention [I] group) N = 411 order sheets (control [C] group) Period = July 2001	**Aim** To determine whether the use of a structured order sheet reduces the incidence of medication errors in paediatric ED **Intervention** Use of pre-printed, formatted prescription order sheets **Control** Use of blank prescription order sheets	1. Medication error rate 2. Medication error severity	Chi-square test and multivariable logistic regression 1. Significant reduction (9.8% in I-group versus 16.6% in C-group, OR = 0.55 [95% CI = 0.34–0.90], $p < 0.05$) 2. Significant reduction (3.7% in I-group versus 8.8% in C-group, OR = 0.39 [95% CI = 0.21–0.77], $p < 0.05$)	The use of pre-printed structured order forms significantly reduces medication error rates and severity of the errors among paediatric patients in the ED
Lane, 1999 USA	UBA Medical-surgical/critical care patients N = 101 (baseline) N = 98 (post-intervention) Period = 1988 (baseline), 1995 (post-intervention)	**Aim** To evaluate the effectiveness of a falls prevention programme in reducing patient fall rate **Intervention** Falls prevention programme, including: • identifying patients at risk of falling • establishing guidelines for interventions promoting patient safety for patients at risk **Control** NA	1. Fall rate (falls per 1,000 patient days) 2. Injury rate after fall (number of injuries per 100 falls)	Statistical methodology is unclear 1. No change in fall rate (2.27 [baseline] versus 3.89 [post-intervention], $p > 0.05$) 2. Decrease in injury rate (27.7% [baseline] versus 8.2% [post-intervention], *p*-value not provided)	No effect of falls prevention programme in inpatients at risk of falling

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Larsen, 2005 USA	UBA Paediatric inpatient care N = 12,109 infusion doses (pre-intervention) N = 12,377 infusion doses (post-intervention) Period = 2002 (12 months pre-intervention), 2003 (12 months post-intervention)	**Aim** To determine if combining standard drug concentrations with smart-pump technology reduces reported medication-infusion errors **Intervention** 1. Standard drug concentrations development 2. 'Smart' syringe pumps selection criteria 3. Human-engineered medication labels replacing pharmacy-generated labels **Control** NA	1. Reported CMI error rate (per 1,000 doses) 2. Adherence to intervention	2-sample test of proportion 1. Error rate decreased from 3.1 to 0.8 per 1,000 doses (absolute risk reduction = 2.3 [95% CI = 1.1-3.4], $p < 0.001$) 2. 87% of CMIs in neonatal ICUs and >99% in other areas of the hospital used standard drug concentrations after the implementation	The use of standard drug concentrations, smart syringe pumps and user-friendly labels reduces reported errors associated with CMIs. Standard drug concentrations can be chosen to allow most neonates to receive needed medications without concerns related to excess fluid administration
Leape, 1999 USA	CBA Intensive care Intervention (I) group: N = 75 (pre-intervention) N = 75 (post-intervention) Control (C) group: N = 50 (pre-intervention) N = 75 (post-intervention) Period = February 1993 – July 1993 (pre-intervention), October 1994 – July 1995 (post-intervention)	**Aim** To measure the effect of pharmacist participation on medical rounds in the ICU on the rate of preventable ADEs caused by ordering errors **Intervention** Senior pharmacist participates in doctors' rounds (each morning), is present in the unit for consultation and assistance to the nursing staff during the rest of the morning, and is available on call as necessary throughout the day **Control** Usual practice where the pharmacist is available in the unit for part of the day, but does not make rounds	1. Rate of ADEs (per 1,000 patient days) 2. Rate of preventable ADEs in the ordering stage (per 1,000 patient days) 3. Acceptance of intervention recommended by the pharmacist	Unpaired t-test 1. Significant reduction (11.6 [I-group, after] versus 46.6 [C-group, after], $p < 0.001$) 2. Significant reduction (3.5 [I-group, after] versus 12.4 [C-group, after], $p < 0.001$) 3. Majority (366 of 398) of the pharmacist interventions were related to drug ordering, of which 362 (99%) were accepted by doctors	Presence of pharmacist was associated with a substantially lower ADE rate and high acceptance rate

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Lehmann, 2007 USA	ITS (but analysed as UBA) Medical university hospital N = 1 hospital Period = October 1999 – April 2007 (intervention started in October 2000)	**Aim** Development of a non-punitive reporting system and CPOE to decrease the potential for drug harm **Intervention** • Strategy sessions with senior management about non-punitive reporting (Autumn 1999) • Revised medication event reporting policy (October 2000) • Implementation of CPOE throughout the organisation (December 2005) **Control** NA	1. The number of error reports received per month 2. The type of reported errors	ANOVA 1. Significant increase (19 reports before intervention started versus 102 reports after start, $p < 0.001$) 2. The type of reported errors changed. In pre-intervention phase, majority of reported incidents occurred after medication administration, leading to actual patient harm or delayed care. In post-intervention phase, majority of reported errors occurred during medication-use processes before actual drug administration	Significant increase in the number of reports and substantial change in type of reported errors

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Manning, 2007 USA	RCT Hospital discharge patients N = 138 Period = May 2004 – February 2005	**Aim** To determine whether the 3D medication discharge form, relative to MDW, reduces self-reported medication errors and improves patient satisfaction and understanding **Intervention** A new education tool (3D). Features include: 1. Space in which a tablet or pill is affixed and displayed 2. Trade name 3. Unit strength 4. Number (and/or fraction) of units to be taken 5. Purpose (indication) 6. Comment/caution 7. Larger font 8. Card stock durability 9. A reconciliation feature **Control** Standard MDW	1. Number of self-reported medication errors 2. Patient satisfaction with discharge form 3. Patient understanding of prescribed medication instructions	T-test and Mann-Whitney U-test 1. No effect (I-group versus C-group = 0.78 [SD = 0.42] versus 0.79 [SD = 0.41], $p = 0.876$) 2. No effect (I = group versus C-group = 4.24 [SD = 0.70] versus 4.26 [SD = 0.88], $p = 0.5204$) 3. Better understanding of medication instructions (I-group versus C-group = 1.96 [SD = 0.76] versus 1.66 [SD = 0.69], $p = 0.0282$)	Both tools are associated with high levels of patient satisfaction and low rates of self-reported medication error. 3D appears to promote patient understanding

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Paoletti, 2007 USA	CBA Inpatient nursing units Intervention 1 (cardiac telemetry unit): N = 308 doses (pre-intervention) N = 318 doses (post-intervention) Intervention 2 (medical-surgical unit): N = 320 doses (pre-intervention) N = 310 doses (post-intervention) Control (cardiac telemetry unit): N = 306 doses (pre-intervention) N = 306 doses (post-intervention) Period = 2003–2005 (implementation period = August 2003 – July 2004)	**Aim** The implementation of a multidisciplinary approach to systematically decrease medication errors **Intervention** The use of observation methodology, electronic medication-administration records and bar-coded medication administration **Control** Usual care	1. Medication error rate 2. Accuracy rate of medication administration	Statistical methodology is unclear 1. Medication error rates decreased (-35.9% change from baseline, $p = 0.035$) in intervention group 2, was unchanged in intervention group 1 (-24.1% change from baseline, $p = 0.065$) and was unchanged in control group (5.1% change from baseline, $p = 0.762$). 2. Improved accuracy rate (86.5% before versus 97% after, *p*-value not provided)	Multidisciplinary approach reduced error rates, but did not reach statistical significance

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Plews-Ogan, 2004 USA	UBA Ambulatory internal medicine practice N = NC Period = 1 year before and 1 year after the implementation	**Aim** To determine the feasibility and effectiveness of clinician-based near miss/AE voluntary reporting, coupled with system analysis and redesign as a model for continuous quality improvement in the ambulatory setting **Intervention** • Reporting system for near miss or AEs • Root cause analysis by committee • Improvements of practice, education, systems and equipment **Control** NA	1. Clinical-based near misses and AEs 2. Type of reporter 3. Type of error 4. Acceptance of recommendations	Statistical methodology is unclear 1. Number of reports increased from 5 to 100 reports (including 83 near misses and 17 AEs) 2. 44% of the events were reported by doctors, 22% by residents, 31% by nurses and 3% by managers 3. Errors involved medication (47%), lab or X-ray (22%), office administration (21%) and communication processes (10%) 4. 75% of recommendations were implemented during the study period	The intervention was effective in increasing error reporting and in promoting system change to improve care and prevent errors
Poon, 2006 USA	UBA Tertiary care (735-bed) academic medical centre N = 155,164 (pre-intervention) and 253,984 (post-intervention) dispensed medication doses Period = 2003–2004 (20 months)	**Aim** Reduction in dispensing errors and potential ADEs by bar-code technology **Intervention** A bar-code-assisted storage and retrieval system implemented in three configurations (in two, all doses were scanned once during the dispensing process and in one, a dose was scanned if several doses of the same medication were being dispensed) **Control** NA	**Primary outcomes** 1. Target dispensing error rate 2. Target potential ADEs rate **Secondary outcome** 3. Nature of target errors	Fisher exact test Overall effect, across the three configurations: 1. 85% reduction (error rate pre = 0.37% versus post = 0.06%) 2. 74% reduction (ADE rate pre = 0.17% versus post = 0.04%) 3. Decrease in wrong medication error rate (56% reduction)	Substantial decrease in dispensing errors and potential ADEs

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Ramnarayan, 2006a United Kingdom	UBA Paediatric emergency room N = 751 case episodes, handled by 76 doctors (ie consultant, registrar, senior house officer or student) Period = February – August 2002	**Aim** To assess the impact of a novel diagnostic reminder system (ISABEL) on the quality of clinical decisions made by various grades of clinicians during acute assessment **Intervention** Web-based diagnostic reminder system that suggests important diagnoses during clinical assessment, ie a CDSS **Control** NA	**Primary outcome** 1. Number of diagnostic errors of omission **Secondary outcomes** 2. Quality of diagnostic test ordering and treatment plan 3. Number of irrelevant diagnoses contained within the diagnostic workup 4. Proportion of case episodes in which at least one additional 'important' diagnosis, test or treatment decision was considered by the doctor after CDSS consultation 5. Additional time taken for CDSS consultation	Two-way mixed-model ANOVA 1. Significant reduction (5.5 [SD = 1.6] errors before versus 5.0 [SD = 1.5] errors after, $p < 0.001$) 2. Mean diagnostic quality score increased significantly (increase = 0.044, 95% CI = 0.032–0.054, $p < 0.001$). Also quality of test-ordering plans and treatment plan improved significantly 3. Number of irrelevant diagnoses increased from 0.7 to 1.4 (increase = 0.7, 95% CI = 0.5–0.75), but number of irrelevant or deleterious tests and treatments remained unchanged 4. In 12.5% of cases at least one diagnostic decision was added; in 9.3% of cases one test decision was added; in 6.5% one treatment step was added 5. Median additional time taken for CDDS consultation was 1 min (IQR = 30 sec–2 min 4 sec)	The provision of patient- and context-specific reminders reduced diagnostic omissions across all subject grades for a range of cases, and increased diagnostic and treatment quality, without a large increase in workload

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Ramnarayan, 2006b United Kingdom	UBA Acute ambulatory paediatric care N = 177 patients, across 4 care units Period = December 2002 – April 2003	**Aim** To examine the impact of a web-based diagnostic reminder system on clinicians' decisions in an acute paediatric setting during assessments characterised by diagnostic uncertainty **Intervention** CDSS for diagnostics **Control** NA	**Primary outcome** 1. Proportion of 'unsafe' diagnostic workups following CDSS consultation **Secondary outcomes** 2. Quality scores for diagnostic workup and clinical action plans 3. Time taken by subjects to complete CDSS usage 4. Number of diagnoses included in the diagnostic assessment	McNemar test for paired proportions 1. Significant decrease (45.2% unsafe workups before and 32.7% unsafe workups after CDSS consultation, $p < 0.001$) 2. Diagnostic quality scores increased by 6.86 points (95% CI = 4.0–9.7) after CDSS consultation. Clinical plan scores improvement was smaller in magnitude (1.5 points increase, SD = 6.7) 3. Median time spent on the CDSS = 1 min 38 sec (IQR = 50 sec–3 min 21 sec) 4. Number of diagnoses increased from 2.2 to 3.2, whereas number of tests ordered rose from 2.7 to 2.9	The quality of diagnostics improved significantly and diagnostic omission errors were reduced
Robinson, 2006 USA	UBA Paediatric oncology N = NC Period = 2001–2004 (intervention in 2002)	**Aim** To assess the impact of identifying the elements of risk and implementing appropriate strategies **Intervention** Use of failure mode and effects analysis (FMEA) to identify risk and for implementing strategies. Strategies could be implemented in three areas: 1. Prescribing process 2. Dispensing process 3. Administration process **Control** NA	1. Prescribing error rate 2. Dispensing error rate 3. Administration error rate 4. Usage rate of reprinted standard order sets	Statistical methodology is unclear 1. The potential prescribing error rate decreased from 23% to 14% 2. Actual dispensing errors decreased from 3 to 1 3. Actual administration errors decreased from 4 to 3 4. Use of reprinted standard order sets increased from 22% to 45% in 2003 and 76% in 2005	The CPOE system, which was designed based on an FMEA, improves the prescribing stage of the chemotherapy process

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Schneider, 2006 USA	RCT 3 community hospitals N = 30 nurses (15 in intervention and 15 in control group) Period = 6 weeks (1 week baseline, 2 weeks after completion of the intervention/post-intervention assessment)	**Aim** To examine the impact of an interactive CD-ROM programme on the rate of medication administration errors made by nurses **Intervention** Educational CD-ROM: *Basic Medication Administration* **Control** Usual care; no intervention	1. Error rate due to deviation from safe administration practices 2. Preparation and administration error rate 3. Error rate due to deviations from prescribed therapy	ANOVA and logistic regression analysis 1. Significant decrease (OR = 0.38 [95% CI = 0.19–0.74], $p = 0.004$) 2. Error rates increased (OR = 1.92 [95% CI = 0.81–4.58], $p = 0.14$) 3. No difference in error rate between groups (OR = 1.03 [95% CI = 0.23–4.62], $p = 0.97$)	An interactive CD-ROM enabled nurses to apply the information learned to identify errors in medication administration and to improve adherence to safe medication administration practices. Other categories of medication errors were not affected
Schwendimann, 2006 Switzerland	ITS Internal medicine, geriatric and surgery inpatient departments N = 34,972 patients Period = 1999–2003 (60 months) with intervention starting in 2000	**Aim** To examine inpatient fall rates and consequent injuries before and after the implementation of the interdisciplinary falls prevention programme (IFP) **Intervention** IFP: • Screening of all patients at admission for risk of falls • Examination of patients considered at risk of falling • Interventions for all patients to provide safety in the hospital • Intervention in patients considered at risk of falling • Reassessment of those patients who fell **Control** NA	1. Inpatient fall rate (per 1,000 patient days) 2. Consequent injury rate (per year)	General linear model, ANOVA, Chi-square test 1. Fall rates fluctuated from 9.1 falls per 1,000 patient days in the first half of 1999 to 8.6 falls in the second half of 2003 ($p = 0.086$) 2. Annual proportion of minor injuries decreased from 32.6% in 1999 to 28.1% in 2003 ($p = 0.015$) and annual proportion of major injuries increased from 2.5% in 1999 to 3.9% in 2003 ($p = 0.014$)	Fall rates did not change after the implementation of the IFP, whereas minor injury rate decreased and major injury rate increased

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Shamliyan, 2007 Worldwide	Review Setting: Inpatient (N=10), outpatient (N = 1), emergency department (N = 1) Number of included studies: N = 12 (1 RCT, 9 UBA and 2 unclear) Search period: 1990–2005 English Countries: no restrictions	**Aim** To test the hypothesis that medication errors and adverse clinical events decrease after computerisation compared with handwritten physician orders in paediatric and adult patients, independent of patient and provider characteristics **Intervention** CPOE system **Control** Handwritten physician orders	1. Medication errors 2. Wrong drug due to prescribing errors 3. Wrong dose due to prescribing errors 4. ADEs	Meta-analysis with fixed and random effects models 1. Significant reduction (pooled OR = 0.14 [95% CI = 0.05–0.43]) 2. No change (pooled OR = 0.80 [95% CI = 0.27–2.36]) 3. Significant reduction (pooled OR = 0.44 [95% CI = 0.23–0.85]) 4. Significant reduction (pooled OR = 0.52 [95% CI = 0.30–0.91])	Implementation of CPOE was associated with a significant reduction in medication errors. Results should be interpreted with caution: possible overestimation due to using non-randomised uncontrolled interventions. Use of CPOE not associated with a substantial improvement in patient safety. Studies do not allow broad generalisability
Silver, 2000 USA	UBA Acute care hospitals Baseline: 12 hospitals, 341 completed surveys Follow-up: 9 hospitals, 219 completed surveys Period = Autumn 1997 (baseline), Autumn 1998 (follow-up)	**Aim** Improve the hospital's medication system, in order to reduce medication error rates **Intervention** Breakthrough Series model: • teams (QI, pharmacy, medical staff) • improving information access • standardising and simplifying medication procedures • restricting physical access to potentially lethal drugs • educating clinical staff about medications • QI facilitators • enhanced error reporting **Control** NA	A. Respondent observing medication error: 1. All errors 2. Mediation ordering 3. Transcription and verification 4. Dispensing and delivery 5. Medication administration B. Respondent indicating errors were discovered and prevented C. Respondent indicating most recent observed error was reported: 1. All errors 2. Error reaching the patient	Logistic regression, with post-hoc analysis A1: sign – decrease from 20.8% to 15.2% (OR = 0.62, p = 0.006) A2: non-sign – decrease from 23.0% to 16.4% (OR = 0.63, p = 0.068) A3: sign – decrease from 24.4% to 15.7% (OR = 0.47, p = 0.003) A4: non-sign – decrease from 20.2% to 16.2% (OR = 0.68, p = 0.127) A5: non-sign – decrease from 15.5% to 12.5% (OR = 0.73, p = 0.278) B: sign – increase from 51.2% to 57.6% (OR = 1.32, p = 0.032) C1: non-sign – increase from 29.0% to 32.3% (OR = 1.16, p = 0.337) C2: sign – increase from 43.9% to 54.5% (OR = 1.67, p = 0.013)	Survey results suggest that the changes implemented in the organisations may have reduced medication errors and improved capacity for error detection and prevention

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Sim, 2002 USA	UBA Community hospital with a wide variety of acute care, critical care, emergency care and surgical and diagnostic services N = NC Period = May 2001 – January 2002 (9 months)	**Aim** To address medication-related patient safety initiatives **Intervention** A multidisciplinary team was formed to address medication-related patient safety initiatives, focusing on: • leadership • strategic planning • analyses of AEs • fostering effective teamwork • improving care-delivery processes • engaging patients in care delivery **Control** NA	Number of reports of medication variances	Statistical methodology not reported The number of reports doubled	Within a nine-month period the number of variance reports doubled. A subcommittee was formed with the specific responsibility of reviewing the reports on a weekly basis
Simon, 2005 USA, United Kingdom, Australia, Hong Kong/China, Canada	Review Number of included studies: N = 11 (4 controlled observational studies and 7 uncontrolled observational studies) Search period = 1994–2004 Language: English	**Aim** To assess the effectiveness of hospital incident reporting systems in improving hospital and clinic performance in terms of patient safety, clinical outcome, costs and operations **Intervention** Incident reporting systems **Control** No incident reporting system; usual care	1. Medical errors 2. AEs 3. Accuracy of incident reporting systems	Narrative analysis 1.+2. Majority of the studies (7 out of 11) reported no reduction in medical errors and AEs after implementation of incident reporting systems 3. Incident reporting and chart-review detection are less accurate than direct observation	Incident reporting can provide valuable qualitative and quantitative data relevant to incidents and AEs, which in turn can potentially guide organisational and clinical interventions to decrease risks. However, the benefits of incident reporting are not well established

First author, year, country	Study design	Intervention	Outcome measures	Analysis and results	Overall conclusion
Simpson, 2004 United Kingdom	ITS Neonatal ICU N = NC Period = January 2002 – January 2003	**Aim** To describe the medication errors occurring within a neonatal ICU, and assess the impact of a combined risk management/clinical pharmacist-led education programme on these errors **Intervention** Combined risk management/ clinical pharmacist-led education programme **Control** NA	1. Medication error rate (per 1,000 activity days) 2. Medication error type 3. Medication error cause	Student's t-test 1. Monthly medication error rates fell from a mean (SD) of 24.1 (1.7) per 1,000 neonatal activity days to 5.1 (3.6) per 1,000 days ($p < 0.001$) in the following three months. The subsequent change of junior medical staff was associated with a significant increase in medication errors to 12.2 (3.6) per 1,000 neonatal activity days ($p = 0.037$) 2. A total of 105 errors were identified: 4 serious, 45 potentially serious and 56 minor. The 4 serious errors included two tenfold dose miscalculations 3. Most (71%) of the errors were due to poor prescribing	The intervention, within the context of a risk management programme, is effective in reducing medication error rates
Snijders, 2007 Worldwide	Review Neonatal ICU Number of included studies: N = 10 (8 prospective studies and 2 retrospective studies) Search period: January 1980 – January 2006 Languages: English, German, Dutch, French	**Aim** To examine the characteristics of incident reporting systems in neonatal ICUs in relation to type, aetiology, outcome and preventability of incidents **Intervention** Various modes of incident reporting systems **Control** NC	Characteristics of incident reporting systems	Narrative analysis Overall, medication incidents were most frequently reported. Total error rate was much higher in studies using voluntary reporting than in a study using mandatory reporting. Multi-institutional reporting identified rare but important errors. A substantial number of incidents were potentially harmful. When a system approach was used, many contributing factors were identified. Information about the impact of system changes on patient safety was scarce	Multi-institutional, voluntary, non-punitive, system-based incident reporting is likely to generate valuable information on type, aetiology, outcome and preventability of incidents in the neonatal ICU

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Stump, 2000 USA	ITS Hospital care N = 1 hospital Period = First quarter 1997 – second quarter of 2000 (intervention started in 1997 and completed in June 1999)	**Aim** To redesign the medication error reporting process **Intervention** A series of interventions was implemented to optimise medical error reporting. Compared with the historical reporting process, the new process included: • non-punitive reporting • central pharmacy department receiving report within 48 hours rather than 2–3 months • a unified database instead of a fragmented process • near misses captured in every stage of medication-use process and not only in dispensing process • structured check-box reports instead of handwritten free text • staff at operational level involved in reviewing data **Control** NA	Number of reported events	Statistical methodology is unclear Increase in number of reported events from approximately 45 to 276 per quarter within one year of the start of the implementation	Alternative medical error reporting process increases the number of reported incidents

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Tideiksaar, 1993 USA	RCT Geriatric hospital unit N = 70 patients (35 intervention + 35 control) Period = 9 months	**Aim** To examine the clinical efficacy of a bed alarm system in reducing falls from bed on a geriatric evaluation and treatment unit **Intervention** Bed alarm system during hospital stay **Control** Usual care, without bed alarm	1. Number of patients sustaining fall from bed 2. Number of patients sustaining other falls	1. No statistical difference in falls from bed between the experimental (N = 1) and control (N = 4) group (p = 1.00) 2. Clinical trend towards reduced falls in the experimental group	The data suggest that bed alarm systems are beneficial in guarding against bed falls and are an acceptable method of preventing falls
Voeffray, 2006 Switzerland	ITS Chemotherapy unit of the pharmacy service within a hospital N = 940 prescriptions (pre-intervention) N = 978 prescriptions (post-intervention) Period = 36 months (15 months pre-intervention, 21 months post-intervention)	**Aim** Reducing the number of prescription errors by implementing a CPOE system **Intervention** CPOE, such that a prescription by a junior doctor is first validated by a senior doctor online before being processed. After validation the order is automatically transferred to nursing staff and pharmacy services. Any correction on initial prescription is transmitted to all professionals involved **Control** NA	Prescription error rate (per 100 prescription protocols)	Binomial test 1. Significant reduced error rate (15% before versus 5% after) 2. Average error rate with handwritten prescriptions greater than with computerised prescriptions (13.1% versus 0.6%) 3. Number of errors reduced dramatically when 50% of protocols were prescribed through CPOE	Errors almost disappeared after implementation of CPOE

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Walsh, 2008 USA	ITS Paediatric service in a general hospital N = 627 admissions Period = September 2001 – May 2002 (pre-intervention), April 2002 – June 2002 (implementation) September 2002 – May 2003 (post-intervention)	**Aim** To evaluate the effect of CPOE on the rate of inpatient paediatric medication errors **Intervention** Use of a commercial CPOE system. After order entry, the system uses a weight-based dosage calculator to automatically check medication dosage, generating wrong dosage alerts. Other features include drug–drug interaction alerts and allergy alerts. All CPOE users attended a two-hour training session Pre-CPOE situation: nursing medication records were paper based, and only the hospital pharmacy was automated with a system to check drug–drug interaction and allergies **Control** NA	1. Overall medication error rate 2. Serious medication error rate 3. Non-intercepted serious interactions 4. Preventable ADEs 5. Rate of dosing errors 6. Rate of administration errors	Time series analysis (Proc Autoreg) and univariate analysis 1. No change (44.7 errors/1,000 patient days [before] versus 50.9 errors [after], IRR = 1.14 [95% CI = 0.80–1.51]) 2. No change (31.7 errors/1,000 patient days [before] versus 33.0 errors [after], IRR = 1.04 [95% CI = 0.70–1.54]) 3. No change (23.1 errors/1,000 patient days [before] versus 20.6 errors [after], IRR = 0.89 [95% CI = 0.69–1.78]). Time series analysis showed a statistically significant drop (7%, $p = 0.0495$). 4. No change (7.9 errors/1,000 patient days [before] versus 6.5 errors [after], IRR = 0.83 [95% CI = 0.37–1.874]) 5. No change (8 errors/1,000 patient days [before] versus 11 errors/1,000 patient days [after]; p = NC) 6. No change (6 errors/1,000 patient days [before] versus 4 errors/1,000 patient days [after]; p = NC)	CPOE in paediatric inpatient care is not effective in reducing medication errors

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Williams, 2007 Australia	UBA Medical wards of 1 hospital N = 1,357 patient admissions Period = December 2002 – May 2004 (December 2002 – May 2003 pre-intervention, December 2003 – May 2004 post-intervention)	**Aim** To evaluate a systematic, co-ordinated approach to limit the severity of falls and minimise their number in an acute care hospital **Intervention** Patients were classified based on three levels of risk: low, medium, high. Appropriate interventions (environment, mobility, elimination) were developed for each risk level in an individual fall care plan **Control** NA	1. Number of falls per 1,000 OBD 2. Severity of falls	The Mann-Whitney U-test and Student's t-test 1. Significant reduction in falls (9.5/1,000 OBD [before] versus 8.0/1,000 OBD [after] [95% CI of the difference = -0.14–-0.16], $p < 0.001$) 2. No change in severity of falls	Approach was effective in reducing fall incidence

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Wolff, 2002 Australia	UBA ED N = 2,575 (pre-intervention) N = 2,371, 2,461, 2,392, 2,664, 2,720, 2,373 and 2,494 (post-intervention) Period = October – December 1997 (pre-intervention), January 1998 – September 1999 (post-intervention)	**Aim** To determine if retrospective medical record screening and clinical review followed by appropriate action can effectively detect and reduce AEs in an ED **Intervention** Retrospective screening of patient files in two phases: by computer with 5 general patient outcome criteria; 'positive' files by hand by nurse. ED director screened AEs. Then, preventive action was taken: • changes in hospital policies • focused auditing • staff discussion • guideline implementation • weekly/quarterly reports • promotion of clinical-incident reporting **Control** NA	Number of ED attendances associated with an AE	Chi square test Significant decrease from 84 (3.26%) in first quarter to 12 (0.48%) in last quarter (RR reduction = 85.3% [95% CI = 62.7%–100%], $p < 0.0001$)	AEs in EDs can be efficiently detected and their rate reduced using retrospective medical record screening together with clinical review, analysis and action to prevent recurrences

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