Patient safety: Mapping the Literature

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Executive summary

Objectives

To draw together a diverse collection of research and provide a map of the patient safety research literature. In particular the following questions were addressed:

1. What have been the goals of patient safety research?
2. What methods have been used in patient safety research?
3. What types of studies have shown what kinds of results?

Methods

Design
A mapping exercise of the research literature on patient safety was undertaken, as far as possible this was in accordance with CRD’s Guidelines for Undertaking Systematic Reviews (http://www.york.ac.uk/inst/crd/report4.htm).

All types of research were considered, both quantitative and qualitative to reflect the approaches used in patient safety research. As this was a small, 8-week scoping exercise, publications that were potentially of interest but were not empirical research were not included, due to time constraints.

Searching
Fifteen databases were searched for studies relevant to patient safety, including relevant literature from non-health fields, such as the aviation and nuclear industries. A broad approach to searching was undertaken to ensure that potentially relevant studies were not missed.
Review strategy

The titles and (where available) abstracts, were scanned for relevance by one reviewer and those that appeared potentially relevant were retrieved. These were also assessed for relevance by one reviewer. A classification system was developed and used to classify all relevant studies:

- Systematic reviews - meeting the criteria for inclusion on the Database of Abstracts of Reviews of Effectiveness (DARE)

- Direct interventions - prospective studies of a direct intervention, which was not a reporting system, to reduce the occurrence of or mitigate the consequences of adverse events (including automated instruments for detecting error)

- Reporting systems - prospective studies of design and/or implementation of reporting systems

- Information analysis - retrospective analysis of adverse event information, e.g. from reporting systems which were not prospective studies

- General risk management - any potentially relevant paper which did not fit the above classifications

- Workload and stress - studies on the effects of workload/working conditions or stress on the occurrence of adverse events

- Organisational culture - studies of the barriers to adverse event reporting, attitudes of professional groups to risk management, acceptability to professional groups of interventions to reduce adverse events, practical implementation issues relating to interventions to reduce adverse events

- Government or professional body policy documents
Where possible, data were extracted from papers in the ‘direct interventions’ and ‘reporting systems’ categories. Data were extracted on the aims, study design, intervention, setting, participants, results, and whether the research might be useful to the implementation of the intervention.

**Results**

A total of 4,444 papers were identified from the searches. 3,525 papers were excluded on the following criteria:

- Not relevant to the field of patient safety
- Not reporting original research
- Concerned with methodology

Of the 728 full articles that were received by the time of writing this report, a further 343 were excluded according to the above criteria. The remaining 385 articles were categorised as follows:

- Government documents – 3
- Non-government policy documents – 11
- Systematic reviews - 6
- Direct interventions – 50
- Reporting systems – 46
- Information analysis – 88
- General risk management – 109
- Organisational culture – 32
- Workload and stress – 39
1. What have been the goals of patient safety research?

Overall, the goals of patient safety research have been diverse. Some studies have pursued very tight objectives, for example evaluating the effectiveness of a single intervention in reducing errors, whilst others have had the more general aim of improving patient safety. Setting boundaries for research relevant to the aim of improving safety is difficult, as many studies whilst not focusing specifically on errors or accidents cover areas which are important and relevant to the safety agenda.

2. What methods have been used in patient safety research?

Research in the area of patient safety appears to be dominated by studies which have used an observational or survey type design, although the type of study design used was often poorly described. Overall, the quality of original research appeared to be variable (it must be noted that formal quality assessment was not carried out) and often the studies lacked focus. Most studies were conducted on a relatively small scale in single hospitals or local groups of tertiary care units, limiting the generalisability of their findings.

3. What types of studies have shown what kinds of results?

A significant proportion of direct intervention studies have evaluated computerised or automated systems to control medication errors (prescribing, ordering, dispensing, administration). Though most of these evaluations have reported positive results, and evidence from systematic reviews suggests that these interventions can enhance clinical performance, the findings are limited. There is little evidence about the comparative benefits of different systems, and there is little research relating to the implementation of these systems and their acceptability to health professionals.

There was a small body of dissimilar studies evaluating local education and training programmes, which in the main reported positive but ungeneralisable findings.
The current research evaluating the effectiveness of reporting systems is limited and in the main of poor quality. There have been very few studies that have evaluated both the effectiveness of reporting systems for information gathering purposes and the utility of the information obtained for developing and implementing error-reducing strategies. The Australian Incident Monitoring Study (AIMS) represents ‘work in progress’ on an integrated, national reporting system and as such may provide one model for future developments in this area.

Recommendations for future research

- Development of a reporting system to be evaluated in terms of reporting rates, patient outcome and ease of use may be of value.
- Further identification of the perceived barriers to adverse event reporting, using validated measures could be used to inform the development of a reporting system specifically targeting identified user concerns.
- Interventions to compare anonymous and named reporting of error could be tested.
- An investigation into the broader use of reporting systems in enhancing the safety of care provided may be of value. Mechanisms for feedback from reporting systems could be developed.
- Initiatives could be developed based on the principles of openness and accountability where the reporting of mistakes becomes routine. Leadership is likely to play a key role in promoting such organisational change.
- Computerised or automated systems for detecting and preventing medication error may be a fruitful area for larger scale research in the UK. In particular, there is a lack of research investigating issues relating to the implementation and acceptability of such systems to health professionals.
- A programme of research to investigate the effectiveness of continuing professional education programmes in reducing adverse events may be of value.
• A systematic review of studies (both empirical and theoretical) of accident causation, (both within and outside of health care), including both individual and organisational factors may provide useful insights into how accidents may be prevented.
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1. Background

Patient safety, medical error and adverse event reporting is becoming a major issue in health care systems in the UK and across the world, particularly the United States of America and Australia. In the USA the publication in 1999 of the Institute of Medicine's (IOM's) report 'To Err is Human: Building a Safer Health System'\(^1\) highlighted the risks of medical care and the magnitude of medical error related deaths (44,000 to 98,000 deaths and approximately 1 million excess injuries per year). These estimates make medical errors the eighth leading cause of death in the USA. Publication of the report prompted a number of legislative and regulatory initiatives concerned with documenting errors and finding solutions to the problem, along with a federally funded patient safety and medical errors research programme. In Australia, publication of the Quality in Australian Health Care Study in 1995\(^2\) prompted Health Ministers to establish a Taskforce on Quality and in 1996 the National Expert Advisory Group on Safety and Quality in Australian Health Care was established.

A similar pattern of events occurred in the UK, with the publication of ‘An Organisation with a Memory’\(^3\) along with an agenda for patient safety research.\(^4\) ‘An Organisation with a Memory’\(^3\) highlighted the extent of medical accidents in the NHS. Every year around 400 people die or are seriously injured in adverse events arising from medical devices, and nearly 10,000 people are reported to have experienced serious adverse reactions to drugs.\(^3\) Yet, these figures are thought to be an underestimation of the true scale of the problem, due to the patchy and incomplete information systems within the NHS. Some estimates have put the occurrence of adverse events in NHS hospitals alone as high as 850,000 per year, with a cost of £2 billion a year in additional hospital stays. Clinical negligence claims cost the NHS around £400 million per year with a potential liability of around £2.4 billion. There is also a cost to the nation in terms of lost earning capacity. Costs to both patients and staff in terms of mental and physical distress are unquantifiable.
Many of the accidents that take place are reported to be replicas of earlier ones and it appears that the mechanisms for learning from these experiences are absent or could be greatly enhanced. Building a Safer NHS for Patients sets out the Government's plans for promoting safety and places patient safety in the context of the quality programme. In particular the report has identified risk management strategies, and system-based approaches designed to tackle organisational factors that may facilitate human error, as crucial to improving the quality of service delivery in the NHS.

In addition to recommendations about changes in practice there is also an agenda for patient safety research. The key themes identified in the research agenda include:

- establishing the size and nature of the problem
- detecting problems
- understanding the factors which cause harm
- developing interventions to reduce errors
- assessing the effects of implementing approaches to reduce error
- implementing mechanisms to ensure sustained change in both individuals and organisations

However, before new research is commissioned it is important to have an understanding of the current evidence base around patient safety. In addition research from other areas of high-risk activity where risk management strategies are well established, such as aviation and the military, may have a potential application to the NHS.
1.1 Objectives

To draw together a diverse collection of research and provide a map of the patient safety research literature. Established risk management systems from other high-risk spheres, e.g. aviation and the oil and nuclear industries, will also be considered for their potential application to the NHS.

In particular the following questions were addressed:
1. What have been the goals of patient safety research?
2. What methodologies have been used in patient safety research?
3. What types of studies have shown what kinds of results?
2. Methods

2.1 Design
A mapping exercise of the research literature on patient safety has been undertaken, as far as possible this was in accordance with CRD’s Guidelines for Undertaking Systematic Reviews (http://www.york.ac.uk/inst/crd/report4.htm).

2.2 Review boundaries
Relevant studies are those in which patient safety falls somewhere on the continuum from what have been called errors and deviations, through dangerous situations and near misses to accidents. Research studies that have investigated the roots of individual or system failure, detection of error and direct interventions designed to reduce accidents have been included. Hospital care has been the main focus (as this is where the majority of research has been conducted) although other health care settings have been considered. Efforts to improve safety require an understanding of the organisational culture and working conditions that influence safe conduct, therefore research studies addressing this issue have also been included. All types of research have been considered, both quantitative and qualitative to reflect the approaches used in patient safety research.

Publications that are potentially of interest but which fall outside of being empirical research have not been included, due to constraints of time. In particular there are a number of key texts, for example: Clinical Risk management: Enhancing Patient Safety, edited by Vincent which presents useful material, ranging from the principles of risk management through to the implementation of risk management strategies, which haven't been included as they present little if any direct research.

The searches have dated back to 1990, as this is when a body of research documenting the problem of medical errors began to emerge. Key references prior to this date have been sought from the National Patient Safety Foundation Bibliography (1939 - 2000).
Established risk management or reporting systems from other high-risk spheres, e.g. aviation and the oil and nuclear industries, have also been considered for their potential application to the NHS.

It is recognised that patient safety is related to quality of care, in that safety can be viewed as a subset of quality. However, activities to manage quality such as clinical audit, quality assurance, continuous quality improvement and efforts to introduce evidence based practice such as clinical guidelines were outside the remit of this scoping exercise, unless they have focused specifically on patient safety issues.

2.3 Searching

One of the problems in attempting to draw together such a diverse collection of literature is the lack of a standard terminology to describe the field of study. In recognition of this issue a broad approach to searching was undertaken to ensure that potentially relevant studies were not missed. A wide variety of terms used in safety research and identified via a published review of the literature were used (e.g. mishap, error, accident, misconduct, failure, mistake, complication, adverse event, adverse outcome, etc.).

The following health and medical databases were searched:

- MEDLINE
- Cinahl
- EMBASE
- Health Management Information Consortium (King's Fund, DH, HELMIS)
- Healthstar

The MEDLINE strategy follows as an example of the search approach used. Full strategies for all databases are given in Appendix 1. No language or geographical restrictions were applied.

1. "Accident-Prevention"
2. "Safety"/ all subheadings
3. "Accident-Proneness"
4. "Medical-Errors"/ all subheadings
5. "Medication-Errors"/ all subheadings
6. patient safety in ti ab
7. medical error* in ti ab
8. medication error* in ti ab
9. human error* in ti ab
10. detect* near ((error* or incident* or accident*) in ti ab)
11. reporting near ((error* or incident* or accident* or system*) in ti ab)
12. information system* in ti ab
13. prescribing system* in ti ab
14. "Organizational-Culture"
15. "Fatigue"/ all subheadings
16. explode "Stress-Psychological"/ all subheadings
17. explode "Information-Systems"/ all subheadings
18. "Risk-Management"/ all subheadings
19. "Safety-Management"/ all subheadings
20. Risk Management in ti ab
21. Safety Management in ti ab
22. (fatigue or workload* or tired*) near ((error* or harm or incident* or accident* or patient safety or job performance or work performance) in ti ab)
23. incident* report* in ti ab
24. #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23
25. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9
26. #25 and #24

As the remit of the review considered safety issues and systems in dangerous industries such as nuclear power, other databases were searched:

- Aerospace Database
- Nuclear Science Abstracts
- Chemical Safety Newsbase
- Enviroline
- Energy Scitech
- National Technical Information Service (NTIS)
- Occupational Safety and Health
- Conference Papers Index
- Dissertation Abstracts
- SciSearch
These databases were searched simultaneously using the OneSearch facility on the Dialog database host service. These databases also include services that capture grey literature such as conference proceedings, reports and dissertations.

The following strategy was used to search the non-health databases:

s risk()management()system? ?
s risk()reporting()system? ?
s safety()management()system? ?
s accident?(2n)reporting
s serious()incident()reporting
s serious()incident()monitoring
s incident?(2n)report?
s incident(2n)monitoring
s accident(2n)monitoring
s promoting(w)safety
s safety()promotion
s preventing(w)serious(w)(error? ? or accident? ? or incident? ? or mishap? ? or misconduct or failure? ? or mistake? ?)
s avoiding(w)serious(w)(error? ? or accident? ? or incident? ? or mishap? ? or misconduct or failure? ? or mistake? ?)
s error()reduction
In addition grey literature has also been sought by searching the web-sites of relevant organisations both nationally and internationally, for example the Agency for Healthcare Research and Quality (USA) and the Medicare Advisory Committee (Australia). In particular, patient safety organisations such as The National Patient Safety Foundation (NPSF) in the USA and The Australian Patient Safety Foundation (APSF) were targeted. The NPSF is funding a programme of research on human and organisational error and the prevention of accidents in health care. It is also developing a bibliography of patient safety research projects supported by government agencies and health care foundations in addition to the bibliography of articles and books that it already maintains.

2.4 Review strategy
Once the searches were completed the citations identified were imported into the reference manager Endnote, which allows for easy de-duplication of records. The titles (and where available) abstracts, have been scanned for relevance by one reviewer and those that appeared potentially relevant have been retrieved. The full papers were assessed again for relevance by one reviewer. A classification system was developed and used to classify all relevant studies:

- Systematic reviews - meeting the criteria for inclusion on the Database of Abstracts of Reviews of Effectiveness (DARE)
• Direct interventions - prospective studies of a direct intervention, which is not a reporting system, to reduce the occurrence of or mitigate the consequences of adverse events (including automated instruments for detecting error)

• Reporting systems - prospective studies of design and/or implementation of reporting systems

• Information analysis - retrospective analysis of adverse event information, e.g. from reporting systems which are not prospective studies

• General risk management - any potentially relevant paper which does not fit the above classifications

• Workload and stress - studies on the effects of workload/working conditions or stress on the occurrence of adverse events

• Organisational culture - studies reporting the barriers to adverse event reporting, attitudes of professional groups to risk management, acceptability to professional groups of interventions to reduce adverse events, practical implementation issues relating to interventions to reduce adverse events

• Government or professional body policy document

Where possible, data were extracted from papers in the ‘direct interventions’ and ‘reporting systems’ categories. Data were extracted about the aims, study design, intervention, setting, participants, results, and whether the research might be relevant to implementation of the intervention (see appendices 2 & 3). Data extraction was carried out by one reviewer. These data have been summarised in the Results section. Studies in the other categories have also been summarised in the Results section.
3. Results

A total of 4,444 papers were identified from the searches. The titles and/or abstracts of these papers were scanned, and inclusion/exclusion decisions made. Full articles were ordered for 919 references, of which 728 were received by the time of producing this report. The other 3,525 papers were excluded on the following criteria:

- Not relevant to the field of patient safety (e.g. studies investigating the effect of aeroplane cockpit layout on pilot decisions, studies of stress fractures in industrial structures).
- Not reporting original research (e.g. editorials, opinion pieces, letters, news articles).
- Concerned with methodology (e.g. theoretical papers on the application of various mathematical models to risk management, although these papers may be of interest at a later date).

Of the 728 full articles that were ordered and received, 340 were excluded according to the above criteria. The remaining 388 articles were categorised as follows:

- Government documents – 3
- Non-government policy documents – 14
- Systematic reviews - 6
- Direct interventions – 50
- Reporting systems – 46
- Information analysis – 88
- General risk management – 109
- Organisational culture – 32
- Workload and stress – 39

Structured abstracts for the 6 systematic reviews identified have been prepared (see appendix 4) and the main findings are summarised in this section. An overview of all the identified studies is given in table 1. The design of each included study has been reported, although in some cases classification was difficult as very limited
information was presented in the paper. These studies are then discussed in summary sections by the above categories.

Due to time constraints, 17 of the retrieved non-English language papers could not be assessed for inclusion in this report.9-25
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3.1 Summary of systematic reviews

Six systematic reviews were identified. Five had specific remits and focused questions whilst one was more general and collected and appraised evidence relating to improving patient safety. All six reviews were published between 1998 and 2001. (See appendix 4 for details of the individual reviews)

As one review covered a large and diverse literature (including three of the other systematic reviews identified in the searches) its methods and findings are summarised below.

Making health care safer: a critical analysis of patient safety practices

The Agency for Healthcare Research and Quality (AHRQ) recently published a systematic review of the evidence on practices relevant to improving patient safety. This was a very wide ranging review which included practices directly related to patient safety such as prevention of adverse drug events, as well as practices that could be considered more relevant to general quality initiatives, such as providing care in large volume centres and pain management.

The following domains and practices were included:

- reporting and responding to patient safety problems (incident reporting and root cause analysis)
- patient safety practices including adverse drug events; infection control; prevention of nosocomial urinary tract infections, intravascular catheter-associated infections, ventilator associated pneumonia; surgery, anesthesia and perioperative medicine (e.g. localizing care to high volume centres, learning curves, prevention of surgical site infections; ultrasound guidance, beta-blockers and reduction of perio-operative cardiac events); safety practices for hospitalized and institutionalised older people (e.g bed alarms, special hospital flooring, hip protectors); general clinical topics (e.g nutritional support); organisation, structure and culture (e.g closed intensive care units, nurse staffing); systems, issues and human factors; the role of the patient
- promoting and implementing safety practices including practice guidelines, and critical pathways.
analysing the practices (summarising the evidence)

For each of the domains (and 79 practices) the following study designs were included; controlled observational studies, clinical trials, and systematic reviews identified in the peer reviewed medical literature, non-health care literature and grey literature. Each study design was classified into a level of evidence ranging from 1 (systematic reviews and RCTs) through to 4 (observational studies without controls). It was stated that the primary outcomes had to consist of a clinical endpoint (i.e. morbidity or mortality). A summary of each of the main sections follows.

**Reporting and responding to patient safety problems**

Five studies of reporting systems were included: two were prospective investigations of incident reporting compared with observational data collection, one used retrospective chart review, and two compared enhanced incident reporting using personal contact with existing hospital QA systems. Three uncontrolled observational trials of reporting systems were referenced but excluded. The Australian Incident Monitoring Study (AIMS) and the JCAHO Sentinel Event database were also discussed.

The types of reporting system evaluated by the included studies were representative of those found in studies identified and included in the current scoping document. Our report includes a greater number of studies, as our remit was to map the patient safety research literature, therefore we have not excluded any studies on the basis of study quality. The AHRQ review also commented on the lack of studies evaluating the impact of reporting systems on patient safety outcomes. No studies which reported outcome measures such as morbidity, mortality or error rates were identified.

This section of the report also included a narrative description of the practice of Root Cause Analysis and its’ application to medicine.

**Patient safety practices**

Within this section six chapters focused on adverse drug events. Evidence for computerised physician order entry with clinical decision support systems
(CPOE) comes from eight studies, two of which were systematic reviews (details of these two reviews can be found in Appendix 4, the emphasis in one review was on physician performance, rather than specifically on the prevention of adverse events). Overall, the authors conclusions supported the use of CPOEs in reducing the frequency of medication errors but were less supportive of its impact on adverse drug events. **Computerised detection and alert systems** for preventing adverse drug events (ADEs) were evaluated in five studies (level 1 - 3 evidence, no details given for individual studies). Computerised systems were considered to be important facilitators for the detection of actual and potential ADEs, but evidence for their prevention was limited. **Unit dose drug distribution systems** (medication is dispensed in a package ready to give to the patient) are standard practice at hospitals in the USA. Their effectiveness has been evaluated in four cross sectional studies and one before-after study which were reported to show a positive impact on error reduction. **Automated medication dispensing devices** (storage devices that electronically dispense medications in a controlled way and track use) were evaluated in five studies (level 2 and 3) which suggested that in their current form they may not be beneficial. Also in this section were **protocols for reducing adverse events related to anticoagulants** (inpatient, outpatient and patient self-monitoring).

Seventeen studies were included in total (level 1 - 3). In inpatient settings a trend towards increases in excessive anticoagulation was noted, outpatient clinics were found to achieve superior measures of anticoagulation and patient self-management was found to be at least equivalent to usual care.

This section also included six chapters on practices relating to **infection control**. These were all related to the implementation of best practice and, as such, for the purposes of the current scoping report came under the broader heading of “quality of care” and were not considered as patient safety interventions.

Eight chapters which pertained to **surgery, anaesthesia and perioperative medicine** were included. The majority of these were not directly relevant to patient safety by the criteria of the current scoping report. The exceptions were chapters on retention of surgical instruments, pre-anaesthesia checklists and intra-operative monitoring. The chapter on retained surgical instruments described the available estimates of the prevalence of the problem and reported on a single study on the effectiveness of
sponge and instrument counts; this was a case study without controls and reported outcomes in terms of retained sponges only and not clinical consequences. The AHRQ report commented on the scarcity of the literature in this area. The report identified and included 15 articles on anaesthesia checklists and summarised two of these pertaining to the detection of equipment faults. The outcomes of these studies, in terms of effectiveness of checklists for detecting faults were inconclusive and both studies had significant methodological flaws, pointed out by the review. Twelve studies of perioperative monitoring were identified, of which two were included in the report. The two included studies reported morbidity and mortality attributable to anaesthesia. One of the studies showed a positive impact for monitoring and the other no effect. The report concluded that, since a large multi-centre RCT found no impact for pulse oximetry (which it suggested is widely regarded as the most useful monitor), “the magnitude of benefit may be so small that an adequate study to detect it may not be feasible”.

Five chapters relating to issues in care of the elderly were also included, none of which (e.g. prevention of pressure ulcers in older patients) were directly relevant to patient safety as defined in this report.

Seven chapters came under the category of general clinical topics. These were mainly concerned with quality of care issues, with the exception of a chapter on reducing errors in the interpretation of plain radiographs and computed tomography scans. Here, four before-and-after studies of educational interventions and quality improvement initiatives were found. These provided some evidence for educational interventions, but the studies had several limitations. The authors noted the relative dearth of studies of evaluating interventions to reduce radiological misinterpretation by non-radiologists, even though dozens of studies have documented the problem.

Three chapters examined the effects of organisation, structure, and culture on clinical outcomes. The critical care medicine literature, comprising mainly of observational research, strongly supported the role of an ‘intensivist’ (a physician with primary training in medicine, surgery, anaesthesiology or paediatrics followed by 2-3 years of critical care medicine training), though how the type of intensivist model
or the intensivist’s background influence clinical outcomes is unclear. Evidence on nurse staffing, models of care delivery and interventions (primarily from controlled observational studies) was mixed, although overall seemed to indicate that the proportion of RN hours per total hours and richer RN-to-patient hours do not affect 30-day mortality, may be associated with lower in-hospital mortality, and are probably associated with decreased adverse events such as postoperative complications, nosocomial infection, medication errors, falls, and decubitus ulcers. Evidence for promoting a culture of safety was found to be predominantly based on self-reported data, of which none directly supported the effect of promoting a culture of safety. Further research in this area was considered to be necessary.

Seven chapters on systems issues and human factors were also included:

A non-systematic, narrative review of the application of human factors analysis to the evaluation of medical devices drew positive conclusions on the utility of human factors testing. A chapter covering information transfer included two randomised controlled studies of written pharmacy care discharge plans, both of which reported positive outcomes but not outcomes in terms of adverse events. The report highlighted the lack of studies evaluating the impact of these interventions on clinical outcome. A chapter on the prevention of misidentifications found, in several studies, machine-readable automatic identification systems such as barcoding to be fast and accurate, though little evidence is available on practices to reduce or eliminate wrong-site surgery. Also included in this section was the research relating to crew resource management (CRM), which was mostly carried out in the field of aviation. In the health care setting, research focused on anaesthesia crisis resource management (ACRM) and the MedTeams behaviour-based teamwork system. It was found that weak study designs meant that little rigorous evaluation of such interventions was available, and there were no published data to describe the effects on medical error rates of the MedTeams approach. Another chapter concluded that there was no evidence that simulator-based training leads to improved patient outcomes, though this may be due to the difficulties in undertaking studies which measure such outcomes. Sleep deprivation and disturbances of circadian rhythm were found to lead to fatigue, and poor performance on standardised testing. Although the authors found data from non-medical fields that suggest that sleep deprivation leads to poor job performance, they state that, though the link between fatigue and medical error
seems intuitive, this link has not been established in medicine. Six studies relating to safety during transport of critically ill patients were found. Three of these studies provided a small amount of evidence to support the use of specialised transport teams in interhospital transport, but further research on the topic was recommended. The other three studies evaluated manual versus mechanical ventilation during intrahospital transport of patients. Although one RCT in paediatric postoperative cardiac patients showed an increase in the markers for patients in the manually-ventilated group, manual ventilation otherwise appeared to achieve results comparable to portable mechanical ventilation.

Three chapters related to the role of the patient. Very little literature was found that examined the impact of different procedures for obtaining informed consent on the quality of the consent obtained. The review authors indicate that more research is needed to establish the best practices to improve informed consent, and to test the impact of such practices on patient safety. Other practices related to patient participation, such as advance planning for end-of-life care focussed on quality-of-care issues rather than patient safety per se.

Promoting and implementing safety practices
This section contained five chapters. Convincing evidence that practice guidelines are effective in positively influencing the process and, to a lesser extent, outcome of care was reported. However, studies in this area were prone to methodological shortcomings, and there was a dearth of evidence specific to the use of guidelines in patient safety. The evaluation of implementation strategies was considered an important area for further research. Evidence for the effectiveness of critical pathways came from eight studies (level 1 and 2). Although a few of these studies suggested that they may impact clinician practice and, to a lesser extent, complication rates and other clinical outcomes, the data were inconsistent, and the need for further studies was highlighted. The scarcity of information on the application of pathways to patient safety was also highlighted. Evidence from five systematic reviews and two ‘well-designed’ studies (one cluster randomised trial and one prospective time series) suggested that clinical decision support systems are effective in the prevention of medical errors, especially when coupled with a computerised medical record and
directly intercalated into the care process. However, the results of support systems have been far less positive when used in the ongoing care of patients with chronic diseases or to help with diagnostic decision making. Evidence from randomised controlled trials of *educational techniques used in changing provider behaviour* found traditional programmes of conferences, lectures and printed materials to be ineffective. Some benefit has been shown for academic detailing, local opinion leaders, reminder systems, and audit and feedback, though there are few data regarding the specific utility of these techniques in increasing patient safety and/or the prevention of medical errors. The final chapter covered *legislation, accreditation, market-driven and other approaches to patient safety*. The report concluded that there was little objective evidence to determine whether such patient safety initiatives will result in meaningful change, or to consider their relatives advantages and disadvantages. However, it was considered that the work and involvement of diverse, powerful organisations and institutions may prove to be valuable adjuncts to the more traditional mechanisms of change represented by practice guidelines, continuing medication education programs, and decision support systems.

**Analysing the practices**

The final part of the AHRQ report described their *methodology for summarising the evidence of the practices*. Three major categories of information were gathered for each practice. These were: potential impact of the practice (based on prevalence and severity of the patient safety target and current utilisation of the practice); strength of the evidence to support the practice (including an assessment of the relative weight of the evidence, effect size, and need for vigilance to reduce any potential negative collateral effects of practice implementation) and; implementation (considering costs, logistical barriers and policy issues). A 4-person editorial team developed a rating form that captured the patient safety target, practice description, and general rating categories (e.g. High, Medium, Low) for some of the previously described elements. Tables were constructed and presented at the end of the report. The first set of tables displayed *practices rated by strength of evidence* regarding their impact and effectiveness score, and were subdivided into 5 ‘zones’ which ranged from “greatest strength” to “lowest impact/evidence scored practices”. The second set of tables summarised overall ratings for “research priority” score, subdivided into three zones: “Further research likely to be *highly* beneficial”, “Further research likely to be
beneficial” and “Low priority for research”. The final chapter was a listing of all practices, categorical ratings, and comments. Tables in this chapter contained data for each practice on: chapter number, patient safety target(s), patient safety practice description, potential impact (high, medium, low, insufficient information), study strength (high, medium, low), effect size (robust, modest, negligible, unclear), vigilance (low, medium, high), implementation cost (low, medium, high), and political/technical implementation complexity (low, high).

**Systematic reviews not included in The AHRQ report**

Three systematic reviews were identified and met our criteria for inclusion which had not been included in the AHRQ report. Summaries of these reviews are presented below and details can be found in Appendix 4.

One review evaluated the effectiveness of interventions aimed at reducing medical errors (which ranged from medication errors to inappropriate or harmful diagnostic tests). The review included both randomised and non-randomised trials (before-after, controlled trials), but the recommendations were based largely on the evidence from the RCTs. Individual interventions varied greatly and included: computerised reminders, leaflets, automated bedside dispensing, automated medication systems. A total of 13 RCTs and 24 non-randomised studies were included. In nine of the 13 RCTs the interventions were found to be effective in reducing error rates (the relative risks ranged from 0.17 to 0.69). Twenty-one of the 24 non-randomised studies reported the intervention to be effective.

Another systematic review focused on surgical adverse events and had a remit to assess whether common and potentially avoidable adverse events in surgery could be measured. The review also appraised methods for monitoring the occurrence of adverse events and aimed to identify effective monitoring systems. The surgical adverse events included were wound infections, anastomotic leak, deep vein thrombosis (DVT) and surgical mortality. Studies using a prospective design were eligible for inclusion. The review found inconsistency in the quality of reporting of postoperative adverse events which limited the accuracy in comparing rates over time and between institutions. A number of implications for research are reported. Most of the review was devoted to defining the individual surgical adverse events.
The third systematic review was carried out to estimate the incidence of serious and fatal adverse drug reactions (ADRs) in hospital patients. A total of 39 prospective studies carried out in the USA were included in the review. Meta-analysis revealed the overall incidence of serious ADRs was 6.7% (95% CI: 5.2% to 8.2%) and of fatal ADRs was 0.32% (95% CI: 0.23% to 0.41%) of hospitalised patients. The authors estimated that in 1994 overall 2,216,000 (95% CI: 1,721,000 to 2,711,000) hospitalised patients in the USA had serious ADRs and 106,000 (95% CI: 76,000 to 137,000) had fatal ADRs, making these reactions between the fourth and sixth leading cause of death.
3.2 Summaries of primary research studies identified in the searches

As this project was a mapping of the research literature relating to patient safety details of primary studies identified via the electronic searches and considered relevant to the topic have been summarised below. Data extraction tables have also been included (Appendices 2 and 3) to provide more detailed information.

3.2.1 Summary of direct interventions

Of the primary studies identified from the searches, fifty<sup>32-81</sup> were categorised as ‘direct interventions’. This broad category included any primary study that evaluated a specific intervention intended to reduce errors or adverse events. These are grouped below, according to the type of intervention evaluated. Nine<sup>32, 33, 40, 44-46, 50-52</sup> of these studies were included in the AHRQ review.

Summary of computerised/automated systems

Twenty-nine of the 50 direct intervention studies evaluated the use of computerised or automated systems in clinical practice. All 29 studies were published between 1990 and 2000, predominantly in the USA, though others originated from the UK,<sup>37, 49</sup> Canada,<sup>33, 38</sup> China,<sup>40</sup> Italy,<sup>39</sup> France<sup>81</sup> and Belgium.<sup>41</sup>

Insufficient detail was available to determine the design of four of the computerised/automated systems studies,<sup>32-35</sup> whereas eleven provided sufficient detail to be simply categorised as ‘observational’ studies.<sup>36-43, 71, 76, 81</sup> Of the remaining 14 studies, there was one RCT,<sup>79</sup> six before-and-after designs,<sup>44-49</sup> two time series,<sup>50, 51</sup> one RCT,<sup>52</sup> two cohort-type design,<sup>53, 73</sup> one case-series<sup>54</sup> and one survey.<sup>55</sup>

With the exception of one study that reported data from two independent hospitals,<sup>39</sup> all studies of computerised interventions were conducted in single or multiple units of individual hospitals. Only nine studies<sup>33, 38, 40, 41, 50, 52, 54, 55, 71</sup> reported the number of
included participants. The remaining studies analysed data from medical records, prescriptions, or failed to provide sufficient detail regarding participants.

Seven of the studies specifically examined computerised prescribing systems, such as physician order entry systems which automate the medication ordering process. Six studies examined automated dispensing systems, five evaluated wrong-dose alert systems, three evaluated computerised systems for use in administration/nursing, and a further three focused on computerised medication administration records. The remaining five studies examined an electronic radiograph archiving system, a verification system to monitor the blood transfusion process, a wristband system for reducing transmission errors in blood transfusion, a record and verify system for radiation treatment delivery, and computer-aided continuing education system.

Almost all studies of computerised or automated systems reported positive results, with just a single study of portable bedside terminals reporting no overall benefit for the study intervention.

Summary of education/training interventions
Six of the direct intervention studies, all published between 1996 and 2000, evaluated the impact of education or training programmes on error. With the exception of one Canadian study, all were US studies.

Of the ‘education/training’ studies there were three before-and-after studies, one RCT, and two surveys.

Study settings varied according to whom the intervention was aimed at, and ranged from single hospitals to primary care. Participants in these studies varied widely and included registered nurses, clinical anaesthesia residents, family practice residents, and emergency response service workers.
The education/training studies were too dissimilar to be further grouped by type of intervention. Most of the studies evaluated the introduction of interventions to reduce or prevent error or accidents, with one exception that studied the impact of eliminating a yearly medication test for staff nurses.57

All but one of the education/training studies57 reported positive effects as a result of the intervention.

Summary of ‘independent checking’ interventions
A total of nine direct intervention studies evaluated interventions which involved the work of an individual being carried out with, or independently checked by, a second individual.61-64, 69, 72, 74, 77, 80 Publication dates ranged from 1990 to 2000, and the studies were carried out in the USA,62, 63 UK64 Australia,69, 72, 74, 77 France80 and Italy.61

Six of the nine studies presented very limited information about study design and appeared to be observational type studies.61, 62, 64, 74, 77, 80 Of those remaining, two were before-and-after studies,63, 72 and the other was a crossover study.69

All studies were carried out in single hospital settings, with the exception of one, where data were obtained from six different hospitals.64 Though all eight studies focused on clinical errors, only two gave any details about patients.61, 64 As with the education/training studies, there was considerable variation in the types of intervention evaluated in these studies.

A single study which evaluated the administration of medication by two nurses69 was the only intervention in this section to report no overall benefit for the intervention being studied.

Summary of other interventions
The remaining six direct intervention studies65-68, 70, 75 did not comfortably fit into the above categories. These were published between 1991 and 2000. Four of the studies
were carried out in the USA\textsuperscript{65-67, 70, 75} and one in Italy.\textsuperscript{68} All included single hospitals, but varied in the type of intervention being evaluated. One study\textsuperscript{70} evaluated an intervention that contained elements of both education and independent checking. This intervention initially required accident and emergency staff to review clinically significant errors in the interpretation of radiographs. A file of clinically significant errors was created and used for teaching, prior to a system being developed which required all standard radiographs to be independently interpreted by an emergency physician and a radiologist. The authors reported that the system reduced the number of both clinically significant errors and potential adverse effects. Other interventions evaluated in these studies were: a specific blood transfusion system,\textsuperscript{68, 75} an automatic stop order (ASO) policy,\textsuperscript{65} outsourcing of an IV admixture programme,\textsuperscript{66} and different levels of illumination in an outpatient pharmacy.\textsuperscript{67} As with the majority of direct intervention studies, all of these reported positive effects for the intervention being evaluated, though the statistical significance was not always reported.
3.2.2 Summary of reporting systems

A total of 46 studies focusing on the development and implementation of adverse event reporting systems were retrieved from the literature searches, of which seven \textsuperscript{82-88} were cited in the AHRQ report.\textsuperscript{26} Eight studies were descriptions of the development process only and did not report an evaluation or information on implementation issues. Six of the eight were conducted in health care settings\textsuperscript{89-94} and the remaining two were set in the nuclear power industry.\textsuperscript{95, 96}

The majority of the remaining studies (see appendix 3) evaluated voluntary and/or anonymous reporting systems.\textsuperscript{82-84, 87, 97-117} The nature of the reporting system was unclear in a further ten studies.\textsuperscript{85, 86, 118-125} One study reported on a compulsory system enforceable in law, (the French haemovigilance system).\textsuperscript{126} The most common type of reporting system (n=26) described, relied upon written incident report forms,\textsuperscript{82, 84-88, 100, 101, 103-117, 121, 124, 125} seven of these used forms based on that of the Australian incident Monitoring System (AIMS), introduced in 1996.\textsuperscript{82, 100, 101, 103, 105, 110, 112} Six studies used computer-based reporting systems,\textsuperscript{97, 99, 118, 119, 123, 127} five did not clearly describe the system used\textsuperscript{98, 102, 120, 122, 126} and two used personal contact by the investigator\textsuperscript{83, 97} (one of these also used computer-based data collection).\textsuperscript{97}

Study design was usually observational,\textsuperscript{82-85, 88, 97-104, 106, 108-110, 112-118, 121, 122, 124-127} with one cohort study,\textsuperscript{107} one experimental study,\textsuperscript{123} one retrospective chart review,\textsuperscript{105} two surveys\textsuperscript{87, 111} and three studies in which the design was unclear.\textsuperscript{86, 119, 120}

Included studies were conducted between 1990 and 2001. Of the studies conducted in health care settings, most occurred during or after 1995,\textsuperscript{82, 83, 85, 87, 88, 97-108, 110-112, 117-119, 121, 123, 126} the year of publication of the major national study of adverse events in health care “Quality in Australian Health Care”, with a concentration in the years immediately following the introduction of AIMS (1996-1998).\textsuperscript{82, 85, 87, 99-101, 103, 107, 108, 110, 111, 119, 121, 126} There were no apparent increases in publication rates in this field following publication of the US government report “To Err is Human” in 1999 or the UK Department of Health report “An Organisation with a Memory” in 2000.
By far the largest number of studies of reporting systems were conducted in the US. A further five studies each were conducted in Australia and Hong Kong, three in the UK, two in Malaysia and one each in Pakistan, Sweden, Norway, France and New Zealand.

Seven studies describing national reporting systems were identified. These included two studies of national blood transfusion services in the UK and France, two studies of Australian General Practice, two reports on the AIMS-ICU project and one US infection control study. In addition there was one web-based survey of adverse events in anaesthesia with no apparent nationality restrictions. Twenty-six of the remaining 28 health care studies were on local, hospital-based reporting systems with the locations of the other two being unclear. The only non-health care study of an incident reporting system was conducted in a single UK, offshore oil operating company.

Adverse event reporting systems in health care were concentrated in general tertiary care, Anaesthesia, and Intensive Care with the remainder spread across Nursing, Transfusion Services, Pharmacy and General Practice.

In general the quality of studies relating to adverse event reporting systems was low. Only one study attempted to describe the complete process of development, implementation and evaluation (in terms of both numbers of reports received and effect on adverse events) of a reporting system. Both of these measures are important: numbers of reports received would be expected to rise with the introduction of an, effective, new reporting system; six studies evaluated reporting systems in these terms. For a reporting system to be truly effective, the data collected must be used to inform the development of strategies for reducing the occurrence of adverse events. Two studies reported the development and evaluation of strategies in this way, but contained no information on the impact of the system on reporting rates. In all, 15 studies contained some information relating to the process of implementation of a new reporting system.
Ideally the effectiveness of a reporting system would be evaluated in terms of reporting rates, patient outcome and ease of implementation.
3.2.3 Summary of information analysis studies

In total 88 of the studies included in this report were designated “information analysis” that is retrospective analysis of adverse event information from local or national databases, of which five were cited in the AHRQ report. Studies in this category were published between 1990 and 2001. Before 1999, the rate of publication remained relatively constant, with between three and eight studies published each year. The publication rate then increased sharply, with 20 and 17 studies being published in 1999 and 2000 respectively, coincident with the publication of the US government and UK department of health reports “To Err is Human” and “An Organisation with a Memory”. Thirteen of the 17 studies published in 2000 were conducted in the US, as were all three studies published in 2001.

The majority of all studies in this category used data recorded in the US. Sixteen reported data that originated in Australia, six in the UK, six in Canada, three in France, and one each in Germany, Denmark, the Netherlands, Italy, Israel, Saudi Arabia, Tunisia, and Japan. There was limited reporting of information from national adverse event databases (19 studies), six of these related to the Australian Incident Monitoring System (AIMS).

Where studies were conducted in a specific health care discipline, 14 were in Pharmacy, six each in Emergency Medicine, Anaesthesia, and Blood Transfusion Services, plus three in Oncology, and two each in Obstetrics, Nursing, Pathology, and Care of the Elderly. Medication errors were the most common type of adverse event investigated; these were the focus of 39 studies.
In general, the type of retrospective “information analysis” study described in this section is of limited value. To date, there has been a notable dearth of published national adverse event data, with the existing studies based mainly in Australia and the USA. At best, the small-scale local studies conducted in a wide variety of settings, which represent the bulk of this category, provide only a point estimate of adverse event rates current at the time of publication; data is specific to the study setting. Very few (n=9) of these retrospective “information analysis” studies presented any form of causal analysis of the adverse events that they report.137, 141, 143, 148, 160, 189, 204, 213, 216
3.2.4 Summary of general risk management

One hundred-and-nine of the studies retrieved from the literature searches and considered to be potentially relevant to the subject of patient safety have been designated “general risk management”; i.e. they do not fit into the any of the major categories defined in this report. This is a reflection of the diverse and unfocussed nature of research in the field. Fourteen of the studies designated “general risk management” were conducted in non-health care environments (aviation/military, industry, nuclear power, and general population). None of these were cited in the AHRQ Report.

A body of broadly similar, prospective studies, conducted in health care settings, emerged from the “general risk management” category. The studies attempted to quantify and/or analyse adverse events either by surveying health care practitioners or by using a cohort-type design and a sample of patients or procedures. None of the surveys, but four of the cohort-type studies were cited in the AHRQ report.

Of the thirteen surveys of health practitioners, eight were postal and five used methods involving direct contact by the researcher with the respondents. Health care disciplines represented included: Emergency medicine (1), Nursing (5), Pathology (1), Anaesthesia (2), Pharmacy (2), Intensive care (1) and general tertiary care (1). Surveys covered time periods from 6-30 months and represented a wide range of numbers of respondents (66-1428), located in the UK (3), the US (7), Canada (1), New Zealand (1) and Spain (1). Three studies reported sufficient detail to estimate adverse event rates: Diagnostic Histopathology 0.06/Pathologist/month, general medication error 0.4/Nurse/month and chemotherapy medication error 0.06/Nurse/month. It is likely that these findings represent significant underestimates, as indicated by those surveys which examined rates of error reporting: General medication error 30.5%, Anaesthesia 39.9% and chemotherapy medication error 86%.
Prospective observational studies, in particular those which are not totally reliant on data from reporting systems, are likely to represent a more accurate estimation of adverse event rates. Of the twenty-four cohort-type studies identified, only two were dependent on voluntary incident reporting alone.\textsuperscript{128, 254} Health care disciplines represented included: Intensive care (4), Pharmacy (2), Paediatrics (1), Transfusion service (1), anaesthesia (1), radiology (1) and surgery (1); the remaining 12 studies cover general tertiary care. Studies covered a wide range of time periods, 12 days to one year and were conducted in the US (13), UK (2), Canada (2), France (2), India (1), Australia (1), Israel (1) and Switzerland (1). The number of patient days studied across the studies ranged from 88 to 15,838 and seven studies described only numbers of patients or interventions (e.g. prescriptions or phlebotomy). Six studies provided sufficient information to estimate adverse event rates per patient day. Three of these were in general tertiary care; one excluding intensive care reported an incident rate of 0.01/patient day\textsuperscript{244} and two for whole hospital populations reported incident rates of 0.3/patient day\textsuperscript{245} and 0.2/patient day\textsuperscript{249} respectively. Three were in intensive care and reported 0.02, 1.5 and 0.3 incidents/patient day respectively\textsuperscript{244, 250, 253}

The remaining 58 health care studies designated “general risk management”, two\textsuperscript{267, 268} of which were cited by the AHRQ report\textsuperscript{26} included: surveys of risk management measures in place in various health care settings,\textsuperscript{267, 269-274} experimental studies of factors perceived to effect patient safety (e.g. staff skills),\textsuperscript{275-292} techniques for analysing the causes of error (e.g. human factors analysis)\textsuperscript{293-297} and descriptions of the development of systems or guidelines aimed at reducing adverse events.\textsuperscript{268, 298-305}
3.2.5 Summary of the research literature relating to organisational culture

Thirty-two studies were assigned to the category of organisational culture, of which four were included in the AHRQ report. This category included studies investigating the barriers to reporting errors, attitudes toward errors and error reporting, organisational factors affecting error, etc. These studies were published between 1991 and 2001, with the majority being published in the last five years. Most of the studies originated from either the USA or the UK, but others came from the Netherlands, Australia, Norway, Finland and Sweden. Studies in this category largely adopted a survey type (questionnaire, semi-structured interview and/or focus group) design.

Several studies in this section surveyed nurses, clinicians and chart reviewers to investigate the factors which are likely to influence the reporting of adverse events within hospitals. Most of these surveys were small scale involving only one hospital. Although one US study included 24 hospitals, another six hospitals, and another two hospitals. Another study whose primary objective was to develop and test an instrument about nurse perceptions or reasons that medication errors may not be reported, included 29 hospitals in the US. The instruments or questionnaires were in most cases designed specifically for use in each particular study, and little if any information about validity or reliability was reported. One notable exception being a US study which used an existing instrument: The Culture and Quality Improvement Implementation Scale.

Overall, the factors which emerged most frequently appeared to be linked to individuals, such as blame, fear of reprisal, unwillingness to accept responsibility when several individuals may have been involved and loss of clinical confidence. This was in contrast to more situational or organisational factors such as 'circumstances or outcome of a particular event didn't warrant a report', and the 'effort required to report an event' which were reported less frequently. One study which investigated Australian pharmacists' beliefs about the factors contributing to dispensing errors found that errors were thought to be related to high prescription volumes, fatigue and overwork.
Surveys of employees in other environments included manufacturers, nuclear power workers, engineers and offshore oil workers. These surveys unlike the hospital surveys where the focus was on factors affecting the reporting of adverse events were concerned largely with employee perceptions of safety and how perceptions were affected by the organisational culture. Studies reported that employee views of management commitment, support and priorities for safety were associated with positive perceptions about safety at work.

Other studies in this category investigated the chain of events leading to an adverse event occurring, developed a taxonomy for classifying organisational causes of safety related incidents and discussed the risks and benefits of transferring tools and knowledge between different areas, compared the attitudes towards errors, stress and teamwork of over 1000 doctors and nurses in the USA and Europe with over 30,000 airline cockpit crew. Others focused entirely on issues of teamwork and two review papers discussed culture and error in space and defence and safety. Three studies reported the outcomes of a survey of clinicians attitudes about the introduction of an electronic medical record system, a computer based provider order-entry system and of staff members confidence in two health care organisations during a period of organisational change. One study examined the association between the leadership style of mental health treatment teams and consumer satisfaction and quality of life and a review paper discussed the importance of good leadership and its effects on financial management and the quality of care provided. A final paper described a series of studies (surveys, focus groups, observations and audits) exploring the efficacy of health and safety management systems in the UK.

Despite the numerous studies highlighting the importance of culture and the focus on 'safety cultures' no studies were identified which had attempted to either evaluate or implement interventions to promote a safety culture.
3.2.6 Summary of the research literature relating to workload and stress

Thirty-nine studies were assigned the category of ‘workload and stress’.\textsuperscript{338-374} This category included studies investigating the effects of factors such as high workloads, long hours and shift-work on performance and error. The studies were published between 1983 and 2001, though two-thirds of these were published between 1997 and 2001. The majority of studies originated in either the USA or the UK, though other studies came from Australia, New Zealand, Canada, Bulgaria, Italy, Norway and the Netherlands. Most studies in this category adopted either an observational study (e.g. collection and analysis of routine data) design, or survey-type design, though some were literature reviews of the area.

Health care studies

Twenty-two of the 39 studies were carried out in the field of health care. These studies were primarily concerned with the impact of workload, stress and fatigue on physicians,\textsuperscript{348, 350, 355, 359, 369, 371-373} nurses\textsuperscript{343, 349, 354, 356, 374} and anaesthetists,\textsuperscript{338, 340, 342, 352} whilst a single study investigated the effect of interruptions and distractions on dispensing errors in an ambulatory care pharmacy.\textsuperscript{339}

With the exception of two observational studies\textsuperscript{356, 374} and five surveys,\textsuperscript{355, 368, 371-373} observational/survey study designs were carried out within single hospitals or institutions. The majority of hospital-based studies focussed on the factors such as long working hours and fatigue\textsuperscript{338, 340, 348, 369, 372} and staffing issues\textsuperscript{342, 343, 349, 354, 356, 374} on stress and/or performance. Junior doctors were found to report poor performance as a result of long working hours\textsuperscript{348}, and a high proportion of anaesthetists reported fatigue related errors.\textsuperscript{338} The level of reported stress amongst nurses was associated with the number of patient incidents,\textsuperscript{349} whereas the proportion of RN care hours was inversely related to outcomes such as medication errors, patient falls, respiratory and urinary tract infections, skin breakdown and patient complaints.\textsuperscript{356} Other studies examined specific factors such as interruptions/distractions,\textsuperscript{339} external environmental
factors, \textsuperscript{350} production pressure, \textsuperscript{352} and the emotional impact of mistakes on physicians. \textsuperscript{368, 370}

Among the studies which analysed data from more than one hospital, were two Australian studies \textsuperscript{340, 343} which included numerous reports from the Australian Incident Monitoring Study (AIMS) to determine the causative or contributory effects of fatigue and staff shortages on medical incidents. The studies found that 2.7\% of reported anaesthesia incidents listed fatigue as a contributory factor, \textsuperscript{340} and that incidents due to nursing staff shortage were associated with undesirable patient outcomes such as major physiological change, patient/relative dissatisfaction, and physical injury. \textsuperscript{343} A further two studies used survey data to investigate the role of psychological factors such as personality traits and coping strategies on stress amongst consultant grade medical staff in Scotland. \textsuperscript{375, 376}

\textbf{Non-health care environments}

Seventeen studies were concerned with workload and stress issues in general, or were carried out in environments other than health care. Themes such as the impact of working hours on fatigue and subsequent performance were similar to those identified in the health care literature, though there appeared to be greater emphasis on shift-work, and less on staffing issues.

Three articles reviewed the literature on occupational factors which can impact on stress, health and performance, \textsuperscript{346, 357, 367} two of which \textsuperscript{346, 367} discussed the effects of shift working on health and performance.

Four studies were carried out in the field of aviation. \textsuperscript{360-362, 365} Three of these aviation studies were concerned with the impact of fatigue and stress on pilot error and air traffic incidents, \textsuperscript{361, 362, 365} and one reviewed the literature on ‘Crew Resource Management’ training. \textsuperscript{360}
4. Overview

The mapping exercise around patient safety has included only publications which have reported original research. This approach has resulted in the exclusion of a large number of publications of potential interest, since the majority of the literature identified was opinion pieces, letters, editorials and news articles, rather than reports of empirical research. Some of the excluded publications may have potential relevance and have been included in the annotated bibliography to which accompanies this report. At the time of writing this report nearly 200 articles had been ordered but had not yet been received. These papers have been included in the annotated bibliography.

4.1 What have been the goals of patient safety research?
Overall, the goals of patient safety research have been diverse. Some studies have pursued very tight objectives, for example evaluating the effectiveness of a single intervention in reducing errors, whilst others have had the more general aim of improving patient safety. Setting boundaries for research relevant to the aim of improving safety is difficult, as many studies whilst not focusing specifically on errors or accidents cover areas which are important and relevant to the safety agenda. However, it was possible to classify the identified studies according to eight main areas: (1) government documents relating to the patient safety agenda, (2) non-government policy documents, (3) direct interventions to reduce error, (4) description and implementation of adverse event reporting systems, (5) information analysis (i.e. retrospective analysis of adverse event information from local or national databases), (6) general risk management, (studies which attempted to quantify and/or analyse adverse events either by surveying health care practitioners or by following a sample of patients or procedures), (7) studies relating to the organisational culture and to (8) workload and stress.

4.2 What methods have been used in patient safety research?
The type of study design used across the identified studies varied and was often poorly described. Research in this area appears to be dominated by observational and survey type studies. This was true for the ‘direct intervention’ studies, where the
majority of studies were simply classified as ‘observational’ designs or were before-and-after studies of the implementation of an intervention in a hospital setting. Observational study designs were by far the most prevalent design in the ‘reporting systems’ category, where only a single experimental study was found. ‘Information analysis’ studies were limited to retrospective analysis of adverse event information, whereas in the ‘organisational culture’ and ‘workload and stress’ categories, there was a preponderance of survey-type designs. There was a greater variety of study designs included in the ‘general risk management’ category than elsewhere, though the observational studies and surveys were also common here.

Overall, the quality of original research appeared to be variable (although it must be noted that formal quality assessment has not been carried out) and often the studies lacked focus. Most studies were conducted on a relatively small scale in single hospitals or local groups of tertiary care units. The results would therefore be difficult to generalise on either a national or international scale.

4.3 What types of studies have shown what kind of results?

A significant proportion of those studies which have evaluated a direct intervention to reduce adverse events in health care settings have focused on computerised or automated systems to control medication errors (prescribing, ordering, dispensing, administration). Such systems appear to be more widely used in the USA than in the UK and although their evaluation appears to be somewhat limited, most studies identified reported positive findings. However, much of this research failed to adequately discuss the statistical or clinical significance of the observed benefits. Also, there is little evidence about the comparative benefits of such systems. The three systematic reviews in this area plus the large AHRQ report conclude that computerised systems can enhance clinical performance. Computerised or automated systems for detecting and preventing medication error may be a fruitful area for larger scale research in the UK. In particular, there is a lack of research investigating issues relating to the implementation and acceptability of such systems to health professionals.
There was a small body of dissimilar studies evaluating local education and training programmes, which in the main reported positive but ungeneralisable findings. Although, not included in this report as they do not focus specifically on patient safety issues, there are a number of systematic reviews which have evaluated the effectiveness of educational techniques on physician performance, which may provide additional useful evidence (see The Cochrane Library).377 Given the increasing emphasis on nationally accredited, often compulsory, continuing professional education programmes for both medical practitioners and professions allied to medicine, a programme of research to investigate the effectiveness of such programmes in reducing adverse events may be of value.

The development and implementation of adverse event reporting systems has become a major national priority in the UK and elsewhere. The current research evaluating the effectiveness of reporting systems is limited and in the main of poor quality. Most studies have been conducted using individual, locally designed systems in single hospitals or local tertiary care group settings. There have been very few studies which have evaluated both the effectiveness of reporting systems for information gathering purposes and the utility of the information obtained for developing and implementing error-reducing strategies. Locally developed reporting systems, even when well evaluated, often lack the infrastructure to allow “lessons learned” to be applied nationally.

Retrospective ‘information analysis’ studies have mainly been concerned with local data on medication errors. Unfortunately, due to a lack of generalisability, these small-scale studies may be of limited value. It is difficult to envisage a means of carrying out useful, large-scale research studies to improve patient safety without a reliable method of measuring adverse events nationally. There is a notable lack of published national adverse event data, with the exception of a few studies from Australia and the USA. The Australian Incident Monitoring Study (AIMS) represents ‘work in progress’ on an integrated, national reporting system and as such may provide one model for future developments in this area. To date it has generated a large body of data on adverse events in a variety of clinical disciplines, although reports of its use to initiate error-reducing strategies are, as yet, lacking.
Studies which have investigated attitudes toward errors and error reporting, barriers to reporting errors, and the organisational factors which affect error, have identified a number of factors as being important. The factors which emerged most frequently appeared to be linked to individuals, such as blame, fear of reprisal, unwillingness to accept responsibility and loss of clinical confidence. Interventions specifically targeting the identified beliefs about and barriers to reporting errors could be developed, and evaluated, particularly if adverse event reporting systems are to implemented successfully.

Studies of the impact of workload and stress have been carried out in both health care and other working environments. Perhaps unsurprisingly, surveys in this area indicate health professionals feel that long working hours and fatigue can lead to increased stress and/or poorer performance. Though an association between greater fatigue/stress and increased error makes intuitive sense, there has been little research which has attempted to measure the strength of any such relationship. Only two studies (both utilising reports from the Australian Incident Monitoring Study) have attempted to determine the causative or contributory effects of fatigue and staff shortages on medical incidents.

The diverse and unfocussed nature of patient safety research in general is reflected by the research included in the ‘general risk management’ category. Here, a variety of study designs were used to quantify and/or analyse errors and adverse events, though the utility of many of these small-scale studies is questionable.
5. Recommendations for future research

Based on the identified primary research together with the six systematic reviews, including the large AHRQ report (USA), the following recommendations for research can be made.

- The development of a reporting system to be evaluated in terms of reporting rates, patient outcome and ease of use. Examination of trends will be unreliable unless all incidents are reported. The Australian Incident Monitoring Study (AIMS) represents ‘work in progress’ on an integrated, national reporting system and as such may provide one model for future developments in this area. To date it has generated a large body of data on adverse events in a variety of clinical disciplines, although reports of its use to initiate error-reducing strategies are, as yet, lacking.

- User concerns will affect the success of any reporting system. Further identification of perceived barriers to adverse event reporting, using validated measures, could be used to inform the development of a system specifically targeting identified concerns.

- Interventions to compare anonymous and named reporting of error could be tested.

- Investigate the broader use of reporting systems in enhancing the safety of care provided. Develop mechanisms for feedback from reporting systems. The aim of all such systems is to reduce error in the future. Approaches such as audit and feedback have been extensively evaluated in the context of quality assurance, although their application in relation to increasing patient safety may be limited.

- Success of any reporting system is likely to be dependent on a culture where staff are convinced of the importance of safety. No specific initiatives aimed at developing a culture of safety were identified. Initiatives could be developed based on the principles of openness and accountability where the reporting of
mistakes becomes routine. Leadership is likely to play a key role in promoting such organisational change.

- Computerised or automated systems for detecting and preventing medication error may be a fruitful area for larger scale research in the UK. In particular, there is a lack of research investigating issues relating to the implementation and acceptability of such systems to health professionals.

- Given the increasing emphasis on nationally accredited, often compulsory, continuing professional education programmes for both medical practitioners and professions allied to medicine, a programme of research to investigate the effectiveness of such programmes in reducing adverse events may be of value.

- A systematic review of studies (both empirical and theoretical) of accident causation, (both within and outside of health care), including both individual and organisational factors may provide useful insights into how accidents may be prevented. This could draw upon a number of the studies identified in this scoping exercise.
6. **Appendices**

**Appendix 1 - Search strategies**

A range of databases were searched and details of these are given below. In addition to database searches the web sites of Departments, Ministries of Health and Patient Safety Groups in Europe, Canada, Australia and the USA were searched. The reference lists of major reports were also scanned for relevant items.

**Cinahl (Silverplatter/ARC – searched - 06/07/01)**

1982 – 2001/04

1. "Patient-Safety"/ all topical subheadings / all age subheadings
2. explode "Treatment-Errors"/ all topical subheadings / all age subheadings
3. explode "Diagnostic-Errors"/ all topical subheadings / all age subheadings
4. patient safety in ti ab
5. medical error* in ti ab
6. detect* near ((error* or incident* or accident*) in ti ab)
7. reporting near ((error* or incident* or accident* or system*) in ti ab)
8. information system* in ti ab
9. prescribing system* in ti ab
10. "Organizational-Culture"
11. "Fatigue"/ all subheadings / all age subheadings
12. explode "Stress-Psychological"/ all subheadings / all age subheadings
13. explode "Information-Systems"/ all subheadings / all age subheadings
14. "Risk-Management"/ all subheadings / all age subheadings
15. Safety Management in ti ab
16. (fatigue or workload* or tired*) near ((error* or harm or incident* or accident* or patient safety or job performance or work performance) in ti ab)
17. incident* report* in ti ab
18. #1 or #2 or #3 or #4 or #5
19. #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17
20. #18 and #19

**Embase (Silverplatter/ARC – searched - 06/07/01)**

1980 – 2001/06

1. "Medical-Errors"/ all subheadings
2. "Medication-Errors"/ all subheadings
3. patient safety in ti ab
4. medical error* in ti ab
5. medication error* in ti ab
6. human error* in ti ab
7. detect* near ((error* or incident* or accident*) in ti ab)
8. reporting near ((error* or incident* or accident* or system*) in ti ab)
9. information system* in ti ab
10. prescribing system* in ti ab
11. "Risk-Management"/ all subheadings
12. Risk Management in ti ab
13. Safety Management in ti ab
14. (fatigue or workload* or tired*) near ((error* or harm or incident* or accident* or patient safety or job performance or work performance) in ti ab)
15. incident* report* in ti ab
16. ("Accident-Prevention") or ("Safety"/ all subheadings) or ("Accident-Proneness") or #1 or #2 or #3 or #4 or #5 or #6
17. #7 or #8 or #9 or #10 or ("Fatigue"/ all subheadings) or #11 or #12 or #13 or #14 or #15 or (explode "stress"/ all subheadings)
18. #1 or #2 or #3 or #4 or #5 or #6
19. #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15
20. #18 and #19

Kings Fund Database (Silverplatter/ARC – searched - 06/07/01)
1979 - current

Helmis (Silverplatter/ARC – searched - 06/07/01)
1984 - 1998

DHData (Silverplatter/ARC – searched - 06/07/01)
1983 – current

1. "Accident-Prevention"
2. "Accident-Proneness"
3. patient safety in ti ab
4. medical error* in ti ab
5. medication error* in ti ab
6. human error* in ti ab
7. detect* near ((error* or incident* or accident*) in ti ab)
8. reporting near ((error* or incident* or accident* or system*) in ti ab)
9. information system* in ti ab
10. prescribing system* in ti ab
11. Risk Management in ti ab
12. Safety Management in ti ab
13. (fatigue or workload* or tired*) near ((error* or harm or incident* or accident* or patient safety or job performance or work performance) in ti ab)
14. incident* report* in ti ab
15. #1 or #2 or #3 or #4 or #5 or #6
16. #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14
17. #15 and #16

HealthStar (Silverplatter/ARC – searched - 06/07/01)
1981 – 2000/12

1. "Accident-Prevention"
2. "Safety"/ all subheadings
3. "Accident-Proneness"
4. "Medical-Errors"/ all subheadings
5. "Medication-Errors"/ all subheadings
Medline (Silverplatter/ARC searched – 03/07/01)
1966 – 2000/12

6. "Accident-Prevention"
7. "Safety"/ all subheadings
8. "Accident-Proneness"
9. "Medical-Errors"/ all subheadings
10. "Medication-Errors"/ all subheadings
11. patient safety in ti ab
12. medical error* in ti ab
13. medication error* in ti ab
14. human error* in ti ab
15. detect* near ((error* or incident* or accident*) in ti ab)
16. reporting near ((error* or incident* or accident* or system*) in ti ab)
17. information system* in ti ab
18. prescribing system* in ti ab
19. "Organizational-Culture"
20. "Fatigue"/ all subheadings
21. explode "Stress-Psychological"/ all subheadings
22. explode "Information-Systems"/ all subheadings
23. "Risk-Management"/ all subheadings
24. "Safety-Management"/ all subheadings
25. Risk Management in ti ab
26. Safety Management in ti ab
27. patient safety in ti ab
28. medical error* in ti ab
29. medication error* in ti ab
30. human error* in ti ab
31. detect* near ((error* or incident* or accident*) in ti ab)
32. reporting near ((error* or incident* or accident* or system*) in ti ab)
33. information system* in ti ab
34. prescribing system* in ti ab
35. "Organizational-Culture"
36. "Fatigue"/ all subheadings
37. explode "Stress-Psychological"/ all subheadings
38. explode "Information-Systems"/ all subheadings
39. "Risk-Management"/ all subheadings
40. "Safety-Management"/ all subheadings
41. Risk Management in ti ab
42. Safety Management in ti ab
43. (fatigue or workload* or tired*) near ((error* or harm or incident* or accident* or patient safety or job performance or work performance) in ti ab)
44. incident* report* in ti ab
45. #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23
46. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9
47. #25 and #24
27. (fatigue or workload* or tired*) near ((error* or harm or incident* or accident* or patient safety or job performance or work performance) in ti ab)  
28. incident* report* in ti ab  
29. #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23  
30. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9  
31. #25 and #24

Aerospace Database (Dialog searched – 24/08/01)  
1962 – 2000/Aug

Nuclear Science Abstracts (Dialog searched – 24/08/01)  
1948-1976 This is a closed database

Chemical Safety Newsbase (Dialog searched – 24/08/01)  
1981-2001/Aug

Enviroline (Dialog searched – 24/08/01)  
1975-2001/Aug

Energy Scitech (Dialog searched – 24/08/01)  
1974-2001/Jul

National Technical Information Service (NTIS) (Dialog searched – 24/08/01)  
1964-2001/Aug

Occupational Safety and Health (Datastar searched – 24/08/01)  

Conference Papers Index (Datastar searched – 24/08/01)  
1973-2001/July

Dissertation Abstracts (Datastar searched – 24/08/01)  
1861-2001/July

SciSearch (Datastar searched – 24/08/01)  
1990-2001/Aug

b108,109,317,40,103,6,161,294,77,35  
1. s risk()management()system? ?  
2. s risk()reporting()system? ?  
3. s safety()management()system? ?  
4. s accident?(2n)reporting  
5. s serious()incident()reporting  
6. s serious()incident()monitoring  
7. s incident(2n)report?  
8. s incident(2n)monitoring  
9. s accident(2n)monitoring  
10. s promoting(w)safety
11. s safety()promotion
19. s error()reduction
26. s high(w)reliability()organization? ?
27. s pilot? ? or aviation or air()industry or airline()industry or air()travel or air()traffic()control or flight()control?
28. s oil()industry or chemical()industry or petrochemical()industry
29. s nuclear()power or nuclear()industry
30. s dt=letter or dt=comment or dt=editorial
31. s s1:s26
32. s s27:s29
33. s s31 and s32
34. s s33 not s30
Appendix 2 – Direct intervention studies

1. Computerised/automated systems (alphabetical order)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Field</th>
<th>Author</th>
<th>Year</th>
<th>Country</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To assess the potential alteration of the frequency of errors associated with the use of record and verify systems (RVS) during radiation treatment delivery.</td>
<td>Health (radiotherapy)</td>
<td>BarthelEMY-Brichant41</td>
<td>1999</td>
<td>Belgium</td>
<td>Direct interventions</td>
<td>Observational study</td>
<td>Computerised record and verify system (RVS) which prevents the delivery of ionising radiations when the settings of the treatment machine do not match the intended parameters within some maximal authorised deviation.</td>
<td>Single hospital.</td>
<td>Treatment sessions of 593 cancer patients treated by external radiation beam.</td>
<td>Of the 147,476 parameters examined during the 6 month study period, 678 (0.46%) were set erroneously. At least one error occurred in 628 (3.22%) of the 19,512 treated fields. An erroneous parameter was introduced in the RVS memory in 22 (1.17%) of the 1885 fields.</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>Aims</td>
<td>Field</td>
<td>Author</td>
<td>Year</td>
<td>Country</td>
<td>Aims</td>
<td>Design</td>
<td>Intervention</td>
<td>Setting</td>
<td>Participants</td>
<td>Results</td>
<td>Comments</td>
<td>Relevant to implementation?</td>
</tr>
<tr>
<td>Direct interventions</td>
<td>To develop a new method to improve the detection and characterisation of adverse drug events (ADEs) in hospital patients.</td>
<td>Health</td>
<td>Classen71</td>
<td>1991</td>
<td>USA</td>
<td>Direct interventions</td>
<td>Observational study</td>
<td>Computerised ADE monitor and computer programs written using an integrated hospital information system to allow for multiple source detection of potential ADEs occurring in hospital patients.</td>
<td>Single hospital.</td>
<td>Treatment sessions of 593 cancer patients treated by external radiation beam.</td>
<td>Over 18 months, 36,653 hospitalised patients were monitored.</td>
<td>The system identified 731 ADEs in 648 patients. 701 ADEs were classified as moderate or severe and 664 were classified as type A reactions. During the same period, only nine ADEs were identified using traditional detection methods. Physicians, pharmacists and nurses voluntarily reported 92 of the 731 ADEs detected using the automated system.</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Classification
- Direct interventions

### Field
- Health care

### Author
- Bates

### Year
- 1998

### Country
- USA

### Aims
To evaluate the efficacy of 2 interventions for preventing non-intercepted serious medication errors, defined as those that either resulted in or had potential to result in an adverse drug event (ADE) and were not intercepted before reaching the patient.

### Design
Before and after comparison between phase 1 (baseline) and phase 2 (after intervention was implemented) and, within phase 2, a randomised between physician computer order entry (POE) and the combination of POE plus a team intervention.

### Intervention
1) POE - online ordering system which provided physicians with a menu of medications from the formulary and default doses and a range of potential doses for each medication. Physicians were required to enter dosage, route, and frequency of all orders. For some medications, laboratory results or consequent orders were displayed at the time of ordering. Also included limited drug-allergy, drug-drug interaction, and drug-laboratory checking.

2) POE plus team intervention - POE plus process changes including: changing the role of the pharmacist; distributing a recommended dilutions chart; making available a computerised drip-rate calculation program; standardising labeling of intravenous bags, tubes, and pumps; and implementing a pharmacy communication log so that nursing staff could communicate better with the pharmacy staff.

### Setting
- 6 units (6 months, Phase 1) and 8 units (9 months, Phase 2) in a women's hospital.

### Participants
- 2491 admissions (12,218 patient days) at Phase 1. 4220 admissions (24,539 patient days) at Phase 2.

### Results
In paired analysis comparing phase 1 and phase 2, the rate of non-intercepted serious medication errors fell 55%, from 10.7 to 4.86 events per 1000 patient days (p=0.01), and the rate of non-intercepted ADEs fell 84% (p=0.002). The rate of preventable ADEs fell, but not significantly (p=0.37), in phase 2, and the rate of nonpreventable errors remained unchanged. Similar results were found with unpaired analysis.

When the team intervention was controlled for, the results did not change. Contemporaneous analyses comparing phase 2 POE plus team intervention with POE-only units showed no significant differences for any of the event types.

### Comments
- Relevant to implementation?
  - Yes
### Classification
- Direct interventions
- Field: Health (prescribing)
- Author: Bates
- Year: 1999
- Country: USA

### Aims
To evaluate the impact of computerised physician order entry (POE) with decision support in reducing the number of medication errors.

### Design
- Prospective time series, with 4 periods.

### Intervention
- POE system refined over each study period.
- Baseline: Orders written on paper. No automated decision support.
- Period 1: Basic POE in place.
- Period 2: Improved allergy checking introduced.
- Period 3: Improved potassium ordering and improved drug-drug interaction checking introduced.

### Setting
- Three medical units in a single hospital.

### Participants
- All patients admitted for 7-10 week periods in 4 different years, and their inpatient prescriptions.

### Results
- Non-missed-dose medication error rate fell 81% from 142 per 1000 patient-days (baseline) to 26.6 per 1000 patient-days (final period), p<0.0001. Non-intercepted serious medication errors fell 86% from baseline to the final period (p=0.0003).
- Large differences were seen for all main types of medication errors: dose errors, frequency errors, route errors, substitution errors, and allergies.

### Comments
- Temporal effects may have accounted for the large effect seen, immediately after the introduction of the intervention.

### Relevant to implementation?
- Yes

---

### Classification
- Direct interventions
- Field: Health (dispensing)
- Author: Borel
- Year: 1995
- Country: USA

### Aims
To determine the effect of an automated drug-dispensing system on medication error rates.

### Design
- Before-and-after study. Observations were made for one month before (phase 1), and two months after (phase 2) implementation of the intervention.

### Intervention
- Implementation of Medstation Rx (Pyxis, San Diego, CA) - an automated, computer controlled dispensing device that stores drugs directly on the nursing unit so that they are immediately available to the nurse.

### Setting
- Single nursing unit.

### Participants
- 873 'observations' during phase 1, 929 observations during phase 2.

### Results
- In phase 1 there was an error rate of 16.9% (148/873), during phase 2 the error rate was 10.4% (97/929). In both phases, most medication errors were wrong-time errors. The mean (SD) difference between actual and scheduled administration times was 34.5 (48.9) minutes in phase 1 and 30.1 (31.6) minutes in phase 2. Both the decrease in error rate and departure from scheduled administration times were statistically significant.

### Comments
- The authors question the practical value of the observed decrease in wrong-time errors.

### Relevant to implementation?
- No
<table>
<thead>
<tr>
<th>Classification</th>
<th>Direct interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Health (nursing)</td>
</tr>
<tr>
<td>Author</td>
<td>Brown</td>
</tr>
<tr>
<td>Year</td>
<td>1995</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
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</tbody>
</table>

**Aims**
To evaluate the impact of bedside terminals on: (1) the proportion of time RNs spend in direct care activities, (2) RN overtime, (3) unit medication error rate, (4) RN attitudes regarding bedside terminal technology.

**Design**
Before-and-after study.

**Intervention**
Hand-held portable bedside terminal system (BTS), including a screen for displaying patient data, a menu-driven key pad for entering, reviewing and retrieving clinical information, and an optical bar code reader for medication administration and recording of clinical charges.

**Setting**
Single nursing unit.

**Participants**
Unclear.

**Results**
RN spent 31.5% of their time in direct care activities after implementation, compared to 38.5% before implementation. 5% of RNs time was spent in interaction with bedside computer units. Overall RN attitudes toward bedside automation became less positive after implementation of the system (p<0.05). Total RN overtime decreased from 66 hours in the pre-implementation two weeks, to 38 hours in the postimplementation two weeks. Unit medication errors remained unchanged (0.7 errors per 1000 doses).

**Comments**
The authors state that the internal validity of these results was threatened by organisational changes that directly and indirectly affected the study unit.

**Relevant to implementation?**
No

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<table>
<thead>
<tr>
<th>Classification</th>
<th>Direct interventions</th>
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<tbody>
<tr>
<td>Field</td>
<td>Health (prescribing/dispensing)</td>
</tr>
<tr>
<td>Author</td>
<td>Cherici</td>
</tr>
<tr>
<td>Year</td>
<td>1993</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
</tbody>
</table>

**Aims**
To determine whether a computerised medication administration record (CMAR) would reduce medication errors.

**Design**
Unclear.

**Intervention**
CMAR implemented with the input of a collaborative team representing nurses, pharmacists, staff development, medical staff, management information and medical records.

**Setting**
Single hospital.

**Participants**
Unclear.

**Results**
Error rate in creased in the first 3 months after implementation of CMAR, but quickly returned to its previous level and continued to fall. Within the next year, the rate reached 50% of the average incident rate from the pre-implementation period.

**Comments**
The paper describes the implementation process, but it is unclear how outcome data was obtained.

**Relevant to implementation?**
No
<table>
<thead>
<tr>
<th>Field</th>
<th>Author</th>
<th>Year</th>
<th>Country</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
<th>Relevant to implementation?</th>
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<tr>
<td>Health (psychiatry)</td>
<td>Dumortier</td>
<td>1999</td>
<td>France</td>
<td>To estimate the impact of pharmaceutical interventions on the</td>
<td>Observational study</td>
<td>Interventions made by pharmacists, including checking high dose prescriptions</td>
<td>Single hospital</td>
<td>Unclear</td>
<td>In one year, pharmacists intervened in 510 prescriptions: 315 high</td>
<td>No</td>
<td>No</td>
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<td>security of the treatment prescribed.</td>
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<td>and providing pharmaceutical advice to physicians.</td>
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<td>prescribing doses were checked. The interventions rate was estimated</td>
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<td>Design</td>
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<td>to be 3.6% of new prescriptions. In 14.1% of these cases, they appeared as</td>
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<td></td>
<td>to be 3.6% of new prescriptions. In 14.1% of these cases, they</td>
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<td>Intervention</td>
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<td>clinically significant.</td>
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<td>appeared as clinically significant.</td>
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<td>Results</td>
<td></td>
<td>The computer-based monitoring strategy identified 2,620 alerts, of which 275</td>
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<td>Setting</td>
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<td>were determined to be ADEs. The chart review found 398 ADEs, whereas</td>
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<td>Participants</td>
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<td>voluntary report detected 23. Of the 617 ADEs detected by at least one</td>
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<td>Results</td>
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<td>method, 76 were detected by both computer monitor and chart review. The</td>
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<td>Setting</td>
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<td>computer monitor identified 45%; chart review, 65%; and voluntary report,</td>
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<td>Participants</td>
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<td>4 percent.</td>
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<td></td>
<td>Results</td>
<td></td>
<td>Comments</td>
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<td></td>
<td>Though producing many alerts, the computerised monitor detected less</td>
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<td>Setting</td>
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<td>Actual events than did chart review.</td>
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<td>Actual events than did chart review.</td>
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<td>Participants</td>
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<td>Comments</td>
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<tr>
<td>Health (dispensing)</td>
<td>Kratz</td>
<td>1992</td>
<td>USA</td>
<td>To compare the accuracy of unit dose cart fill with an automated</td>
<td>'Cohort' study</td>
<td>The Baxter Automatic Tablet Control (ATC-212) System, which automatically</td>
<td>Single hospital</td>
<td>15, 153 total doses, dispensed over 43 days. 12, 660 (83.6%) dispensed</td>
<td>Statistical significance not assessed.</td>
<td>Yes</td>
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<td>computerised system and manual filling.</td>
<td></td>
<td>packages and labels oral solid medications into unit dose form.</td>
<td></td>
<td></td>
<td>by ATC-212, 2,493 (16.4%) dispensed manually.</td>
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<td></td>
<td>Design</td>
<td></td>
<td>Results</td>
<td></td>
<td></td>
<td>A total of 187 errors were made, 3 (1.6%) made by ATC-212 filling, and</td>
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<td>Intervention</td>
<td></td>
<td>Results</td>
<td></td>
<td></td>
<td>184 (98.4%) made by manual filling. ATC-212 cart fill was 99.98%</td>
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<td>Setting</td>
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<td>Results</td>
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<td></td>
<td>accurate, and manual cart fill was 92.62% accurate.</td>
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<td>Participants</td>
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<td>Comments</td>
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<td></td>
<td></td>
<td></td>
<td>Results</td>
<td></td>
<td>Comments</td>
<td></td>
<td></td>
<td>Statistical significance not assessed.</td>
<td></td>
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</tr>
</tbody>
</table>

61
### Aims
To evaluate the effect of an automatic alerting system on the time until treatment is ordered for patients with critical laboratory results.

### Design
Prospective randomised controlled trial

### Intervention
A computer system to detect critical conditions and automatically notify the responsible physician via the hospital’s paging system.

### Setting
Single hospital

### Participants
Medical and surgical inpatients.

### Results
192 alerting situations (94 interventions, 98 controls) were analysed. The intervention group had a 38% shorter median time interval (1.0 hours vs. 1.6 hours, p=0.003; mean, 4.1 vs. 4.6 hours, p=0.003) until an appropriate treatment was ordered. There was no significant difference between the groups in the number of adverse events.

### Comments

**Relevant to implementation?**
No

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### Aims
To determine whether the user interface of a patient-controlled analgesia (PCA) pump could be made safer and more efficient if redesigned using human factors techniques and principles.

### Design
Unclear.

### Intervention
A redesigned PCA pump user interface, based on the findings of cognitive task analysis of bench tests and field observations.

### Setting
Unclear.

### Participants
Twelve student nurses.

### Results
The results showed significantly faster programming times (p=0.025), lower mental workload ratings (p=0.025), and fewer errors with the new interface (p=0.05).

### Comments
These findings were not obtained in a clinical setting.

**Relevant to implementation?**
No
### Lau (2000, China)

**Classification**
Direct interventions  
Field: Health (blood transfusion)  
**Author**: Lau  
**Year**: 2000  
**Country**: China

**Aims**
To evaluate a wristband system for reducing transmission errors due to blood sampling from the wrong patient.

**Design**
Observational study.

**Intervention**
Transfusion wristband with 4 special features:  
(i) once attached, can only be removed by cutting;  
(ii) has a pocket containing a transfusion label;  
(iii) a unique transfusion barcode is printed on each transfusion label and the corresponding wristband simultaneously by computer;  
(iv) a transfusion label removed from the wristband after attachment to the patient has a characteristic tear-mark distinguishing it from one removed prior to attachment.

**Setting**
Single hospital

**Participants**
2189 patients receiving pretransfusion compatibility tests.

**Results**
Of 2189 patient samples tested using this procedure, 2 potential mismatched transfusions which would not previously have been detected were avoided. The system was well accepted by both ward and blood bank staff.

**Comments**
No comparison group.

**Relevant to implementation?**
Yes

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### Marconi (2000, Italy/USA)

**Classification**
Direct interventions  
Field: Health (transfusion)  
**Author**: Marconi  
**Year**: 2000  
**Country**: Italy/USA

**Aims**
To evaluate the feasibility of using an electronic identification system to improve safety and documentation of blood transfusions.

**Design**
Observational study.

**Intervention**
I-TRAC Plus (Immucor, Inc., Norcross, GA), a computerised bedside verification system designed to monitor the blood transfusion process. The system consists of a handheld barcode scanner and data terminal, portable label printer, and related software.

**Setting**
Two hospitals: one in Italy, one in the USA.

**Participants**
A total of 621 blood components were transfused to 177 patients using 331 blood samples.

**Results**
All I-TRAC Plus functions, including the reading of wristband bar codes, generation of blood sample labels, printing of labels for blood components, and positive identification of blood transfusion recipients, were 100 percent accurate. The sample label barcode provided 100 percent positive identification in both laboratories.

**Comments**
Primarily a description of the technology, with very few available study details.

**Relevant to implementation?**
No
<table>
<thead>
<tr>
<th>Classification</th>
<th></th>
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<tbody>
<tr>
<td>Direct interventions</td>
<td></td>
</tr>
<tr>
<td>Field</td>
<td>Health (dispensing)</td>
</tr>
<tr>
<td>Author</td>
<td>McMullin43</td>
</tr>
<tr>
<td>Year</td>
<td>1997</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
<tr>
<td>Aims</td>
<td>To describe a hospital’s experience with an automated system for screening drug orders for potential dosage problems.</td>
</tr>
<tr>
<td>Design</td>
<td>Observational study.</td>
</tr>
<tr>
<td>Intervention</td>
<td>‘DoseChecker’ system which identifies patients receiving any of 35 identified medications, evaluates appropriateness of current dosages, and generates alerts for patients potentially needing dosage adjustments.</td>
</tr>
<tr>
<td>Setting</td>
<td>Single hospital.</td>
</tr>
<tr>
<td>Participants</td>
<td>Unclear.</td>
</tr>
<tr>
<td>Results</td>
<td>The system detected potential dosage problems in 2859 (10%) of 28,528 drug orders. It recommended a lower dose in 1992 cases (70%) and a higher dose in 867 (30%). Pharmacists contacted physicians concerning 1163 (41%) of the 2859 alerts; in 868 cases (75%), the physicians agreed to adjust the dosage.</td>
</tr>
<tr>
<td>Comments</td>
<td>-</td>
</tr>
<tr>
<td>Relevant to implementation?</td>
<td>Yes</td>
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</table>

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<tbody>
<tr>
<td>Direct interventions</td>
<td></td>
</tr>
<tr>
<td>Field</td>
<td>Health (prescribing)</td>
</tr>
<tr>
<td>Author</td>
<td>McMullin36</td>
</tr>
<tr>
<td>Year</td>
<td>1999</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
<tr>
<td>Aims</td>
<td>To evaluate the use of a web-based clinical information system to serve as a safety net intended to compensate for the limitations of a commercially available drug-interaction screening system.</td>
</tr>
<tr>
<td>Design</td>
<td>Retrospective analysis of prescribed contraindicated drug combinations.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Web-based clinical information system which identifies drug interactions with newly marketed medications not screened by an existing commercial program, and generates a second alert on dangerous interactions that were overridden during the order process.</td>
</tr>
<tr>
<td>Setting</td>
<td>Hospital pharmacy department.</td>
</tr>
<tr>
<td>Participants</td>
<td>265 medical records.</td>
</tr>
<tr>
<td>Results</td>
<td>The rate of dangerous drug combinations declined from 9.0% of cisapride orders in 1994/5 to 3.1% in 1996/7 (p&lt;0.001). There was a significant reduction in the mean [SD] duration of contraindicated therapy (4.1 [3.8] vs 1.6 [1.4] days, p&lt;0.001) and number of patients being discharged under treatment with a dangerous drug combination (36.2% vs 7.7%, p&lt;0.001). During the control period, three patients (1.7%) experienced serious adverse events that may have been related to the targeted drug reactions. No symptomatic cardiac events were identified during the study period (p=0.21).</td>
</tr>
<tr>
<td>Comments</td>
<td>Authors state that the low specificity of computerised screening systems results in many alerts of questionable significance being generated. This may lead to busy users ignoring all alerts.</td>
</tr>
<tr>
<td>Relevant to implementation?</td>
<td>Yes</td>
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<tr>
<td>Classification</td>
<td>Direct interventions</td>
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</tr>
<tr>
<td>Author</td>
<td>Miller42</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
<tr>
<td>Aims</td>
<td>To develop and implement a display pager strategy for notifying clinical pharmacists of alerts generated in real-time by two pharmacy expert systems: one for drug dosing and the other for adverse drug event prevention.</td>
</tr>
<tr>
<td>Design</td>
<td>Observational study.</td>
</tr>
<tr>
<td>Intervention</td>
<td>DoseChecker and PharmADE alerts presented to pharmacists by display pager.</td>
</tr>
<tr>
<td>Setting</td>
<td>Single hospital.</td>
</tr>
<tr>
<td>Participants</td>
<td>Eleven clinical pharmacists rating 147 DoseChecker and 4 PharmADE alerts over 30 days.</td>
</tr>
<tr>
<td>Results</td>
<td>Overall pharmacist agree rate increased from 39% from the previous ‘batch’ system to 52% for the new system. Pharmacists said the display pager was the most appropriate delivery method 67% (76/114) of the time. 74% (84/114) agreed the alerts were delivered in a clinically appropriate time frame. 23% (26/114) were considered to be delivered earlier than clinically appropriate, and 3% (4/114) delivered late than clinically appropriate.</td>
</tr>
<tr>
<td>Comments</td>
<td>Relevant to implementation? Yes</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Classification</th>
<th>Direct interventions</th>
<th>Field</th>
<th>Health (dispensing)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Milliken38</td>
<td>Year</td>
<td>1990</td>
</tr>
<tr>
<td>Country</td>
<td>Canada</td>
<td></td>
<td></td>
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<tr>
<td>Aims</td>
<td>To evaluate the impact of computerisation of a centralised unit dose drug distribution system on the number and source of medication discrepancies.</td>
<td></td>
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<tr>
<td>Design</td>
<td>Twelve day missing dose audit.</td>
<td></td>
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<tr>
<td>Intervention</td>
<td>Computerisation of a centralised unit dose drug distribution system.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setting</td>
<td>Two nursing units in a single hospital.</td>
<td></td>
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<tr>
<td>Participants</td>
<td>Physicians, pharmacy and nursing staff.</td>
<td></td>
<td></td>
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<tr>
<td>Results</td>
<td>After computerisation, there was a 17% reduction in medication discrepancies and a 41% decrease in the number of phone calls received for missing doses.</td>
<td></td>
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<tr>
<td>Comments</td>
<td>Conclusions are based on a comparison with a previous audit, the results of which are not given or discussed. Relevant to implementation? Yes</td>
<td></td>
<td></td>
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<tr>
<td>Classification</td>
<td>Aims</td>
<td>Design</td>
<td>Intervention</td>
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</tr>
<tr>
<td>Direct interventions</td>
<td>To use computer-enhanced clinical practice evolution to improve quality while reducing costs.</td>
<td>Unclear.</td>
<td>'Computer-enhanced clinical practice evolution'. An educational process driven by the medical literature and monitored by clinical outcome measurement.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To implement and assess a rules based computerised prescribing system with the aim of improving the safety of prescriptions and the administration of drugs.</td>
<td>Observational study of performance of computerised system plus questionnaire survey of users.</td>
<td>Implementation of a rules based computerised prescribing system in routine clinical use.</td>
<td>Single hospital renal services unit</td>
<td>System analysis: 87,789 prescriptions, related to patients with end stage renal failure, and/or renal transplantation. User survey: 18 doctors, 34 nurses.</td>
<td>Over 11 months, the system cancelled 58 (0.07%) out of 87,789 prescriptions on the grounds of clinical safety. 427 (57%) of attempted prescriptions generating high level warnings and 1257 (8%) generating low level warnings were not completed. 82% (31/38) of doctors and nurses considered the system to be an improvement on conventional procedures.</td>
<td>Introduction of the system has not been examined on patient outcomes.</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Aims: To determine whether automated, guideline-based reminders to physicians, provided as they wrote orders, could reduce errors of omission.

Design: RCT

Intervention: Implementation of a rule-based reminder program which, when given a 'trigger' order by a physician, analysed the data in a patient's electronic medical record and determined which, if any, corollary orders should be presented.

Setting: Six independent services within a single teaching hospital.

Participants: 2,181 different patients over 30 weeks.

Results: Reminders about corollary orders were presented to 48 intervention physicians and withheld from 41 control physicians. Intervention physicians ordered the suggested corollary orders in 46.3% of instances where they received a reminder, compared with 21.9% compliance by control physicians (p<0.0001). Physicians discriminated in their acceptance of suggested orders, readily accepting some while rejecting others. There were one third fewer interventions initiated by pharmacists with physicians in the intervention than control groups.

Comments: Errors of omission were defined as where 'physicians often fail to order tests or treatments needed to monitor/ameliorate the effects of other tests or treatments.

Relevant to implementation?: Yes

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Aims: To evaluate the implementation of the medication-management component of a point-of-care information system.

Design: Unclear.

Intervention: Point-of-care information system (CliniCare) which provides online medication profiles, medication administration scheduling, and other patient data. All medications are bar coded and are scanned at or near the patient's bedside by using hand-held scanners; this prompts a safety check, records medication administration, and generates the drug charge.

Setting: Single hospital

Participants: Unclear.

Results: Authors report that use of the system has resulted in a lower medication rate, improved medication records, improved scheduling of medications, better communications between nursing and pharmacy staff, more efficient drug monitoring, and more accurate and timely billing. Problems included the need for a bar-coding operation for unit dose oral solids and injectable dosage forms, the steep learning curve for nurses and some physicians, and resistance to change from a manual system.

Comments: It is unclear exactly how the data were obtained to support these findings.

Relevant to implementation?: No
### Classification
- Direct interventions
- Field: Health (prescribing)
- Author: Raschke "54
- Year: 1998
- Country: USA

<table>
<thead>
<tr>
<th>Aims</th>
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<tbody>
<tr>
<td>To develop, implement, and evaluate a computer alert system designed to correct errors that might lead to ADEs and to detect ADEs before maximum injury occurs.</td>
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<table>
<thead>
<tr>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective case series</td>
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</table>

<table>
<thead>
<tr>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td>Thirty-seven drug-specific ADEs were targeted. The hospital information system was programmed to generate alerts in clinical situations with increased risk for ADE-related injury.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Setting</th>
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</thead>
<tbody>
<tr>
<td>Single hospital.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>9306 consecutive nonobstetrical adult patients admitted during the last 6 months of 1997.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>During the study, the system fired 1116 times and 596 were true-positive alerts (positive predictive value of 53%). The alerts identified opportunities to prevent patient injury secondary to ADEs at a rate of 64 per 1000 admissions. 265 (44%) of the 596 true-positive alerts were unrecognised by the physician prior to alert notification.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Comments</th>
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<tbody>
<tr>
<td>Relevant to implementation?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

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### Classification
- Direct interventions
- Field: Health (oncology)
- Author: Rastoul "81
- Year: 1996
- Country: France

<table>
<thead>
<tr>
<th>Aims</th>
</tr>
</thead>
<tbody>
<tr>
<td>To compute medication errors during 49 days of dispensation using a unit dose drug distribution system (UDDS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observational study</td>
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</table>

<table>
<thead>
<tr>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td>Pharmaceutical team-designed, computerised UDDS</td>
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<tr>
<th>Setting</th>
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<tr>
<td>Single hospital</td>
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<table>
<thead>
<tr>
<th>Participants</th>
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<tbody>
<tr>
<td>Unclear</td>
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</table>

<table>
<thead>
<tr>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>A 2.3% global rate of errors was found (236 errors among 10,267 of prescribed drugs) including 0.54% of prescriptions errors, 1.4% of keyboarding errors and 0.4% of dispensing errors. Among the 236 errors, 53 (about 0.5%) were not detected by the pharmacy team.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>No comparison group or period.</td>
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</table>

<table>
<thead>
<tr>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
<tr>
<td>Classification</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Direct interventions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To quantify and describe the types of discrepancies that occur when health professionals interact with an automated storage and distribution cabinet (ASDC).</td>
<td>Observational study</td>
<td>The Pyxis Medstation (Pyxis Corporation, San Diego, CA)</td>
<td>Single hospital</td>
<td>188 transactions involving access to an ASDC by nursing staff were included in the analysis.</td>
<td>Of the 188 transactions which were analysed, 13 were access discrepancies (6.9%). The discrepancies comprised of nine cases of access without an active physicians order (69.2%), two incorrect frequencies (15.4%), one incorrect dose (7.7%), and one incorrect dosage form (7.7%). No discrepancies involved the incorrect patient or incorrect drug.</td>
<td>Relevant to implementation? No</td>
</tr>
<tr>
<td>Classification</td>
<td>Aims</td>
<td>Design</td>
<td>Intervention</td>
<td>Setting</td>
<td>Participants</td>
<td>Results</td>
<td>Comments</td>
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</tr>
<tr>
<td>Direct interventions</td>
<td>To evaluate the impact of implementing a computerised patient record system (CPRS).</td>
<td>Survey of staff members and two 'time studies'.</td>
<td>CPRS.</td>
<td>Single nursing home.</td>
<td>Survey of all staff.</td>
<td>61% of survey respondents reported that CPRS increased efficiency in finding patient information. 66% percent reported it leading to increased efficiency in patient documentation. 100% felt it had a positive effect on the work of staff members. CPRS resulted in 61% time savings for finding radiology reports (p=0.006) and 52% time savings for patient documentation and ordering (p=0.001).</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To assess the impact of an inpatient computerised physician order entry system on prescribing practices.</td>
<td>Time series.</td>
<td>Computerised physician order entry system.</td>
<td>Single hospital.</td>
<td>Inpatient prescriptions (total number unclear).</td>
<td>Use of a computerised guideline resulted in a change in use of the recommended drug (nizatidine) from 15.6% of all H2-blocker orders to 81.3% (p&lt;0.001). Implementation of dose selection menus resulted in a decrease in the SD of drug doses by 11% (p&lt;0.001). The proportion of doses that exceeded the recommended maximum decreased from 2.1% to 0.6% (p&lt;0.001). Display of a recommended frequency for ondansetron hydrochloride administration resulted in an increase in the approved frequency from 6% of all ondansetron orders to 75% (p&lt;0.001). The use of subcutaneous heparin sodium to prevent thrombosis in patients at bed rest increased from 24% to 47% when the computer suggested the option (p&lt;0.001). All these changes persisted at 1- and 2-year follow-up analyses.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>Aims</td>
<td>Field</td>
<td>Health (A&amp;E/radiography)</td>
<td>Author</td>
<td>Weatherburn49</td>
<td>Year</td>
<td>2000</td>
<td>Country</td>
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</table>

**Aims**
To identify the benefits to the accident and emergency (A&E) department of a hospital wide Picture Archiving and Communication System (PACS).

**Design**
Before-and-after study. 'Before' period used conventional film images, 'after' period used PACS.

**Intervention**
PACS, which acquires, transports and stores radiographic images electronically. Tools are available which allow clinicians to manipulate the soft copy images, including variation of the grey scale and contrast, and zooming to magnify part of the image and increase its resolution.

**Setting**
Single A&E department.

**Participants**
Unclear. Radiographs from 7933 patients were examined.

**Results**
The overall rate of misdiagnosis across all A&E patients who had radiography was low in both periods and there was a significant reduction when PACS was used (1.5% for film and 0.7% for PACS, 95% CI for difference between proportions: -0.014 to -0.0034), but the rate of serious misdiagnoses involving patient recall did not change significantly (95% CI for difference between proportions: -0.0059 to +0.0001).

**Comments**
'Misdiagnosis' was defined as false negative findings on radiographic images by A&E clinicians.

**Relevant to implementation?**
Yes

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<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Field</th>
<th>Health (prescribing)</th>
<th>Author</th>
<th>Wilson48</th>
<th>Year</th>
<th>1997</th>
<th>Country</th>
<th>USA</th>
</tr>
</thead>
</table>

**Aims**
To assess the improvements resulting from sharing a computerised medication record.

**Design**
Before-after study.

**Intervention**
The implementation of a shared, computerised medication administration record (MAR) for pharmacy and nursing.

**Setting**
Single hospital.

**Participants**
Data about medication occurrences' for 1 year before and 1 year after the implementation of the shared MAR system.

**Results**
Average medication occurrences per admission decreased from 0.1084 to 0.0658 (p<0.01). Medication errors per dose decreased from 0.0005 to 0.0003 (p<0.01).

**Comments**
A 'medication occurrence' defined as "any occurrence, accident, injury, event, misadministration or quality issue related to medication administration that could or did result in an injury to a patient".

**Relevant to implementation?**
Yes
### 2. Education/training interventions (alphabetical order)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Direct interventions</th>
<th>Field</th>
<th>Health (prescribing)</th>
<th>Author</th>
<th>Howell(^o)</th>
<th>Year</th>
<th>1993</th>
<th>Country</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>To determine whether the the review of duplicate prescriptions could be enhanced by adding the patient's diagnosis to the prescription.</td>
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<tr>
<td></td>
<td></td>
<td><strong>Design</strong></td>
<td>Before-and-after study.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td><strong>Intervention</strong></td>
<td>In-service training to instruct all first-year residents in prescription writing and to review common prescription-writing errors.</td>
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<tr>
<td></td>
<td></td>
<td><strong>Setting</strong></td>
<td>Primary care.</td>
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<td></td>
<td></td>
<td><strong>Participants</strong></td>
<td>Eight first-year family practice residents.</td>
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<td><strong>Results</strong></td>
<td>The number of prescriptions with the patient's diagnosis increased significantly following the in-service training (from 20% to 61%, (p&lt;0.001)). The rate of prescription-writing errors (omissions, dose or direction, legal requirements, nonprescription product, quantity, and incomplete directions) and markers (indication of use and duration of therapy) were not significantly changed between the before and after periods.</td>
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<td></td>
<td></td>
<td><strong>Comments</strong></td>
<td>Relevant to implementation?</td>
<td>No</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Direct interventions</th>
<th>Field</th>
<th>Health</th>
<th>Author</th>
<th>Alibhai(^78)</th>
<th>Year</th>
<th>1999</th>
<th>Country</th>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>To determine the amount of time spent providing medication education to older patients, the impact of medication education on patients’ knowledge and satisfaction, and barriers to providing medication education.</td>
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<td></td>
<td></td>
<td><strong>Design</strong></td>
<td>Survey</td>
<td></td>
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<td></td>
<td></td>
<td><strong>Intervention</strong></td>
<td>Medication education</td>
<td></td>
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<td></td>
<td></td>
<td><strong>Setting</strong></td>
<td>Single internal medicine ward</td>
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<tr>
<td></td>
<td></td>
<td><strong>Participants</strong></td>
<td>Forty-seven patients (mean age 77.1 years) participated in the survey. Physicians, pharmacists and nurses involved in the care of these patients were also interviewed.</td>
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<td><strong>Results</strong></td>
<td>Respondents reported that physicians spent a mean of 10.5 minutes (range 0-60 mins) and pharmacists spent a mean of 5.3 mins (range 0-40 mins) providing medical education. Fifty-one reported receiving no education from either physician or pharmacist, and only 30% reported receiving written medication instructions. Respondents were generally quite satisfied with their education. Physicians identified one or more barriers to providing education 51% of the time and pharmacists 80%. Lack of time was the most common barrier (18%) identified by physicians, but pharmacists cited lack of notification discharge plans (41%) and lack of time (39%) as the main barriers. Respondents made many medication errors and knew little about their medication.</td>
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<td></td>
<td></td>
<td><strong>Comments</strong></td>
<td>Relevant to implementation?</td>
<td>No</td>
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</table>

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<table>
<thead>
<tr>
<th>Classification</th>
<th>Direct interventions</th>
<th>Field</th>
<th>Health (nursing)</th>
<th>Author</th>
<th>Ludwig-Beymer</th>
<th>Year</th>
<th>1977</th>
<th>Country</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aims</strong></td>
<td>To explore the impact of eliminating a yearly medication test for staff nurses.</td>
<td><strong>Design</strong></td>
<td>Retrospective before-and-after study, plus postal survey and telephone interview.</td>
<td><strong>Intervention</strong></td>
<td>Discontinuation of an annual written medication exam, consisting of 22 multiple choice and 12 matching questions, as well as 5 dosage calculation questions.</td>
<td><strong>Setting</strong></td>
<td>Single hospital.</td>
<td><strong>Participants</strong></td>
<td>14 RNs responded to the questionnaire, 5 participated in telephone interview.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Direct interventions</th>
<th>Field</th>
<th>Health (anaesthesia)</th>
<th>Author</th>
<th>Olympio</th>
<th>Year</th>
<th>1996</th>
<th>Country</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aims</strong></td>
<td>To determine clinical anaesthesia (CA) residents' performance of institutional checkout procedures and the degree of their improvement after instrucional video review.</td>
<td><strong>Design</strong></td>
<td>RCT. Both intervention and control groups were videotaped (VT1) performing a list of pre-use checkout procedures. The control group had a second videotaping (VT2), whereas the intervention group received instructional review of VT1 prior to VT2.</td>
<td><strong>Intervention</strong></td>
<td>Instructional review prior to second videotaping.</td>
<td><strong>Setting</strong></td>
<td>Single hospital.</td>
<td><strong>Participants</strong></td>
<td>Twenty-nine CA residents.</td>
</tr>
<tr>
<td>Classification</td>
<td>Aims</td>
<td>Field</td>
<td>Health and safety</td>
<td>Author</td>
<td>Weidner59</td>
<td>Year</td>
<td>1997</td>
<td>Country</td>
<td>USA</td>
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</tr>
<tr>
<td>Direct interventions</td>
<td>To evaluate the impact of training on emergency response personnel responding to hazardous material incidents.</td>
<td>Design</td>
<td>Postal and telephone surveys.</td>
<td>Intervention</td>
<td>'Hazmat' training for the emergency response community at the New Jersey/New York Hazardous Materials Worker Training Center.</td>
<td>Setting</td>
<td>Emergency response community (career and volunteer firefighters, police officers, and emergency medical personnel).</td>
<td>Participants</td>
<td>180 trainees responding to the postal survey, including 43 also contacted by telephone.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Field</th>
<th>Health (dispensing)</th>
<th>Author</th>
<th>Weber56</th>
<th>Year</th>
<th>1991</th>
<th>Country</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To evaluate the impact of a drug error awareness program (DEAP) in preventing common medication errors.</td>
<td>Design</td>
<td>Before-and-after study.</td>
<td>Intervention</td>
<td>Drug error awareness program (DEAP) designed to: increase pharmacy and nursing staff awareness of frequently occurring medication errors; review and monitor medication purchasing and at the hospital, and; inform pharmaceutical companies of packaging and labeling that could potentially cause problems.</td>
<td>Setting</td>
<td>Single hospital.</td>
<td>Participants</td>
<td>Unclear</td>
</tr>
</tbody>
</table>
### 3. ‘Independent checking’ interventions (alphabetical order)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To evaluate the execution of an independent control of monitor units (MU) and dose distribution calculation, together with a check of the data reported in the treatment chart, as a tool to detect systematic errors in external radiotherapy before treatment delivery.</td>
<td>Observational study.</td>
<td>Implementing daily checking of the MU and the dose distribution calculations which have been performed by another operator, together with a check of the irradiation data reported on the treatment chart.</td>
<td>Single hospital</td>
<td>6272 independent checks for around 5000 patients, collected over 5 years.</td>
<td>A total of 217 errors (3.5%) were detected by the independent check. 70 (1.1%) were daily dose serious errors (DDSEs; errors that would have caused a deviation larger than 5% of the daily dose), and 37 (0.6%) would have resulted in a deviation of 10% or more. Rate of total dose serious errors (TDSEs) was 0.74%.</td>
<td>The error rate was found to be strongly operator-dependent.</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To evaluate whether an antimicrobial review system is associated with a reduction in antimicrobial-associated adverse events.</td>
<td>Observational study</td>
<td>A monitoring program through which all antimicrobial orders are reviewed.</td>
<td>Single hospital.</td>
<td>102,200 antimicrobial orders were reviewed</td>
<td>1663 interventions intended to avoided adverse antimicrobial effects took place, a rate of 16 interventions per 1000 orders. A total of 452 interventions were classified as “high-level”. The incidence of high-level errors necessitating intervention was 4.4 per 1000 antimicrobial orders. An estimated 125 to 198 high-level adverse events were avoided.</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>Direct interventions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Field</strong></td>
<td>Health (dispensing)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Hawkey*64</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>1990</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>UK</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Aims**
To evaluate the medical impact of reactive pharmacy intervention.

**Design**
Observational study of all interventions made over 28 days by 35 pharmacists.

**Intervention**
Every important intervention made by pharmacists to prescriptions for both inpatients and outpatients.

**Setting**
Six hospitals.

**Participants**
Hospital inpatients and outpatients.

**Results**
769 interventions (about 2.9% of prescriptions) were made, of which 60 concerned prescriptions rated as having a major potential for medical harm. The pharmacist’s recommendation was accepted in 639 instances (86%), and the prescription was altered in 575, leading to an appreciable (246 cases) or minor (231 cases) improvement. Interventions had little or no effect on costs.

**Comments**
Relevant to implementation?
No

<table>
<thead>
<tr>
<th>Classification</th>
<th>Direct interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Field</strong></td>
<td>Health (Pathology)</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Kronz*74</td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>1999</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>USA</td>
</tr>
</tbody>
</table>

**Aims**
To determine the impact of mandatory second opinion surgical pathology by measuring the frequency of discordant diagnoses and to determine whether specific organ systems are particularly susceptible to disparate diagnosis.

**Design**
Prospective observational study

**Intervention**
Second opinion surgical pathology

**Setting**
Single hospital

**Participants**
6171 cases were reviewed

**Results**
Second opinion surgical pathology resulted in 86 changed diagnoses (1.4%). Compared with the entire group, 2 organ systems were significantly more likely to undergo a change in diagnosis: serosal surfaces (9.5%, p<0.0001) and the female reproductive tract (5.1%, p<0.0001).

**Comments**
The authors state that ‘although the overall percentage of affected cases is not large, the consistent rate of discrepant diagnosis uncovered by second opinion surgical pathology may have enormous human and financial impact’

Relevant to implementation?
No
<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To compare error rates when medication is administered by two nurses as against a single nurse.</td>
<td>Fifty-two week cross-over study (26 weeks each period).</td>
</tr>
<tr>
<td>Field</td>
<td></td>
<td>Intervention</td>
</tr>
<tr>
<td>Health (nursing)</td>
<td></td>
<td>Policy requiring two nurses to administer all medications.</td>
</tr>
<tr>
<td>Author</td>
<td></td>
<td>Setting</td>
</tr>
<tr>
<td>Kruse69</td>
<td></td>
<td>Three wards of a geriatric assessment and rehabilitation unit.</td>
</tr>
<tr>
<td>Year</td>
<td></td>
<td>Participants</td>
</tr>
<tr>
<td>1992</td>
<td></td>
<td>Unclear.</td>
</tr>
<tr>
<td>Country</td>
<td></td>
<td>Results</td>
</tr>
<tr>
<td>Australia</td>
<td></td>
<td>The error rate for all three wards was lower in the second 26 week period, regardless of whether they had changed medication administration from 1 to 2 nurses, or vice versa. The 'control' group which had 2 nurses administer medications throughout, also showed a significant reduction in error rate during the second period. The combined error rates for one nurse and two nurses were 2.98 and 2.12 per 1000 medications administered, respectively. The difference in error rate (0.86 per 1000) was statistically significant at the 0.05 level.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The authors do not recommend a policy requiring two nurses to administer all medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Relevant to implementation?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To evaluate an alternative system to serologic crossmatch in pretransfusion testing in terms of patient safety.</td>
<td>Observational study.</td>
</tr>
<tr>
<td>Field</td>
<td></td>
<td>Intervention</td>
</tr>
<tr>
<td>Health (blood transfusion)</td>
<td></td>
<td>A system where, if an antibody screen is negative, two technologists confirm the ABO of the same patient sample, and blood of the patients type is released without a serologic or electronic crossmatch.</td>
</tr>
<tr>
<td>Author</td>
<td></td>
<td>Setting</td>
</tr>
<tr>
<td>Kuriyan62</td>
<td></td>
<td>Single hospital</td>
</tr>
<tr>
<td>Year</td>
<td></td>
<td>Participants</td>
</tr>
<tr>
<td>2000</td>
<td></td>
<td>65,628 blood samples collected between January 1989 and December 1996.</td>
</tr>
<tr>
<td>Country</td>
<td></td>
<td>Results</td>
</tr>
<tr>
<td>USA</td>
<td></td>
<td>A total of 1,082 (1.64%) samples were rejected for mislabeling. Discordance in patient ABO typing results between two technologists was 0.43%. Such discrepancies were resolved before the release of blood units. No donor unit mislabeling or unit release errors were detected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No comparison group.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Relevant to implementation?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td><strong>Aims</strong></td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td>----------</td>
<td></td>
</tr>
<tr>
<td>Direct interventions</td>
<td>To measure the effect of pharmacist participation on medical rounds in the ICU on the rate of preventable adverse drug events (ADEs) caused by ordering errors.</td>
<td></td>
</tr>
<tr>
<td><strong>Field</strong></td>
<td><strong>Design</strong></td>
<td></td>
</tr>
<tr>
<td>Health (dispensing)</td>
<td>Before-and-after study</td>
<td></td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td><strong>Intervention</strong></td>
<td></td>
</tr>
<tr>
<td>Leape72</td>
<td>A senior pharmacist making rounds with the ICU team and remaining in the ICU for consultation during the morning, and being available on call throughout the day.</td>
<td></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td><strong>Setting</strong></td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td>Single intensive care unit (plus a second, control ICU)</td>
<td></td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td><strong>Participants</strong></td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>75 patients were randomly selected from each of 3 groups: all patients admitted to the study during phase 1 (baseline) and phase 2 (postintervention) and all patients admitted to the control unit during phase 2.</td>
<td></td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td><strong>Comments</strong></td>
<td></td>
</tr>
<tr>
<td>The rate of preventable ordering ADEs decreased by 66% from 10.4 per 1000 patient-days (95% CI: 7 to 14) before the intervention to 3.5 (95% CI: 1 to 5, p&lt;0.001) after the intervention. There was no significant difference between the same time periods in the control unit: 10.9 (95% CI: 6 to 16) per 1000 patient days before and 12.4 (95% CI: 8 to 17) after. The pharmacist made 366 recommendations related to drug ordering, 362 (99%) of which were accepted by physicians.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relevant to implementation?</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Classification</strong></th>
<th><strong>Aims</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To evaluate the impact of a 'roving pharmacist' system on reported medication incidents.</td>
</tr>
<tr>
<td><strong>Field</strong></td>
<td><strong>Design</strong></td>
</tr>
<tr>
<td>Health (dispensing)</td>
<td>Retrospective before-and-after.</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>Shah63</td>
<td>Placing a full-time pharmacist on nursing units. The 'roving' pharmacist makes rounds every half-hour on designated units, performs order entry, and provides a professional resource to the nursing staff and physicians.</td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td><strong>Setting</strong></td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td><strong>Participants</strong></td>
</tr>
<tr>
<td>USA</td>
<td>Unclear.</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td><strong>Comments</strong></td>
</tr>
<tr>
<td>There was a 29% reduction in incident rate for the first year of implementation, and a 43% reduction in the second.</td>
<td>Potential confounders are not considered.</td>
</tr>
<tr>
<td>Relevant to implementation?</td>
<td>No</td>
</tr>
</tbody>
</table>
4. Other interventions

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To investigate the relationship between level of illumination and prescription-dispensing error rate.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Field</th>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health (dispensing)</td>
<td>Quasi-experimental within-subjects (repeated-measures) design. Illumination levels were randomly assigned to 21 consecutive weekdays to obtain 7 days of observations per level of illumination.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Author</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buchanan</td>
<td>Three levels of illumination: 45, 102 and 146 foot-candles.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Setting</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>Five pharmacists, who filled 10,889 prescriptions.</td>
</tr>
</tbody>
</table>

| Aims | To evaluate differences in intravenous (IV) drug compounding costs and frequency of medication administration errors of omission before and after outsourcing of the hospital's IV admixture refill program to an alternate site home IV infusion pharmacy. |

<table>
<thead>
<tr>
<th>Design</th>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before-and-after study.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outsourcing of IV admixture program, using a redeployed IV technician as an IV recycling technician.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Setting</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three nursing units within a single hospital.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unclear</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>There was a significant difference in the frequency of medication administration errors of omission over the three nursing units between the pre-outsourcing and the postoutsourcing periods (chi-squared=4.11, df=1, p&lt;0.03). Overall, this equated to 0.0387 errors per dose scheduled to be administered pre-outsourcing and 0.0275 errors per dose scheduled to be administered postoutsourcing. A reduction in the cost of drugs and admixing supplies reduced first-year expenses by $56,356. A further one-off $30,000 for IV facility renovation was saved.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comments</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction of omission errors were not limited to IV admixtures, but was extended to drugs no matter what the route of administration.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relevant to implementation?</th>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Classification</td>
<td>Direct interventions</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Field</td>
<td>Health (transfusion)</td>
</tr>
<tr>
<td>Author</td>
<td>Mercuriali*68</td>
</tr>
<tr>
<td>Year</td>
<td>1994</td>
</tr>
<tr>
<td>Country</td>
<td>Italy</td>
</tr>
</tbody>
</table>

**Aims**
To evaluate a system which physically prevents the possibility of human error in patient or specimen identification.

**Design**
Observational study.

**Intervention**
The 'Bloodloc' system, consisting of: 1) a pre-coded coloured wristband with a three-letter code (a total of 12,167 individual non-repetative three-letter codes separated into three colours - blue, red, yellow - are available); 2) a single use plastic combination lock with three letter dial designed to seal the opening of a bag; 3) the outer clear plastic bag.

**Setting**
24 surgical wards within a single institute.

**Participants**
4895 blood units (2469 autologous and 2426 allogeneic units) were transfused to 1478 patients (849 predeposited a mean (SD) of 3.3 (2.0) units).

**Results**
41 methodological errors were detected in the first 4 months of implementation (absence of 3 letter code on the patient's specimen tube, wrong transcription of the code on the blood sample, wrong setting of the Bloodloc in the bloodbank). In the same period, however, three potentially fatal errors were avoided by the Bloodloc (2 cases of misidentification of blood samples at the moment of specimen collection, and one attempt to transfuse the wrong units to the wrong patients).

**Comments**
The study only describes errors reported since implementation of the Bloodloc system.

**Relevant to implementation?**
No

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<table>
<thead>
<tr>
<th>Classification</th>
<th>Direct interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Health (dispensing)</td>
</tr>
<tr>
<td>Author</td>
<td>Pena*65</td>
</tr>
<tr>
<td>Year</td>
<td>1992</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
</tbody>
</table>

**Aims**
To describe the successful implementation and enforcement of an automatic stop order (ASO) policy using a multidisciplinary, collaborative approach.

**Design**
Unclear.

**Intervention**
ASO policy - Antibiotics, anticoagulants, steroids: 7 days; Class II controlled substances: 3 days; Class III-V controlled substances: 7 days; all other drugs: 30 days.

**Setting**
Single hospital.

**Participants**
Unclear.

**Results**
An audit of 350 physician orders conducted six months after the ASO enforcement policy was initiated revealed no discrepancies.

**Comments**
This is primarily a descriptive account of the process of implementing an ASO policy.

**Relevant to implementation?**
No
<table>
<thead>
<tr>
<th>Classification</th>
<th><strong>Aims</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct interventions</td>
<td>To evaluate a patient and blood unit identification system designed to confirm the identity of crossmatched blood products and that of the intended recipient.</td>
</tr>
<tr>
<td>Field</td>
<td><strong>Design</strong></td>
</tr>
<tr>
<td>Health (transfusion)</td>
<td>Survey</td>
</tr>
<tr>
<td>Author</td>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>Wenz75</td>
<td>The Blood-Loc system, consisting of: 1) a pre-coded coloured wristband with a three letter code; 2) a single use plastic combination lock with three letter dial designed to seal the opening of a bag; 3) an outer clear plastic bag.</td>
</tr>
<tr>
<td>Year</td>
<td><strong>Setting</strong></td>
</tr>
<tr>
<td>1991</td>
<td>Single hospital</td>
</tr>
<tr>
<td>Country</td>
<td><strong>Participants</strong></td>
</tr>
<tr>
<td>USA</td>
<td>672 units of red cells were issued to 312 recipients over five months.</td>
</tr>
<tr>
<td></td>
<td><strong>Results</strong></td>
</tr>
<tr>
<td></td>
<td>The authors state that ‘the product and procedure were accepted unanimously and enthusiastically, and three potential mistransfusions were avoided by use of the system during the limited period of observation’.</td>
</tr>
<tr>
<td></td>
<td><strong>Comments</strong></td>
</tr>
<tr>
<td></td>
<td>This study focuses primarily on the acceptability of the system to staff.</td>
</tr>
<tr>
<td></td>
<td><strong>Relevant to implementation?</strong></td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>
### Appendix 3 – Reporting systems studies

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Field</th>
<th>Health (infection control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Unclear</td>
<td>Year</td>
<td>2000</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Aims | The purposes of National Nosocomial Infection Surveillance (NNIS) are to establish national risk-adjusted benchmarks for hospital-acquired infection rates and for device use ratios by using uniform case definitions and data collection methods and computerised data entry and analysis. |
| Design | Observational, retrospective report |
| Intervention | National, voluntary, hospital-based reporting system for hospital-acquired infection. |
| Setting | Hospitals with at least 100 beds |
| Participants | Unclear; in 1999 285 participating hospitals in 42 states, report covers period 1990-1999 |
| Results | During 1990-1999, risk-adjusted infection rates for respiratory tract, urinary tract and bloodstream, monitored in ICUs decreased. |
| Comments | The authors comment on the limitations of their report: Improvements in NNIS hospitals may reflect other national efforts to prevent infections. Some rate reductions may be attributable to the shift in the US health-care system from hospital-based care to non-hospital settings. Most event reporting is by patient record review. |
| Relevant to implementation? | Yes |

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Field</th>
<th>Health (pharmacy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Adams</td>
<td>Year</td>
<td>1992</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<p>| Aims | Unclear; appears to report a Continuous Quality improvement (CQI) initiative to identify and improve upon points of breakdown in an existing medication administration system. |
| Design | Observational study |
| Intervention | Incident reporting by staff, identification of breakdown point (from pre-defined flow chart generated by “multi-disciplinary task force”) by pharmacist and risk manager and entry of data into database. |
| Setting | 260-bed, acute care community hospital |
| Participants | Unclear |
| Results | During the first six months of the system 23% of breakdowns occurred before orders reached pharmacy, 15% whilst they were in pharmacy and 62% after dispensing. Total number of errors reported, 141. |
| Comments | No detailed breakdown of causative factors or outcomes and no baseline data for comparison. |
| Relevant to implementation? | No |</p>
<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Field</th>
<th>Health (ICU)</th>
<th>Aims</th>
<th>To develop and evaluate a tool suitable for use at a national level to systematically identify and analyse incidents in the intensive care environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Beckmann 100</td>
<td>Year</td>
<td>1996</td>
<td>Design</td>
<td>Observational study</td>
</tr>
<tr>
<td>Country</td>
<td>Australia</td>
<td>Setting</td>
<td>7 ICUs, 6 general and 1 surgical; 1 paediatric, 1 adult and 5 mixed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participants</td>
<td>All staff in participating ICUs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Results</td>
<td>Time to detection of reported incidents: &lt;1 minute 14%, within 1-5 minutes 15%, within 5 minutes to 1 hour 22%, within 1 hour to 1 day 37%, &gt;1 day 8%, unknown 3%. Long term patient outcomes: NO adverse outcome of incident 91%, minor physiological change 1%, major physiological change &lt;1%, morbidity 3%, unknown 5%, death &lt;1%. Contributing factor where reported: System-based factors 33%, human factors 66%, chance 20%.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments</td>
<td>AIMS form provides a detailed breakdown of system-based and human causative factors. Relevant to implementation? Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Field</th>
<th>Health (intensive care)</th>
<th>Aims</th>
<th>To develop and evaluate an incident reporting system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Beckmann 110</td>
<td>Year</td>
<td>1996</td>
<td>Design</td>
<td>Prospective observational study</td>
</tr>
<tr>
<td>Country</td>
<td>Australia</td>
<td>Setting</td>
<td>Three ICUs in separate hospitals</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participants</td>
<td>All ICU staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Results</td>
<td>129 incidents were reported. Incident outcomes: No harm 85%, minor short-term harm 13%, major short-term harm 2%, no incidents of long-term harm. Feedback questionnaires indicated a positive attitude and good understanding of the system by more than 90% of participants.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Comments</td>
<td>AIMS form provides a detailed breakdown of system-based and human causative factors. Relevant to implementation? Yes</td>
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<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Field</th>
<th>Health (general practice)</th>
<th>Aims</th>
<th>To identify how diagnostic incidents occur and to illuminate preventable and especially system causes of such events.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Bhasale 87</td>
<td>Year</td>
<td>1998</td>
<td>Design</td>
<td>Prospective survey</td>
</tr>
<tr>
<td>Country</td>
<td>Australia</td>
<td>Setting</td>
<td>Australian general practice</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participants</td>
<td>219 GPs of whom 169 reported at least once.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Results</td>
<td>Total of 142 diagnostic incidents. Long-term outcomes: no harm 42%, minor sequelae 25%, moderate sequelae 10%, major sequelae 8%, death 13%.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments</td>
<td>Detailed breakdown of causative factors is also provided. Relevant to implementation? No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Classification
Reporting systems
Field
Health (general practice)
Author
Bhasale87
Year
1998
Country
Australia

Aims
To identify how diagnostic incidents occur and to illuminate preventable and especially system causes of such events.

Design
Prospective survey

Intervention
Pilot study of incident reporting in general practice; volunteer GPs reporting anonymously using four page, self-administered reporting form.

Setting
Australian general practice

Participants
219 GPs of whom 169 reported at least once.

Results
Total of 142 diagnostic incidents. Long-term outcomes: no harm 42%, minor sequelae 25%, moderate sequelae 10%, major sequelae 8%, death 13%.

Comments
Detailed breakdown of causative factors is also provided.

Relevant to implementation?
No

Classification
Reporting systems
Field
Health (ICU)
Author
Buckley82
Year
1997
Country
Hong Kong

Aims
To document the frequency of critical incidents in the ICU, to identify the causes of incidents and to develop preventative strategies so as to prevent recurrence of incidents thus decreasing possible morbidity and mortality.

Design
Prospective observational study

Intervention
Voluntary critical incident reporting system

Setting
Single 14-bed ICU in a 1430-bed teaching hospital

Participants
All nursing or medical staff on the ICU

Results
Over a 36 month period 281 critical incidents were reported from 3300 admissions. Human error was a factor in 55% of incidents; violations of standard practice in 28% and ‘slips’ in 18%. Other common causes of accidents included inexperience, ‘stress’, errors of judgement, distraction and inadequate assistance or manpower. 86% of incidents resulted in no adverse outcome, 1% resulted in death.

Comments
No baseline data.
The authors’ stated aims include development of preventative strategies and reduction of AE. Suggested strategies are briefly given but do not appear to have been tested.

Relevant to implementation?
Yes
<p>| Classification | Reporting systems | Field | Health (pain management) | Author | Chen | Year | 1998 | Country | Hong Kong | Aims | Not stated; report of the results of an ongoing incident reporting programme for acute pain management. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| <strong>Design</strong> | Prospective observational study | <strong>Intervention</strong> | Voluntary, anonymous incident reporting system using a questionnaire designed for anaesthetic incidents and returned to locked boxes. |
| <strong>Setting</strong> | 1400-bed teaching hospital | <strong>Participants</strong> | Unclear |<strong>Results</strong> | Over a 12 month period, 53 incidents were reported in 1275 patients who received pain relief treatment. Human factors were involved in 41.9% of incidents reported, most commonly associated with unfamiliar technique/inexperience, inattention and inadequate communication. Four patients developed major morbidity, three others had major physiological changes, no deaths were reported. |
| <strong>Comments</strong> | Strategies to prevent recurrence are described but no results are reported for these. | Relevant to implementation? | No |<strong>Classification</strong> | Reporting systems | Field | Health (anaesthesia) | Author | Choy | Year | 1996 | Country | Malaysia |
| <strong>Aims</strong> | Unclear; study modelled on Australian AIMS | <strong>Design</strong> | Observational study | <strong>Intervention</strong> | Anonymous, voluntary reporting system using standard form. |<strong>Setting</strong> | Single hospital | <strong>Participants</strong> | Unclear |<strong>Results</strong> | Total of 185 reports (May 1994 to June 1995). Outcomes: no untoward effects (82%), minor morbidity (6%), prolonged hospital stay (7%), major morbidity (2%), death (2.2%). |
| <strong>Comments</strong> | No baseline data on numbers of reports pre-introduction of the system. Study provides a breakdown of causative factors and specific types of error, but this is presented in a graphical form and exact figures are not apparent. Percentages for types of outcome do not add up to 100. Relevant to implementation? | No |</p>
<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Field</th>
<th>Health (anaesthesia)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Choy</td>
<td>Year</td>
<td>1999</td>
</tr>
<tr>
<td>Country</td>
<td>Malaysia</td>
<td>Aims</td>
<td>Not stated: “This study analysed the results of cases reported during the period from July 1995 to January 1997 and compared them with a previous report.</td>
</tr>
<tr>
<td>Design</td>
<td>Retrospective case review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>AIMS-type anonymous, voluntary incident reporting system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setting</td>
<td>Single hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>Unclear; 93 reports reviewed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Incident outcomes: No untoward effects 77.4%, minor morbidity 2.2%, prolonged stay 1.1%, major morbidity 5.4%, death 6.5%.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td>Breakdown of incidents by type and causative factors is presented in graph form only and is difficult to interpret. Stated comparison with the previous report is not made except by reference to the total number of incidents; not directly comparable as the reports cover different lengths of time. Relevant to implementation? No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Field</th>
<th>Health care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Cullen</td>
<td>Year</td>
<td>1995</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
<td>Aims</td>
<td>The objectives of this study were 1) to determine the frequency with which adverse drug events result in an incident report (IR) in hospitalised patients; and 2) to determine if there were differences between quality assurance administrators, nurse leaders in quality assurance, and staff nurses as to whether an incident report should or would be filed for each adverse drug event.</td>
</tr>
<tr>
<td>Design</td>
<td>Prospective observational study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>Voluntary self-report using an incident log on the unit, information solicited at personal interview by an independent nurse investigator, chart review by nurse investigator.</td>
<td></td>
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</tr>
<tr>
<td>Setting</td>
<td>Five units in one tertiary care hospital; one medical ICU, two surgical ICU and two general medical.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>All patients admitted to these units over a three month period for the ICUs and six months each for the general medical units. Incidents evaluated by three groups; group one 3 senior hospital administrators, group two 6 senior nurse leaders, group three 6 staff nurses.</td>
<td></td>
<td></td>
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<tr>
<td>Results</td>
<td>Study detected 54 ADE, 3 of which (6%) were recorded by the existing IR system. During the same period the IR system recorded one ADE missed by the study. Of the 54 ADEs, 26 (48%) were classified as serious or life-threatening, of which 2 had a corresponding IR. The quality assurance group voted that 19 of the 54 ADEs (35%) should have been reported, compared to 76% voted by the nurse leaders and 98% by the staff nurses.</td>
<td></td>
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</tr>
<tr>
<td>Comments</td>
<td>No breakdown of incidents detected by each of the three interventions. Relevant to implementation? Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>Aims</td>
<td></td>
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<tr>
<td>----------------------</td>
<td>----------------------------------------------------------------------</td>
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<tr>
<td></td>
<td>Not stated; apparently to design and test a new incident reporting system using a Continuous Quality Improvement approach.</td>
<td></td>
<td></td>
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<tr>
<td><strong>Field</strong></td>
<td><strong>Design</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health care</td>
<td>Prospective observational study</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td><strong>Intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day113</td>
<td>Voluntary self-report incident forms located on the back of existing patient profile cards.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td><strong>Setting</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1994</td>
<td>Single 36-bed medical-surgical unit</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td><strong>Participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>All nursing staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td><strong>Results</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Six times the number of reported incidents compared to the same two months in the previous year. Survey showed 86% of nurses using the new form, with 71% finding it easier to use.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Comments</strong></td>
<td><strong>Comments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No numbers or breakdown of incident reports.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Relevant to implementation?</strong></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>To increase the quantity and improve the quality of data from medication-related occurrences.</td>
</tr>
<tr>
<td><strong>Field</strong></td>
<td><strong>Design</strong></td>
</tr>
<tr>
<td>Health (pharmacy)</td>
<td>Observational study.</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>DeJong121</td>
<td>A multi-disciplinary effort to improve the medication error reporting system: Development of a new occurrence report form, data for input direct to risk management database.</td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td><strong>Setting</strong></td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td><strong>Participants</strong></td>
</tr>
<tr>
<td></td>
<td>Development team included nursing, pharmacy and QA staff, with assistance from physicians and legal staff.</td>
</tr>
<tr>
<td></td>
<td>Implementation, all nursing staff.</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td><strong>Results</strong></td>
</tr>
<tr>
<td></td>
<td>Post-implementation of the new form, total reporting increased by 55% (1995-1996) with a sustained increase of “nearly 40%”, incomplete forms decreased by 40% and the time taken for reports to go through the entire system decreased (not quantified). Patient days and total number of doses dispensed remained essentially constant. The study also reports and intervention to reduce a specific type of transcription error; this was effective in reducing this type of error from 36% to 24% of the total.</td>
</tr>
<tr>
<td><strong>Comments</strong></td>
<td><strong>Comments</strong></td>
</tr>
<tr>
<td></td>
<td>No numbers of medication errors or breakdown of type/causative factors are reported.</td>
</tr>
<tr>
<td><strong>Relevant to implementation?</strong></td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Aims
To obtain information about the occurrence and severity of errors in an ICU.

### Design
Observational study

### Intervention
Anonymous registration of errors. A separate registration form was used, recording the type of error, date and time, sex and age of patient, patient condition (unstable/stable) and where the error occurred (on the ward or during transport). Two intensivists and two ICU nurses independently evaluated the errors using a visual analogue scale with 10 as the worst imaginable error. All four were blinded to the consequence of error.

### Setting
Combined ICU and postoperative ward at a Norwegian University Hospital.

### Participants
Unclear.

### Results
A total of 87 errors was reported: 36 (41.3%) were medication errors, 17 (19.5%) related to intravenous infusions, 15 (17.2%) were due to technical equipment failure, and the rest (19 errors, 21.8%) miscellaneous. No consequences could be detected in 55 cases (63%) (grade 0). Six errors were graded as 1, and 22 (25%) as grade 2 (therapeutic intervention necessary, no damage recorded). Five errors had more serious consequences and one was fatal. The scoring of errors varied a great deal. Mean VAS scale was 4.2 (SD 1.7).

### Comments
The authors believe that this data underestimated the true incidence of errors.

### Relevant to implementation?
No
<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Class</th>
<th>Health (nursing)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Field</strong></td>
<td>Oil industry</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Gordon</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>2001</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>UK</td>
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</tbody>
</table>

**Aims**
To improve the structure and content of the incident reporting form regarding the potential human-factors causes of accidents and near misses.

**Design**
Observational study

**Intervention**
Two human factors incident reporting forms: The Open reporting Form (ORF) contained 11 questions and the Comprehensive Reporting Form (CRF) contained 166 questions/potential causal categories.

**Setting**
5 UK offshore oil installations belonging to one company

**Participants**
All personnel involved in safety incidents over the 8 month study period were requested to complete ORF forms although completion was not mandatory. 10 incidents were used to evaluate the CRF.

**Results**
Total number of incidents reported over the period was 124; 47 (38%) used the ORF. A significantly higher percentage of ORF reports contained information about both immediate and underlying causes (p < 0.01). The CRF was evaluated using 10 incidents (8% of original sample). “A summary of case studies indicated a 66% increase in the number of causes found using the CRF compared with the original report.”

**Comments**
The report states that the 10 incidents used to evaluate the CRF make up 19% of the original set of incidents; this appears to be an overestimate. No detail about the 66% figure for increase in reported causes is provided.

The authors highlight problems with the study in that much of the increase in reported detail appears to occur in those more innocuous sections of the form such as 'Work Environment' which workers were more comfortable with completing.

**Relevant to implementation?**
Yes

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Class</th>
<th>Health (nursing)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Field</strong></td>
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<td></td>
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</tr>
<tr>
<td><strong>Author</strong></td>
<td>Hackel</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>1996</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>USA</td>
<td></td>
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</tr>
</tbody>
</table>

**Aims**
Not stated; apparently to quantify and estimate factors contributing to medication errors in a sample population of nurses.

**Design**
Survey

**Intervention**
Voluntary self-report of medication error

**Setting**
Unclear

**Participants**
146 nurses

**Results**
Estimate of error from nurses self-report, 146-292 over a three month period. Total number of errors reported through the existing Unusual Occurrence form, 46 over the three month period.

**Comments**
Study also reports nurses’ estimates of specific causes of medication error and views about responsibility for reporting.

**Relevant to implementation?**
No
Classification
Reporting systems
Field
Health (intensive care)
Author
Hart84
Year
1994
Country
Australia

Aims
To identify and correct factors leading to reduced patient safety in intensive care.

Design
Prospective observational study

Intervention
Voluntary anonymous incident reporting form located and filed on the unit.

Setting
Single, 13-bed ICU

Participants
All staff

Results
390 incidents were reported over a two year period, with a wide variation in monthly frequency over the duration. 106 events occasioned actual harm, with one death, and 284 potential harm. Incidents were described as: knowledge-based (78), rule-based (57), technical (69), slip/lapse (37), no error (56), unclassifiable (93).

Comments
Stated aims of the study include correcting factors leading to reduced patient safety. Although immediate responses to events are reported in chart form there is no attempt to assess the impact of these.

Relevant to implementation?
No

Classification
Reporting systems
Field
Health (nursing)
Author
Hartmann120
Year
1990
Country
USA

Aims
This article describes a nursing service occurrence screening program to monitor and evaluate adverse patient events and outcomes.

Design
Unclear

Intervention
Unclear

Setting
Unclear

Participants
Unclear

Results
Unclear

Comments
Unclear

Relevant to implementation?
Yes

Classification
Reporting systems
Field
Health care
Author
Hartwig86
Year
1991
Country
USA

Aims
To describe a medication error-reporting program that is based on incident reports and incorporates a severity index for evaluating patient outcome.

Design
Unclear

Intervention
Incident report form + error tracking form completed by nurse manager and providing more detailed information.

Setting
Single 958-bed teaching hospital

Participants
Unclear

Results
Mean +/- sd monthly error rate 107 +/- 23 over the year of the study. ‘A marked increase in the number of errors reported was observed during the year’.

Comments
Detailed breakdown of error type reported. Outcome measured by a numerical severity scale which is not described.

Relevant to implementation?
No
<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Aims</th>
<th>To determine compliance with an ongoing hospital incident reporting system.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Field</strong></td>
<td>Health (anaesthesia)</td>
<td><strong>Design</strong></td>
<td>Prospective observational study</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Jayasuriya112</td>
<td><strong>Intervention</strong></td>
<td>Intra-operative event form; staff were asked to fill in these forms but were unaware of the purpose for which information was to be used.</td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>1995</td>
<td><strong>Setting</strong></td>
<td>Two teaching hospitals</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>Hong Kong</td>
<td><strong>Participants</strong></td>
<td>All adult patients undergoing anaesthesia over a three month period.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Results</strong></td>
<td>During the three month period of study, 226 intra-operative events were recorded. The number of IR over the same period was 56 (24.8%).</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Comments</strong></td>
<td>Existing reporting system was based on AIMS.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Relevant to implementation?</strong></td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
<th>Aims</th>
<th>To meet the need for a near-miss reporting system with a standard and uniform method of classifying root causes of events in the field of transfusion medicine.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Field</strong></td>
<td>Health (blood transfusion)</td>
<td><strong>Design</strong></td>
<td>Description of design process with observational study of implementation</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Kaplan85</td>
<td><strong>Intervention</strong></td>
<td>Medical Event Reporting System for transfusion Medicine (MERS-TM).</td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>1998</td>
<td><strong>Setting</strong></td>
<td>3 blood centres and 3 hospital transfusion services</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>USA</td>
<td><strong>Participants</strong></td>
<td>503 event reports</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Results</strong></td>
<td>Inter-rater reliability of causal classification was high, however, only 25 event reports were used to evaluate this. Linguistic analysis of MERS-TM and FDA reporting system indicated the MERS-TM to be a more time efficient and method of recording the same data in a more readily accessible and analysable form. Personnel participating in the study found the MERS-TM system a practical and useful method for providing insights into conditions producing undesired events, as indicated by increased event reporting and its’ consideration by all 3 participating hospitals as a potential hospital-wide reporting system.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Comments</strong></td>
<td>Relevant to implementation?</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Yes</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>Classification</td>
<td>Aims</td>
<td>Field</td>
<td>Reporting systems</td>
</tr>
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</tr>
<tr>
<td>Field</td>
<td>Design</td>
<td>Observational study</td>
<td>Health (anaesthesia)</td>
</tr>
<tr>
<td>Author</td>
<td>Intervention</td>
<td>Anonymous, single sheet incident reporting forms (partial utilisation of tick boxes for ease of completion). Forms and locked collection box kept in recovery room</td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>Setting</td>
<td>Single teaching hospital</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Participants</td>
<td>Anaesthetists</td>
<td></td>
</tr>
</tbody>
</table>

**Results**
Over 29 months (August 1997 to December 1999) 20,819 anaesthetics were administered; 329 incidents were reported (1.58% of cases).

**Causative factors:** Human error 41.3% (of which knowledge-based 17.6%, skill-based 27.9%, rule-based 25.7%, technical 6.6%, insufficient contextual details 22.0%), equipment error 50.1%, system error 8.5%.

**Comments**
No baseline data for comparison.

**Relevant to implementation?**
No

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Field</th>
<th>Reporting systems</th>
<th>Author</th>
<th>Year</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Design</td>
<td>Experimental study</td>
<td>Health (intensive care)</td>
<td>Kobus</td>
<td>2001</td>
<td>USA</td>
</tr>
<tr>
<td>Author</td>
<td>Intervention</td>
<td>Computer-based medical incident reporting system (MIRS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>Setting</td>
<td>Unclear</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Participants</td>
<td>34 ICU staff (nurses and physicians) reporting on five artificial cases.</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Results**
Inter-rater agreement was significant for all five cases (p < 0.01). The time required to complete the report decreased significantly from the first case to the last (p < 0.01). Overall, MIRS was perceived as a relatively quick (< 6 minutes) and comprehensive reporting tool.

**Comments**
Relevant to implementation?
Yes

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Field</th>
<th>Reporting systems</th>
<th>Author</th>
<th>Year</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Design</td>
<td>Observational study and audit</td>
<td>Health care</td>
<td>Maass</td>
<td>2000</td>
<td>USA</td>
</tr>
<tr>
<td>Author</td>
<td>Intervention</td>
<td>Computerised incident reporting system</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>Setting</td>
<td>Single community hospital</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Participants</td>
<td>All staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Results**
Turnaround time for an incident report decreased from 53 using a paper based system to 12 days using the computerised system. At least 20 hours per month were saved in transcription and data entry time using the new system.

**Comments**
No data is presented on the effects, if any, of the computerised system on numbers of incidents occurring/reported.

**Relevant to implementation?**
Yes
<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Field</strong></td>
<td>Health (blood transfusion)</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Noel</td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>1998</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>France</td>
</tr>
</tbody>
</table>

**Aims**
To detect, gather and analyse all untoward effects of blood transfusion in order to correct their cause and prevent recurrence.

**Design**
Observational study. Description of system development and retrospective report on operation.

**Intervention**
The French Haemovigilance System of compulsory incident reporting.

**Setting**
All French hospitals

**Participants**
Unclear; 1994-October 1997 10,880 incident reports.

**Results**
Rate of reported incident, 1.5/1000 delivered blood products. 46% of cases notified within one day, 23% on day two and 20% between days three and five.
Outcomes of reported incidents: Minor symptoms (grade 1) 82%, long term consequences (grade 2) 13%, vital threat (grade 3) 4%, death (grade 4) 0.73%.

**Comments**
No baseline data. Figures for times to reporting only cover 89% of reported incidents, no indication of time taken to report remaining 11%.

**Relevant to implementation?**
No

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Field</strong></td>
<td>Health</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>O’Neil</td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>1993</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>USA</td>
</tr>
</tbody>
</table>

**Aims**
To assess the effectiveness of housestaff physician reporting as a method for identifying adverse events on a medical service and to compare the physician reporting system with a retrospective record review mechanism.

**Design**
Observational study

**Intervention**
Confidential reporting of potential injuries by medical house staff.

**Setting**
Medical service of a single hospital

**Participants**
Review of 3141 admissions.

**Results**
The house staff reporting method identified 89 adverse events and the record review identified 85. However, the two methods identified only 41 of the same patients (kappa=0.52, CI 0.47-0.57). There were no statistically significant differences clinical or socioeconomic differences between the patients identified as having had an adverse event by the two methods. The house staff did report statistically more preventable adverse events (62.5% vs 32%; p=0.003) and the physician reporting mechanism was less costly (approximately $15 000 compared with $54 000).

**Comments**
-

**Relevant to implementation?**
Yes
<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting systems</td>
<td>Not stated; apparently to design and test a new incident reporting system using a Continuous Quality Improvement approach.</td>
<td></td>
</tr>
<tr>
<td>Field</td>
<td>Design</td>
<td></td>
</tr>
<tr>
<td>Health (anaesthesia)</td>
<td>Observation study</td>
<td></td>
</tr>
<tr>
<td>Author</td>
<td>Intervention</td>
<td></td>
</tr>
<tr>
<td>Posner124</td>
<td>Continuous Quality Improvement (CQI) program</td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>Setting</td>
<td></td>
</tr>
<tr>
<td>1994</td>
<td>Single 390-bed hospital with 18 operating theatres, 5 delivery rooms, 2 endoscopy suites and 3 other types of anaesthetising locations.</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Participants</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Unclear</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The CQI program resulted in an increased reporting of incidents (5% of all anaesthetics) over the checklist system it replaced (2.7% of all anaesthetics). Escalation of patient care (3.2%) and operational inefficiencies (2.2%) were more common than patient injury (1.5% of all anaesthetics). Of the 537 incidents with anaesthesia management problems, 3 were equipment problems and 116 human error.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>More detailed breakdown of incident reports as well as actions taken and resource use of the estimates for the new system are also provided.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Relevant to implementation?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting systems</td>
<td>Not stated; apparently to use data generated by a previously described medication error reporting program to target system-related problems that cause preventable medication errors, to identify problem-prone processes, take steps to improve them and assess impact on medication errors.</td>
<td></td>
</tr>
<tr>
<td>Field</td>
<td>Design</td>
<td></td>
</tr>
<tr>
<td>Health care</td>
<td>Observational, retrospective report</td>
<td></td>
</tr>
<tr>
<td>Author</td>
<td>Intervention</td>
<td></td>
</tr>
<tr>
<td>Schneider116</td>
<td>Voluntary, severity-indexed medication error reporting system with database program used to identify problem areas; review of data by four hospital committees to generate quality improvement interventions.</td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>Setting</td>
<td></td>
</tr>
<tr>
<td>1994</td>
<td>Single 963-bed teaching hospital</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Participants</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Unclear; in 1999 285 participating hospitals in 42 states, report covers period 1990-1999</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Two specific interventions relating to anticoagulant errors and transcription errors remain under development. Errors related to late IV antibiotic dose decreased from 112 over 6 months pre-intervention to 46 over 6 months post-intervention. Narcotic errors (hydromorphone given in place of morphine) decreased from 25 over 5 months pre-intervention to 14 over 5 months post-intervention.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reporting system is described elsewhere (#818)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Relevant to implementation?</td>
<td>No</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td><strong>Aims</strong></td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td>----------</td>
<td></td>
</tr>
<tr>
<td>Reporting systems</td>
<td>Not stated; apparently to evaluate the use of a critical incident technique in an anaesthetic department quality assurance program.</td>
<td></td>
</tr>
<tr>
<td><strong>Field</strong></td>
<td><strong>Design</strong></td>
<td></td>
</tr>
<tr>
<td>Health (anaesthesia)</td>
<td>Prospective observational study</td>
<td></td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td><strong>Intervention</strong></td>
<td></td>
</tr>
<tr>
<td>Short114</td>
<td>Voluntary, anonymous self-report incident forms located in areas where anaesthetic was administered; feedback provided by incident summary reports at two monthly intervals.</td>
<td></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td><strong>Setting</strong></td>
<td></td>
</tr>
<tr>
<td>1992</td>
<td>Single 1430-bed teaching hospital</td>
<td></td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td><strong>Participants</strong></td>
<td></td>
</tr>
<tr>
<td>Hong Kong</td>
<td>All anaesthetists</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Results</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>During the 12 month study period, 125 CI were reported from a total of 16,379 anaesthetics (0.76%). Human error was a factor in 80% of incidents.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physiological outcome:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No physiological consequence, 63 (50.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild/moderate, 56 (44.8%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe, 5 (4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Death, 1 (0.8%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Significant morbidity, 3 (2.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Comments</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No baseline or other comparison data.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Relevant to implementation?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Classification</strong></th>
<th><strong>Aims</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting systems</td>
<td>To examine the role of a critical incident reporting system in three large public hospitals in improving anaesthesia safety.</td>
</tr>
<tr>
<td><strong>Field</strong></td>
<td><strong>Design</strong></td>
</tr>
<tr>
<td>Health (Anaesthesia)</td>
<td>Observational study</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>Short101</td>
<td>Voluntary reporting system, forms based on AIMS.</td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td><strong>Setting</strong></td>
</tr>
<tr>
<td>1996</td>
<td>Three large public hospitals (&gt;1000 beds, &gt;10,000 anaesthetics performed per year)</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td><strong>Participants</strong></td>
</tr>
<tr>
<td>Hong Kong</td>
<td>Unclear</td>
</tr>
<tr>
<td></td>
<td><strong>Results</strong></td>
</tr>
<tr>
<td></td>
<td>Total number of reported incidents April 1990 to June 1994, 1000.</td>
</tr>
<tr>
<td></td>
<td>Contributing factors in the two largest hospitals: Human error 74% &amp; 80%, violations 32% &amp; 35%, slips 2% &amp; 2%.</td>
</tr>
<tr>
<td></td>
<td>13 successful interventions made in response to specific clusters of incidents are reported, whereby similar incidents have been eliminated. 9 unsuccessful interventions are also reported.</td>
</tr>
<tr>
<td></td>
<td><strong>Comments</strong></td>
</tr>
<tr>
<td></td>
<td>Reporting of data from the third hospital is limited. There is no clear reason for this.</td>
</tr>
<tr>
<td></td>
<td>Relevant to implementation?</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>
### Aims
To set up a system to collect anonymous critical incidents in anaesthesia, using a reporting form on the Internet, with a view to gaining insight into the nature of critical events and collecting cases that might have a teaching potential for other anaesthetists.

### Design
Observational study

### Intervention
Critical Incident Reporting System (CIRS) to collect anonymous CI in anaesthesia using a reporting form on the Internet.

### Setting
Undefined, system open to all internet users.

### Participants
Undefined, system open to all internet users, 60 reports since April 1996.

### Results
Most incidents (72%) did not effect outcome. Morbidity reported in 21%. One death reported.

Contributory factors were reported as follows: Communication 34%, lack of situational awareness 30%, lack of experience 30%, not performing a check 28%, error of judgement 23%, Human error 42%, management error 32%, technical error 6%.

### Comments
System is potentially open to all internet users and, although the authors state that the technical nature of their questions would allow them to identify lay users, no checking process is described. The reporting rate is very low given the open nature of the system, no attempt to publicise the project is described. The authors state that they aim to collect data for educational purposes, but no such use is described.

#### Relevant to implementation?
No

---

### Aims
To identify and characterise events or circumstances which could have or did harm a patient in general practice.

### Design
Prospective observational study

### Intervention
Voluntary, anonymous, postal incident reporting administered nationally

### Setting
Australian general practice

### Participants
673 General practitioners

### Results
2582 reports of which 1294 involved medication problems. Incident outcomes: Not reported 469, additional tests or investigations 189, additional treatment 400, hospital admission or prolonged stay 148, permanent disability 7, death 25 (degree of association with event undetermined.

### Comments
Outcome numbers don’t add up, some breakdown of type of events but no causal analysis.

#### Relevant to implementation?
No
<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Health (surgery)</td>
</tr>
<tr>
<td>Author</td>
<td>Svenmarker 119</td>
</tr>
<tr>
<td>Year</td>
<td>1998</td>
</tr>
<tr>
<td>Country</td>
<td>Sweden</td>
</tr>
<tr>
<td>Aims</td>
<td>To investigate the properties and usefulness of prospective routine registration of incidents related to cardiopulmonary bypass and its clinical significance as a quality assurance instrument.</td>
</tr>
<tr>
<td>Design</td>
<td>Unclear</td>
</tr>
<tr>
<td>Intervention</td>
<td>Real-time incident reporting into a computer database.</td>
</tr>
<tr>
<td>Setting</td>
<td>Department of cardiothoracic surgery in a single hospital</td>
</tr>
<tr>
<td>Participants</td>
<td>Perfusionists (numbers unclear); total number of cardiopulmonary bypass patients included for analysis (1989-1997) was 6918.</td>
</tr>
<tr>
<td>Results</td>
<td>General incident rate varied, 4.5-7.6% per year.</td>
</tr>
<tr>
<td>Comments</td>
<td>No comparator</td>
</tr>
<tr>
<td>Relevant to implementation?</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reporting systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Health</td>
</tr>
<tr>
<td>Author</td>
<td>Stump 117</td>
</tr>
<tr>
<td>Year</td>
<td>2000</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
<tr>
<td>Aims</td>
<td>To describe a hospital’s change from a multitiered incident reporting system for medication errors to a standardised, nonpunitive medication-use variance process.</td>
</tr>
<tr>
<td>Design</td>
<td>Observational study</td>
</tr>
<tr>
<td>Intervention</td>
<td>An anonymous, paper-based, one-page medication-use variance report that prompted the reporter for key data elements, including root causes, patient outcomes and possible ways to prevent similar accidents.</td>
</tr>
<tr>
<td>Setting</td>
<td>Single hospital</td>
</tr>
<tr>
<td>Participants</td>
<td>Unclear</td>
</tr>
<tr>
<td>Results</td>
<td>The number of reports increased compared with historical trends, and for the first time potential errors were reported. In the first 6 months of implementation, the number of events captured increased fivefold. The report form was easy to use and the interpretation of reports.</td>
</tr>
<tr>
<td>Comments</td>
<td>Primarily a description of implementing the new approach.</td>
</tr>
<tr>
<td>Relevant to implementation?</td>
<td>No</td>
</tr>
<tr>
<td>Classification</td>
<td>Aims</td>
</tr>
<tr>
<td>----------------</td>
<td>------</td>
</tr>
<tr>
<td>Reporting systems</td>
<td>To describe the process used to develop and test a tool for determining and reporting the severity of medication errors.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting systems</td>
<td>To develop a replicable and potentially sustainable reporting system that relies on house officers to identify AEs.</td>
<td>Observational study</td>
<td>Confidential reporting system for AE potential AE and other quality problems, by interview during morning round and by e-mail.</td>
<td>Two general medical units in a single teaching hospital</td>
<td>House officers (numbers unclear, 150 respondent contacts)</td>
<td>Intervention produced 110 incident reports over a 12 week study period. Hospital reporting system identified 58 incidents in the study unit over the same period; these included only one event identified by house officer report. Chart review corroborated 63.6% of house officer reports. Adverse consequences: Death 2.7%, injury 23.4%, delays 48.2%, problematic discharge 7.3, none 18.2.</td>
<td>The authors identify a number of potential problems with this model for incident reporting: Different professional groups may have different perceptions of what constitutes an AE and who is responsible for reporting it. Cultural barriers to reporting. Peer group interviewers: house officers may be more likely to report AE to a trusted peer, but the applicability of this approach in other disciplines requires further investigation.</td>
<td>No</td>
</tr>
<tr>
<td>Classification</td>
<td>Aims</td>
<td>Design</td>
<td>Intervention</td>
<td>Setting</td>
<td>Participants</td>
<td>Results</td>
<td>Comments</td>
<td>Relevant to implementation?</td>
</tr>
<tr>
<td>----------------</td>
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<td>--------------------------</td>
</tr>
<tr>
<td>Reporting systems</td>
<td>To receive and collate reports of death or major complications of blood or components.</td>
<td>Observational, retrospective report</td>
<td>Serious Hazards of Transfusion (SHOT) initiative; voluntary, confidential reporting system for deaths or serious AE.</td>
<td></td>
<td></td>
<td>In year one 94 out of 424 eligible hospitals submitted 169 reports. Year two 112 hospitals submitted 197 reports. “Nil to report” cards were introduced in the second year and submitted by 164 hospitals. Reports included 191 incidents of incorrect blood transfused and 12 infections. Of 341 cases analysed there were 22 deaths and 81 cases of major morbidity.</td>
<td>No baseline</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Aims</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Participants</th>
<th>Results</th>
<th>Comments</th>
<th>Relevant to implementation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting systems</td>
<td>To assess the incidence and consequences of medication errors, highlight sources of recurrent error and institute changes in practice to prevent their recurrence.</td>
<td>Prospective cohort study</td>
<td>Continuous Quality Improvement approach to an adverse incident reporting scheme</td>
<td></td>
<td></td>
<td>441 reported medication errors over the two year study period for 5315 inpatient days. 4 serious medication errors had “overt clinical consequences”. “During the second year of the scheme, the incidence of all reported errors, administration errors and serious errors fell, but the prescription error rate remained constant.</td>
<td>Despite the stated aims of the study, interventions to reduce error are not described. It is far from clear whether the reported reduction in error is due to an actual decrease or a fall off in reporting.</td>
<td>No</td>
</tr>
</tbody>
</table>
Appendix 4 – Systematic reviews

Each of the following systematic reviews have been appraised according to the criteria used by the Database of Abstracts of Reviews of Effectiveness (DARE: http://agatha.york.ac.uk/darehp.htm)

Title: Making Health Care Safer: A critical Analysis of Patient Safety Practices


Prepared by: University of California at San Francisco (UCSF) – Stanford University Evidence-based Practice Centre

Editorial board: Shojania K. G. (UCSF)
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Authors’ objective
The authors’ stated aims were ‘to collect and critically review the existing evidence on practices relevant to improving patient safety.’

Type of intervention
Organization/Management

Specific interventions included in the review
Interventions targeting Adverse Drug Events:
Computerised physician order entry (CPOE) with clinical decision support system (CDSS)
  The Clinical Pharmacist’s Role in preventing Adverse Drug Events
  Computer Adverse drug Events (ADE) detection and alerts
  Protocols for high risk drugs (anticoagulation)
  Unit-dosing distribution system
  Automated medication dispensing services

Interventions targeting infection control:
  Practices to improve hand washing compliance
  Impact of barrier precautions in reducing the transmission of serious nosocomial infections
  Impact of changes in antibiotic use practices on nosocomial infections and antimicrobial resistance – Clostridium Difficile and Vancomyci-resistant Enterococcus
  Use of silver alloy urinary catheters
  Use of supra-pubic catheters
  Use of maximum barrier precautions during central venous catheter insertion
  Use of central venous catheters coated with antibacterial or antiseptic agents
Use of Chlorhexidine Gluconate at the central venous catheter insertion site

Patient positioning: Semi-recumbent positioning and continuous oscillation to prevent ventilator-associate pneumonia

Continuous aspiration of sub-glottic secretions to prevent ventilator-associated pneumonia

Selective digestive tract decontamination to prevent ventilator-associated pneumonia

Sucralfate and the prevention of ventilator-associated pneumonia

Interventions targeting Adverse Events associated with surgery and anaesthesia:

Localising care to high-volume centres

Learning curves for new procedures

Prophylactic antibiotics

Perioperative normothermia

Supplemental perioperative oxygen

Perioperative glucose control

Ultrasound guidance of central vein catheterisation

Instrument and sponge counting procedures

Pre-anaesthesia checklists

Intra-operative monitoring

Beta-blockers for the reduction of intra-operative cardiac events

Safety practices for hospitalised and institutionalised elders

Identification bracelets for patients at high risk of falls

Interventions that decrease the use of physical restraints

Bed alarms

Hospital flooring materials

Hip protectors

Prevention of pressure ulcers

Prevention of delerium

Multi-disciplinary Geriatric consultation services

Geriatric evaluation and management units for hospitalised patients

General clinical topics:

Prevention of venous thromboembolism

Prevention of contrast-induced nephropathy

Nutritional support

Prevention of clinically significant gastrointestinal bleeding in Intensive Care patients

Reducing errors in the interpretation of Plain Radiographs and Computed Tomography Scans

Pneumococcal vaccination prior to hospital discharge

Use of analgesics in acute abdomen

Acute pain services

Prophylactic anti-emetics during patient-controlled analgesia

Non-pharmacologic interventions for post-operative pain

Interventions targeting organisation, structure and culture:
“Closed” Intensive care units and other models of care for critically ill patients
Nurse staffing, models of care delivery, and interventions
Promoting a culture of safety
Interventions targeting systems issues and human factors:
Use of human factors principles in evaluation of medical devices
Refining performance of medical device alarms
Information transfer between inpatient and outpatient pharmacies
Standardised, structured sign-outs for physicians
Use of structured discharge summaries
Protocols for notification of test results to patients
Use of barcoding for patient ID
“Sign your site” protocols for surgery
Application of aviation style crew resource management
Simulator-based training
Fatigue, sleepiness and medical errors (limiting individual provider’s hours of service, fixed shifts or forward shift rotations, napping strategies)
Specialised teams for inter-hospital transport
Interventions targeting the role of the patient:
Procedures for obtaining informed consent (asking that patients recall and restate what they have been told during informed consent, use of video or audio stimuli, provision of written informed consent information)
Advance planning for end-of-life care (computer-generated reminders to discuss advanced directives, use of physician order form for life-sustaining treatment (POLST))
Incident reporting and Root cause analysis are also discussed in the report, but are not part of the systematic review element.
Patient safety practices were defined as those that reduce the risk of adverse events related to exposure to medical care across a range of diagnoses or conditions.
The inclusion criteria for patient safety practices (no inclusion criteria for individual studies were described) were:
The practice can be applied in the hospital setting or at the interface between the inpatient and outpatient settings AND can be applied to a broad range of healthcare conditions or procedures.
Practices that have only been studied outside the hospital setting or in patients with specific conditions or undergoing specific procedures were included if the authors and editors agreed that the practices could reasonably be applied in the hospital setting and across a range of conditions or procedures.

Participants included in the review
Not Applicable
**Outcomes assessed in the review**
Outcome measures, where available, were reported as error rates or relative risk with 95% CI. A hierarchy of outcome measures also reported:

- **Level 1.** Clinical outcomes – morbidity, mortality, Adverse Events
- **Level 2.** Surrogate outcomes – observed errors, intermediate outcomes (e.g. lab results) with well-established connections to the clinical outcomes of interest
- **Level 3.** Other measurable variables with an indirect or unestablished connection to the target safety outcome (e.g. educational intervention)
- **Level 4.** No outcomes relevant to decreasing medical errors and/or Adverse Events

**Study designs of evaluations included in the review**
The inclusion criteria for patient safety practices (no inclusion criteria for individual studies were described) were:

- “Evidence for the safety practice includes at least one study with a level 3 or higher study design AND a level 2 outcome measure. For practices not specifically related to diagnostic or therapeutic interventions, a level 3 outcome measure is adequate.”

The exclusion criteria were:

- “No study of the practice meets the methodological criteria above”

In addition the following statement described the inclusion of additional studies:

- “To increase the number of potentially promising safety practices from outside the field of medicine, we included evidence from studies that used less rigorous measures of patient safety as long as the practices did not specifically relate to diagnostic or therapeutic interventions. These criteria facilitated the inclusion of areas such as teamwork training and methods to improve information transfer.”

The hierarchy of study designs was described as follows:

- **Level 1A.** Systematic reviews and meta-analyses
- **Level 1.** Randomised controlled trials – includes quasi-randomised processes such as alternate allocation
- **Level 2.** Non-randomised controlled trial – a prospective study with pre-determined eligibility criteria and outcome measures
- **Level 3.** Observational studies with controls – includes retrospective interrupted time series, case-control studies, cohort studies with controls and health services research that includes adjustment for likely confounding variables
- **Level 4.** Observational studies without controls

**What sources were searched to identify primary studies?**
The following electronic bibliographic databases were searched:

- MEDLINE
- Cochrane Library
- CINAHL
- PsycLit
PsycINFO
Science Citation Index
Social Sciences Citation Index
Arts & Humanities Citation Index
INSPEC
ABI/INFORM

Handsearches of bibliographies of retrieved articles and tables of contents of key journals.
Grey literature
Consultation with experts in the field

The authors indicate that not all elements were used for all patient safety practices. They give no details of individual search strategies

**On what criteria was the validity of primary studies judged?**
The authors do not report a method for assessing validity of individual studies, though included articles were ranked according to a hierarchy of study designs (see above).

**How were decisions on the relevance of primary studies reached?**
Practices for inclusion were decided by consensus decision of authors and editorial panel. No information is provided on decision process for individual papers

**How were judgements of validity made?**
The authors do not state how the papers were assessed for validity, or how many of the authors performed any validity assessment

**How was the data extracted from primary studies?**
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

The required abstraction elements were:
1. Bibliographic information
2. Level of study design, with:
   For level 1A:
   - Identifiable description of methods including sources and methods of searching for articles.
   - Stated inclusion and exclusion criteria for articles yes/no.
   - Scope of literature included in study.
   For level 1 and 2:
   - Blinding: blinded, unclear, unblinded.
   - Describe comparability of groups at baseline.
   - Loss to follow-up overall.
   For level 3:
   - Description of study design.
   - Describe comparability of groups at baseline.
Analysis includes adjustment for potential confounders yes/no.

3. Description of intervention
4. Description of study population and setting
5. Level of relevant outcome measure
6. Description of relevant outcome measure
7. Main results: effect size with confidence intervals
8. Information on unintended adverse (or beneficial) effects of practice
9. Information on cost of practice
10. Information on implementation of practice”

Individual authors were not asked to formally synthesise or combine the evidence across studies

**Number of studies included (for interventions directly relevant to patient safety)**

Interventions targeting Adverse Drug Events:
- Computerised physician order entry (CPOE) with clinical decision support system (CDSS) – 8 studies
- Clinical Pharmacist consultation services – 6 studies
- Use of computer monitoring for Adverse Drug Events – 5 studies
- Protocols for high risk drugs (anticoagulation) – 6 studies
- Unit-dosing distribution system – 5 studies
- Use of automated medication dispensing services – 5 studies

Interventions targeting Adverse Events during surgery and anaesthesia:
- Counting sharps, instruments, sponges – 1 study
- Use of pre-operative anaesthesia checklists – 2 studies
- Intra-operative monitoring of vital signs and oxygenation – 2 studies

Interventions targeting organisation, structure and culture:
- Educational interventions and continuous quality improvement strategies – 4 studies
- Change in ICU structure – active management by intensivist – 12 studies
- Changes in nursing staffing – 29 studies
- Promoting a culture of safety – 2 studies

Interventions targeting systems issues and human factors:
- Use of human factors principles in evaluation of medical devices – 3 studies
- Refining performance of medical device alarms – 7 studies
- Information transfer between inpatient and outpatient pharmacy – 2 studies
- Standardised, structured sign-outs for physicians – 1 study
- Use of structured discharge summaries – 1 study
- Protocols for notification of test results to patients – 1 study
- Use of barcoding for patient ID – 2 studies
- “Sign your site” protocols for surgery – 1 study
- Application of aviation style crew resource management – 3 studies
- Simulator-based training – 10 studies
Limiting individual provider’s hours of service – 9 studies

Fixed shifts or forward shift rotations – 10 studies

Napping strategies – 15 studies

Specialised teams for inter-hospital transport – 3 studies

How were the studies combined?

Narrative synthesis.

Details about decision rules and judgement considerations were given as follows:

Potential Impact Factor:

An assessment of potential impact considered the prevalence and severity of the patient safety target, and the current utilisation of the practice being evaluated. The Editorial Team used the data from the chapters and clinical knowledge to order the potential impact as "High," "Medium," "Low," or "Insufficient Information." To qualify for the "High" score, a practice had to target a patient population of greater than 1% of hospitalised patients (about 300,000 patients per year) or target a patient safety problem that can result in death or disability. The "Low" score was used for target populations of less than 0.01% of hospitalised patients (about 3000 patient/year) who might experience reversible adverse effects if an effective practice were not available. Potential impact was deemed a "Medium" if the practice had a patient safety target that fell between the 2 other categories.

An additional decision rule was applied to the Impact rating after the initial assessment based on prevalence and severity was made. If a practice was currently widely used (>75% of hospitals), then the rating was demoted one notch (i.e., from High to Medium or Medium to Low). When this situation occurred, a notation identified that the potential impact level was impacted by its high current utilisation.

We reserved the "Insufficient Information" category for those cases where the prevalence and severity information was quite limited or where the patient safety target was ill-defined.”

Evidence Supporting the Practice:

“Study strength, effect size on target(s), and need for vigilance due to potential harms were rated based more on judgement than pre-specified decision rules. In each case, raters documented their reasons for category choices.

For study strength, the level of study design and outcomes (see Chapter 3 for hierarchies), number of studies, numbers of patients in studies, generalisability, and other methodological issues were specified as factors to consider in weighting the relative study strength for a particular practice. Study strength could be categorised as "High," "Medium," or "Low." The
actual findings of the studies were not considered when scoring study strength because this information was captured in the assessment of effect size on target. If there was minimal or no evidence about a practice, the study strength rating was "Low" and raters did not score the remaining 2 elements of the evidence supporting the practice since that might give undue "credit" to the findings.

The assessment of effect size on target(s) was based on the relative risk reductions or odds ratios reported in the reviewed studies for evidence of effectiveness. The raters only used the findings reported in the practice chapters, and did not perform additional analyses (eg, meta-analysis). If all studies or, in cases where there were a large number of studies, the vast majority showed a positive and appreciable effect size (i.e., greater than 15% relative risk reduction), then the positive effect size was categorised as "Robust." If there was clearly no effect or a very minimal effect (i.e., less than 5% relative risk reduction), then the positive effect size was rated as "Negligible." For findings that were considered suggestive of substantive effect, but not clearly "Robust," the category used was "Modest." The final category, "Unclear," captured those practices for which the effect size results were inconsistent.

For any given practice that reduces one adverse event, it is conceivable that new problems might ensue when the practice is implemented. Thus, we subjectively rated the concern for harm based on the level of vigilance necessary to ensure that the practice, if implemented, would not result in collateral negative effects. The categories available were "Low," "Medium," and "High." Thus, a practice rated as "Low" would require little to no attentiveness to potential harms, while one rated as "High" would merit heightened monitoring for potential negative effects. These ratings were made conservatively, meaning that when in doubt, a higher vigilance category was selected.

Implementation:

Assuming a 3-year lead time for implementation, patient safety practices were rated for their costs and complexity. Costs were based on initial start-up and annual expenditures for full implementation at an average size hospital or healthcare organisation. Potential cost savings were not considered for the rating, but were reported in the practice chapters if they were documented in the literature. If a practice was expected to require expenditures of greater than about $1 million, the rating was "High." Expenditures of approximately $100,000-$1 million were categorised as "Medium." Below this level, practices were rated as "Low" in terms of cost.

The feasibility of implementation was rated by considering potential political (e.g., major shifts in who delivers care) and technical (eg, integration of legacy and newer computer
systems) obstacles. Because relatively few data exist for rating implementation complexity, we used only 2 categories, "Low" and "High," meaning relatively easy and relatively difficult. In cases in which implementation could be accomplished simply with the expenditure of dollars, we gave high cost scores but low feasibility scores.

Overall Rating for Impact/Evidence:

In addition, each member of the team considered the totality of information on potential impact and evidence supporting the practice to score each on a 0 to 10 scale ("Strength of the Evidence"). For these ratings, we took the perspective of a leader of a large healthcare enterprise (e.g., a hospital or integrated delivery system) and asked the question, "If you wanted to improve patient safety at your institution over the next 3 years and resources were not a significant consideration, how would you grade this practice?" For this rating, we explicitly did not consider difficulty or cost of implementation in the rating. Rather, the rating simply reflected the strength of the evidence regarding the effectiveness of the practice and the probable impact of its implementation on reducing adverse events related to healthcare exposure. If the patient safety target was rated as "High" impact and there was compelling evidence (i.e., "High" relative study strength) that a particular practice could significantly reduce (e.g., "Robust" effect size) the negative consequences (e.g., hospital-acquired infections), raters were likely to score the practice close to 10. If the studies were less convincing, the effect size was less robust, or there was a need for a "Medium" or "High" degree of vigilance because of potential harms, then the rating would be lower.

Overall Rating for Research Priority:

Analogously, we also rated the usefulness of conducting more research on each practice, emphasising whether there appeared to be questions that a research program might have a reasonable chance of addressing successfully ("Research Priority"). Here, our "thought question" was, "If you were the leader of a large agency or foundation committed to improving patient safety, and were considering allocating funds to promote additional research, how would you grade this practice?" If there was a simple gap in the evidence that could be addressed by a research study or if the practice was multifaceted and implementation could be eased by determining the specific elements that were effective, then the research priority was high. If the area was one of high potential impact (i.e., large number of patients at risk for morbid or mortal adverse events) and a practice had been inadequately researched, then it also would also receive a relatively high rating for research need. Practices might receive low research scores if they held little promise (e.g., relatively few patients affected by the safety problem addressed by the practice or a significant body of knowledge already demonstrating the practice’s lack of utility). Conversely, a practice that was clearly effective,
low cost and easy to implement would not require further research and would also receive low research scores.”

Caveats to Ratings:

For all elements assessed, divergent assessments among the 4 Editor-raters were infrequent and were discussed until consensus was reached. For each final category where differences in interpretation existed and persisted after discussion, the protocol was to document a comment about these differences (see Chapter 59). Comments were also noted when specific additional information could clarify concerns about fidelity of a specific rating. In a few cases, categories that had not been specified were created for unusual circumstances and again comments to explain the category were documented.

How were the differences between studies investigated?
Studies were discussed according to their design and/or level of evidence.

Results of the review (for interventions directly relevant to patient safety)
Implementation costs and complexity ratings for:

1. Patient Safety Practices with High Strength of Evidence Regarding their Impact and Effectiveness:
   - Use of computer monitoring for potential ADEs - Medium
   - Changes in nursing staffing - Medium
   - Change in ICU structure—active management by intensivist - High
   - Information transfer between inpatient and outpatient pharmacy - Medium

2. Patient Safety Practices with Medium Strength of Evidence Regarding their Impact and Effectiveness:
   - Computerised physician order entry (CPOE) and clinical decision support (CDSS) - High
   - Protocols for notification of test results to patients - Low
   - Specialised teams for inter-hospital transport - Medium
   - Clinical pharmacist consultation services - Medium
   - Education interventions and continuous quality improvement strategies - Low
   - Protocols for high-risk drugs: nomograms for heparin - Low

3. Patient Safety Practices with Lower Impact and/or Strength of Evidence:
   - Simulator-based training - Medium
   - Use of automated medication dispensing devices – Medium
   - Use of bar coding for patient ID - Medium (Varies)
   - Unit-dosing distribution system - Low
   - Intra-operative monitoring of vital signs and oxygenation - Low
   - Standardised, structured sign-outs for physicians - Low
Applications of aviation-style crew resource management (e.g., Anaesthesia Crisis Management; MedTeams) - High
Limiting individual provider’s hours of service – High

4. Patient Safety Practices with Lowest Impact and/or Strength of Evidence:
Use of pre-anaesthesia checklists - Low
Use of structured discharge summaries - Low
Counting sharps, instruments and sponges in surgery - Low
"Sign your site" protocols - Medium

Patient safety practices rated by research priority:

Further Research Likely to be Highly Beneficial (Patient Safety Practice – Impact/Evidence Category (1-5 Scale; 1 is highest)):
Changes in nursing staffing - 2
Computerised physician order entry (CPOE) with clinical decision support (CDSS) - 3
Change in ICU structure—active management by intensivist - 2
Use of bar coding for patient ID - 4
Clinical pharmacist consultation services - 3
Protocols for high-risk drugs: nomograms for heparin - 3
Use of automated medication dispensing devices – 4

Further Research Likely to be Beneficial (Patient Safety Practice - Impact/Evidence Category (1-5)):
Specialised teams for inter-hospital transport - 3
Simulator-based training - 4
Standardised, structured sign-outs for physicians - 4
Applications of aviation-style crew resource management (e.g., Anaesthesia Crisis Management; MedTeams) - 4
Protocols for notification of test results to patients - 3
Limiting individual provider’s hours of service - 4
"Sign your site" protocols - 5
Information transfer between inpatient and outpatient pharmacy - 2
Use of computer monitoring for potential Adverse Drug Events - 2
Intra-operative monitoring of vital signs and oxygenation - 4
Use of structured discharge summaries - 5

Was any cost information reported?
No.

Authors’ conclusions
“This report represents a first effort to approach the field of patient safety through the lens of evidence-based medicine. Just as To Err is Human sounded a national alarm regarding patient safety and catalysed other important commentaries regarding this vital problem, this review seeks to plant a seed
for future implementation and research by organising and evaluating the relevant literature. Although all those involved tried hard to include all relevant practices and to review all pertinent evidence, inevitably some of both were missed. Moreover, the effort to grade and rank practices, many of which have only the beginnings of an evidentiary base, was admittedly ambitious and challenging. It is hoped that this report provides a template for future clinicians, researchers, and policy makers as they extend, and inevitably improve upon, this work.

In the detailed reviews of the practices, the editors have tried to define (to the extent possible from the literature) the associated costs—financial, operational, and political. However, these considerations were not factored into the summary ratings, nor were judgements made regarding the appropriate expenditures to improve safety. Such judgements, which involve complex tradeoffs between public dollars and private ones, and between saving lives by improving patient safety versus doing so by investing in other health care or non-health care practices, will obviously be critical. However, the public reaction to the IOM report, and the media and legislative responses that followed it, seem to indicate that Americans are highly concerned about the risks of medical errors and would welcome public and private investment to decrease them. It seems logical to infer that Americans value safety during a hospitalisation just as highly as safety during a transcontinental flight.”

CRD Commentary
The report focused on the evaluation of a variety of clinical interventions which, for the most part, cannot be classified as specifically “patient safety” interventions. The inclusion and exclusion criteria reported for patient safety practices were ambiguous. In general the methods used in the review were poorly described and are likely to reflect the diverse range of interventions and practices included in the report.
Title: The measurement and monitoring of surgical adverse events

Authors: Bruce J.
Russell E.M.
Mollison J.
Krukowski Z.H.

Authors’ objective
To identify a selection of common and potentially avoidable surgical adverse events and to assess whether they could be reliably and validly measured, to review methods for monitoring their occurrence and to identify examples of effective monitoring systems for selected events.

Type of intervention
Organisation/management

Specific interventions included in the review
Systems for measuring and monitoring specified surgical adverse events

Participants included in the review
Specified surgical adverse events included:
- Surgical wound infection
- Anastomotic leak
- Deep vein thrombosis (DVT)
- Surgical mortality

Outcomes assessed in the review
Not Applicable

Study designs of evaluations included in the review
All prospective studies

What sources were searched to identify primary studies?
Thirty separate, systematic literature searches of health and biomedical bibliographic databases (MEDLINE, EMBASE, CINAHL, HealthSTAR and the Cochrane Library) were conducted. Further searches were also made on the internet and PubMed. The reference lists of retrieved articles were reviewed to locate additional articles. Contact was made with surgical colleges, societies and associations at an early stage in the review for details of unpublished studies related to the measurement and monitoring of surgical complications.
On what criteria was the validity of primary studies judged?
Criteria for study validity were described in the methods section of the review, but no scale was given and no results of any validity assessment were described.

How were decisions on the relevance of primary studies reached?
Each article eligible for inclusion was independently reviewed by two assessors.

How were judgement of validity made?
No details were given.

How was the data extracted from primary studies?
Two reviewers independently assessed each study and discrepancies were resolved by discussion between reviewers or by discussion and further review with other panel members.

Number of studies included
The numbers of included studies relating to each of the specified surgical adverse events were as follows:
- Surgical wound infection - 82 studies
- Anastomotic leak - 240 studies
- DVT - 250 studies (not critically appraised, agreed to be postponed to a later separate review).
- Surgical mortality - numbers not given

How were the studies combined?
Narrative synthesis

How were the differences between studies investigated?
Not Applicable

Results of the review
Surgical wound infection:
“There are examples of comprehensive, hospital-based monitoring systems of surgical wound infection, mainly under the auspices of nosocomial surveillance. To date, however, there is little evidence of systematic measurement and monitoring of surgical wound infection after hospital discharge.”

Anastomotic leak:
“No formal evaluations were found that assessed the validity or reliability of definitions or severity scales of anastomotic leak.”

Deep vein thrombosis:
“Although a critical review of the DVT literature could not be completed within the realms of this review, it was evident that a number of new techniques for the detection and diagnosis of DVT have emerged in the last 20 years.”

Surgical mortality monitoring systems:
“...The definition of surgical mortality is relatively consistent between monitoring systems, but duration of follow-up of death post-discharge varies considerably. The majority of systems report in-hospital mortality rates; only some have the potential to link deaths to national death registers. Risk assessment is an important factor and there should be a distinction between recording pre-intervention factors and postoperative complications. A variety of risk scoring systems was identified in the review. Factors associated with accurate and complete data collection include the employment of local, dedicated personnel, simple and structured prompts to ensure that clinical input is complete, and accurate and automated data capture and transfer.”

Was any cost information reported?
Not Applicable

Authors’ conclusions
“The use of standardised, valid and reliable definitions is fundamental to the accurate measurement and monitoring of surgical adverse events. This review found inconsistency in the quality of reporting of postoperative adverse events, limiting accurate comparison of rates over time and between institutions. The duration of follow-up for individual events will vary according to their natural history and epidemiology. Although risk-adjusted aggregated rates can act as screening or warning systems for adverse events, attribution of whether events are avoidable or preventable will invariably require further investigation at the level of the individual, unit or department.”

CRD Commentary
The majority of this review is devoted to definitions of the individual surgical adverse events listed.

What are the implications of the review?
The authors’ recommendations for future research in the field of patient safety were as follows:
“A critical review is needed of the surgical risk scoring used in monitoring systems. In the absence of automated linkage there is a need to explore the benefits and costs of monitoring in primary care. The growing potential for automated linkage of data from different sources (including primary care, the private sector and death registers) needs to be explored as a means of improving the ascertainment of surgical complications, including death. This linkage needs to be within the terms of data protection, privacy and human rights legislation. A review is needed of the extent of the use and efficiency of routine hospital data versus special collections or voluntary reporting.”
Title: Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review

Authors: Hunt D L
        Haynes R B
        Hanna S E
        Smith K

Authors' objectives
To assess the effects of computer-based clinical decision support systems (CDSSs) on physician performance and patient outcomes.

Type of intervention
Management.

Specific interventions included in the review
CDSSs in clinical settings were studied with CDSSs defined as any software designed to directly aid in clinical decision making in which characteristics of individual patients were matched to a computerized knowledge base for the purpose of generating patient-specific assessments or recommendations that are then presented to clinicians for consideration. Topics studied included the following: drug dosing; diagnosis of paediatric patients, patients presenting with chest or abdominal pain, and identification of patients at high risk of developing respiratory complications; preventive care (including reminders of both single and multiple tests such as blood pressure assessment, vaccination or cancer screening); and other aspects of medical care (including disease specific and numerous medical problems).

Participants included in the review
Study participants were health professionals in clinical practice or post-graduate training.

Outcomes assessed in the review
Assessed outcomes included clinician performance (measuring the process of care) and patient outcomes (including any aspect of patient well-being).

Study designs of evaluations included in the review
Studies were included if they fulfilled the following criteria: participants and outcomes were as defined above; CDSS was evaluated in a clinical setting; and data was collected prospectively with a contemporaneous control group. Trials were excluded if they did not include sufficient results to determine the effects of using CDSS.
What sources were searched to identify primary studies?
Studies from a previous review were included (see Other Publications of Related Interest). This previous review involved searching the US National Library of Medicine, MEDLINE, EMBASE, the International Information Service for the Physics and Engineering Communities (INSPEC), and SCIHEAD from 1974 to February 1992 for studies in any language. Conference proceedings and reference lists of relevant articles were reviewed and authors contacted. The search was updated using a similar strategy from February 1992 to March 1998. The MEDLINE search was conducted using the following terms: computer-assisted decision making; artificial intelligence; computer-assisted diagnosis; computer-assisted therapy; and hospital information systems. SCIHEAD was searched for references to the primary studies from previous reviews. The Cochrane library was searched for relevant citations. Reference lists from all relevant articles were examined and information on additional relevant published or unpublished studies sought from authors of relevant studies.

Criteria on which the validity (or quality) of studies was assessed
The following 5 potential sources of bias were assessed: allocation method (random vs. quasi-random vs. selected concurrent controls); unit of allocation (clinic vs. physician vs. patient); baseline differences between groups that were potentially linked to the study outcome (no baseline differences or appropriate statistical adjustment vs. baseline differences present and no statistical adjustment vs. unable to assess); type of outcome measure (objective or subjective outcome with blinded assessment vs. subjective outcome with no blinding of assessors and no explicit criteria for each outcome); and completeness of follow-up (> 90% vs. 80% to 90% vs. < 80%).

How were decisions on the relevance of primary studies made?
All citations, and index terms and abstracts where available were reviewed and rated as "potentially relevant" or "not relevant". Inter-rater reliability was assessed. Full text articles were reviewed independently by either reviewer regarding inclusion criteria with disagreements being resolved by consensus.

How were judgements of validity (or quality) made?
At least two authors assessed all primary studies independently for validity. A ten point rating scale was used and disagreements were resolved by consensus.

How were the data extracted from primary studies?
One of the authors extracted information concerning patients, setting, intervention and outcomes with this being verified by a second author. Measures of process of care and clinical outcomes were characterised for each study according to whether a statistically significant effect was reported.

Number of studies included in the review
A total of 68 studies were included (28 studies previously reviewed and 40 new studies).
How were the studies combined?
Narrative synthesis.

How were differences between studies investigated?
Linear regression of the validity score of all trials against their year of publication was used to determine changes in validity over time.

Results of the review
Inter-rater reliability for coding of identified studies as potentially relevant or not Kappa = 58% (95%CI: 42%, 75%). Agreement on eligibility of studies Kappa = 86% (95%CI: 76%, 97%). Chance-corrected agreement between reviewers on validity Kappa = 82% (95%CI: 67%, 97%).

The majority of trials were randomised with 9 studies (13%) using quasi-random allocation or selected concurrent controls. The 28 studies in the original review had validity scores ranging from 2 to 9 (mean 6.4) with 7 (25%) scoring between 8 and 10. Validity scores for the new studies ranged from 4 to 10 (mean 7.7) with 21 (53%) scoring 8 to 10. Linear regression of validity vs. year of publication estimated Beta = 0.14 (95%CI: 0.07, 0.20).

65 studies evaluating CDSSs on clinicians’ behaviour with 43 (66%) of these finding at least some benefit. These included 9 of 15 studies evaluating drug dosing; 1 of 5 studies evaluating diagnostic aids; 14 of 19 studies evaluating preventative care; and 19 of 26 studies evaluating other medical care.

14 studies evaluated the effect of CDSSs on patient outcomes with 6 (43%) documenting a benefit. 5 (62%) of trials finding no benefit had a power of less than 80% to detect a moderate or clinically important benefit.

Drug dosing: Benefit was found with the use of CDSSs in achieving or maintaining therapeutic theophylline (4 studies) or lidocaine hydrochloride levels (1 study) or improving anticoagulation control with heparin (1 study). 7 studies evaluating different outcomes in studies of warfarin control reported inconsistent results.

Diagnostic aids: the one study finding a benefit identified patients at high risk of developing respiratory complications postoperatively.

Prevention: all studies evaluated process of care with 14 (74%) of studies finding benefit for at least one care process. 1 study reported patient outcomes (blood pressure control) and noted no change.

Other medical care: inconsistent results were reported for hypertension care (2 studies: one reporting benefit); compliance with recommendations for diabetic care (4 studies: 2 reported improvement); compliance with recommendations for general medical problems (5 studies: all reported benefit).
studies reported patient outcomes with no improvement being reported for blood pressure (3 studies) and beneficial effects noted for changes in weight and quality of life (2 studies).

**Was any cost information reported?**

No.

**Authors' conclusions**

Published studies of computer based clinical decision support systems (CDSSs) are increasing rapidly and their quality is improving. The CDSSs can enhance clinical performance for drug dosing, preventive care, and other aspects of medical care but not convincingly for diagnosis. The effect of CDSSs on patient outcomes have not been sufficiently studied.

**CRD commentary**

The aims and inclusion criteria were clearly stated. A thorough literature search was conducted. Validity was assessed using defined criteria. Methods by which studies were selected for inclusion and validity assessed were described. Given the differences in clinical problems, interventions, and outcome measures, a narrative synthesis was appropriate. Relevant details of studies of drug dosing, preventative care and 'other medical care' were clearly presented.

Different outcomes were reported for some interventions but no discussion of potential causes of this heterogeneity was presented. Without some investigation of the heterogeneity among studies it is difficult to be certain of the aspect of the intervention that leads to benefit.

**What are the implications of the review?**

Clinical: Ambulatory care services and clinics should consider opportunities to acquire preventative care reminder systems. Diagnostic aids systems should only be deployed in settings in which they are being properly evaluated.

Research: Larger confirmatory studies of CDSSs in drug dosing systems may be warranted. Health care centres should include some form of in-house evaluation when incorporating CDSSs.
Title: Evidence on Interventions to Reduce Medical Errors.

Authors: Ionidis JPA
Lau J.

Authors’ objective
To retrieve and critically evaluate the available randomised evidence on interventions specifically aimed at reducing medical errors. To evaluate study designs and limitations in order to make recommendations for improving future research in this field.

Type of intervention
Organisation/management

Specific interventions included in the review
Randomised studies:
- Brand protocol by triage nurse for missed fracture, dislocation or effusion after trauma
- Teaching acute illness observation scales to mothers for parents not recognising illness as serious
- Pain relief with papaveretum for acute abdominal pain for wrong management (operate or not)
- Nurse practitioner vs. junior doctor providing care for significant clinical management error
- Computerised reminders of corollary orders for error of omission
- Multidisciplinary approach for inappropriate drug choice
- Leaflets (easy, moderate, difficult-to-read, none) for medication error
- Automated bedside dispensing for medication error
- Syringe (marked or not) and demonstrated dose for dose error from parents of patients
- Team intervention for serious medical error (non-intercepted)
- Self-medication program for medication error
- Illumination in the workplace (3 levels) for prescription error (content or labelling error)
- Pharmacist participation in rounds for prescription error leading to preventable adverse drug events (ADE).

Non-randomised controlled studies of interventions for the prevention of medication errors:
- Unit dose distribution system
  14 interventions
- Computerised physician order entry
- Computerised physician order entry with decision support
- Automated dispensing system for cart filling
- Counselling elderly before discharge/memory aids
- Computerised unit dose system
- Automated medication system.
Other non-randomised controlled studies:

- Automated drug dispensing for drug-dispensing system errors
- Single prescription sheet for wrong prescription or administration
- Computerised alerts, standard antibiotic administration, prompt physician notification of ADEs for allergic/idiosyncratic reactions and severe ADEs
- Computerised antibiotic management program for wrong antibiotic orders
- Computer-generated protocol for antibiotic dosing errors
- Computer monitoring and disciplinary actions for medication dispensing errors
- Redesigned drug sheet for wrong prescription or administration
- Computerised medication profile for drug interaction prescription errors
- Pharmacist participation in rounds for prescription error leading to preventable adverse drug events
- Computerised unit dose system for medication discrepancies
- Participation in clinical trials for dispensing errors
- Computer-assisted calculations for calculation and labelling errors
- Automated point-of-use unit drug distribution system for dispensing errors
- Computerised records shared by pharmacy and nursing for medication occurrences.

Participants included in the review

The authors do not give data on the included participants, but state that study populations were heterogeneous and that participant mean age ranged from 2 weeks to 83 years.

Outcomes assessed in the review

For the purposes of this review, the authors included medication errors (including prescription, dosing and omission errors), prescription of inappropriate/harmful diagnostic tests or omission of necessary orders/prescriptions directly related to patient safety, and misdiagnosis errors beyond the inherent limitations of applied diagnostic tests.

Studies with emphasis on patient compliance were excluded, unless emphasis was entirely on errors made by patients or parents because of inadequate information given by health care providers. Studies evaluating the omission or orders or actions suggested by preventative medicine guidelines were not included, because they usually constitute omission of potential benefit rather than direct harm to the patient.

Study designs of evaluations included in the review

The authors included all randomised, controlled trials that examined an intervention versus placebo or no intervention and specified the aim of reducing medical errors as the primary or secondary outcome. Only randomised evidence was considered for the main evaluation, though non-randomised studies were also collected for a complementary assessment of the evidence.
What sources were searched to identify primary studies?
The literature search was based on MEDLINE (1966-2000) and EMBASE searches. The main search was conducted in June 1999 and updated subsequently until March 2000. The search terms were 'medical errors', 'prescription errors', 'diagnostic errors' and 'medication errors' in conjunction with an array of terms characteristic of randomised controlled trials. The Cochrane Clinical Trials Registry was also searched. References lists of retrieved papers were screened and experts in the field were contacted. A similar search strategy was used to identify non-randomised studies. There were no language restrictions.

On what criteria was the validity of primary studies assessed?
Study quality was assessed by extracting data on blinding, randomisation, allocation concealment and details on withdrawals and excluded data.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for review, or how many of the reviewers performed the selection.

How were judgements of validity made?
Quality assessment was performed in duplicate and disagreements were discussed in a consensus conference.

How were the data extracted from the primary studies?
Quality assessment was performed in duplicate and disagreements were discussed in a consensus conference. The following data were extracted: year of publication, sample size (number of patients per arm and number of opportunities for error, if the latter was different from number of patients), study setting and study population characteristics, quality components, definition of errors and whether errors were a primary or secondary outcome, number or score of errors per arm and comparative statistics.

Number of studies included
13 (9888 patients, 369 mothers, 12663 opportunities for error) randomised studies were included in the main evaluation. 24 non-randomised studies were also retrieved and evaluated.

How were the studies combined?
For the randomised studies, relative risks, risk differences and numbers needed to treat were calculated where applicable, and presented in tables. Findings of both randomised and non-randomised studies were presented in a narrative synthesis. Comparisons between randomised and non-randomised studies were made on date of publication, reporting of clinically serious errors, finding the intervention ineffective, and specifying sample size.
How were differences between the studies investigated?
The authors noted that there was large heterogeneity of study designs, so a formal test of heterogeneity was not undertaken.

Results of the review
All identified randomised studies provided adequate details on randomisation and 10 of the 13 studies offered adequate data on withdrawals and exclusions. However, in most studies blinding and allocation concealment were impractical or impossible, with only two trials using blinding and just one ensuring the concealment of treatment allocation.

In 9 of the 13 randomised studies, the interventions were found to be effective in reducing error rates (relative risks ranged from 0.17 to 0.69). However, even in the 4 cases where the randomised intervention did not reduce error rates significantly, the conclusion of the study authors was (at least in part) favourable for the tested intervention.

Twenty-four non-randomised studies were retrieved and evaluated. They included 18 before-after studies, and 6 studies with concurrent controls, of which 2 were pseudorandomised. Twenty-one of the 24 non-randomised studies found the tested intervention to be effective.

There was heterogeneity between the included studies in terms of definitions of error, interventions, units of randomisation, and settings.

In the comparison of randomised versus non-randomised, non-randomised reports were more likely to have been published before 1990 (OR 6.5 (95% CI: 1.2, 36, p=0.035)). As compared to non-randomised reports, those of randomised design were more likely to report data on clinically serious errors (OR 3.1 (95% CI: 0.7, 14.7, p=0.229)), to find that the intervention was not effective in reducing errors (OR 3.1 (95% CI: 0.7, 15, p=0.213)), and to specify the sample size (OR, undefined, p=0.14), but these associations were far from being significant.

Authors' conclusions
Medical errors were very frequent in the identified studies, arising sometimes in more than half of the cases where there is an opportunity for error. Relatively simple interventions may achieve large reductions in error rates. Evidence on reduction of medical errors needs to be better categorised, replicated, and tested in study designs maximising protection from bias. Emphasis should be placed on serious errors.

CRD Commentary
This is, on the whole, a methodologically sound review that is well reported. The review question was good and supported by appropriate inclusion and exclusion criteria. The literature search was
comprehensive. Validity was assessed using appropriate criteria. Relevant study details were presented in tables and appropriately discussed in the text. Heterogeneity between studies was addressed and publication bias discussed. Although it was unclear how many reviewers selected papers for inclusion, the review was generally well reported. The conclusions and recommendations reflected the evidence reported.

**What are the implications of the review?**

Implications for research: the authors state that evidence on reduction of medical errors needs to be better categorised, replicated, and tested in study designs maximising protection from bias. They also state that emphasis should be placed on serious errors.

Implications for practice: the authors state that both randomised and non-randomised studies give results for reducing medical errors, and practically almost all of them show that some or all of the interventions under study are worthwhile adopting, based on the results of one or more outcomes. They state that the magnitude of the reported treatment effects is often very large and that this probably means that there is large room for improvements in medical errors, often with relatively simple interventions.
Title: Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies

Authors: Lazarou J
Pomeranz B H
Corey P N

Authors' objectives
To estimate the incidence of serious and fatal adverse drug reactions (ADR) in hospital patients.

Type of intervention
Treatment.

Specific interventions included in the review
All drug treatments.

Participants included in the review
The participants were not selected for particular conditions or specific drug exposures. All hospital patients who were either hospitalised because of an ADR or who suffered an ADR whilst being treated in hospital were included.

Outcomes assessed in the review
The incidence of fatal, serious and all severity ADRs (% number of patients experiencing an ADR) were assessed.

Study designs of evaluations included in the review
All prospective studies which reported sufficient information to calculate the incidence of ADRs. Only studies conducted in the USA were included in the meta-analysis.

What sources were searched to identify primary studies?
The following electronic databases were searched: MEDLINE (1966-1996), Excerpta Medica (1980-1996), International Pharmaceutical Abstracts (1970-1996), Science Citation Index (1989-1996). 'adverse drug' or 'adverse reaction' or 'drug-related' or 'drug-induced' and 'hospital' were used as keywords along with the following MeSH terms where appropriate 'hospitalisation', 'drugs' and 'drug therapy/adverse effects'. The reference sections of all retrieved articles were manually searched and letters were sent to researchers in the field to request unpublished data, in order to try and reduce the possibility of publication bias occurring. Studies were only included if English translations were available.
On what criteria was the validity of primary studies assessed?
The authors do not report a method for assessing validity.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for review, or how many of the authors performed the selection.

How were judgements of validity made?
A formal assessment of validity was not carried out but the authors tried to increase the overall quality of the selected studies by excluding the ‘lowest quality studies’ (ie retrospective studies) and excluding ADRs that were classified as 'possible' (ie an ADR which follows a reasonable temporal sequence and for which the ADR is a known response for the drug, but which may also be explained by the patient's clinical state).

How were the data extracted from primary studies?
A random selection of studies were checked for agreement by two authors independently. The intraclass correlation coefficients ranged from 0.89 to 0.92 for the data extracted including the incidences of serious, fatal and all severity ADRs. The following information was extracted: year of study, ward and hospital type, mean age, average length of time in hospital, average number of drug exposures, information on non-serious, serious and fatal ADRs.

Number of studies included in the review
39 prospective studies (18 in-patient studies including 34,463 participants; and 21 admission studies including 28,017 participants).

How were the studies combined?
The studies were combined and the data analysed in terms of the incidence of in-patient (ADRI\textsubscript{In}) and admission (ADRI\textsubscript{Ad}) ADRs. In addition separate analyses of serious, fatal and all severity ADRs were performed. The studies were combined using a random-effects model and the results presented in terms of mean incidences with 95% confidence intervals.

How were differences between studies investigated?
Steps taken by the authors to reduce the incidence and effects of heterogeneity were discussed. Four factors (age, gender, drug exposure and the length of stay) thought to affect ADR incidence were used in a linear regression version of the random-effects model to assess whether they accounted for the observed heterogeneity.
Results of the review

Linear regression showed that for ADRIn, the number of drug exposures and the length of hospital stay jointly accounted for 43% of the variance ($r=0.65$, $P=0.009$, $n=18$). If age was included for ARDAd, in addition to the aforementioned factors, the variance was reduced to 27% ($r=0.52$, $P=0.04$, $n=14$). The combined sample used in the meta-analysis differed significantly from the US hospital population as a whole with respect to length of stay and gender. There was no significant correlation between the year of publication and the incidences of ADRIn ($r=0.27$, $P=0.14$, $n=18$) and ARDAd ($r=0.23$, $P=0.34$, $n=21$). Medical wards were over represented in the included studies, and unfortunately there was insufficient power to determine the possible effects that ward-type distribution may have on the results. Teaching hospitals were also over represented, however there were no significant differences with regard to teaching and non-teaching hospitals in terms of ARD incidences.

In-patient ADRs (ADRIn): Incidence of ADRs - Serious ADRs (n=12 studies; 22,502 participants) 2.1% (95% CI: 1.9, 2.3); Fatal ADRs (n=10 studies; 28,872 participants) 0.19% (95% CI: 1.13, 0.26); All severity (ie non-serious, serious and fatal) ADRs (n=18 studies; 34,463 participants) 10.9% (95% CI: 7.9, 13.9). Estimated number of hospital patients in 1994 with ADRs in thousands - Serious 702 (95% CI: 635, 770); Fatal 63 (95% CI: 41, 81); All severity 3607 (95% CI: 2618, 4596).

Admission ADRs (ARDAd): Incidence of ADRs - Serious ADRs (n=21 studies; 28017 participants) 4.7% (95% CI: 3.1-6.2); Fatal ADRs (n=6 studies; 17,753 participants) 0.13% (95% CI: 0.04, 0.21); All severity ADRs (not reported as by definition all ADRs are serious otherwise the patient would not have been admitted to hospital). Estimated number of hospital patients in 1994 with ADRs in thousands - Serious 1547 (95% CI: 1033, 2060); Fatal 43 (95% CI: 15, 71); All severity 1547 (95% CI: 1033, 2060). 8/21 ADRAd studies included the proportion of type A (dose-dependent ADRs) and type B (idiosyncratic and/or allergic ADRs).

For All severity 76.2% (95% CI: 71.0, 81.4) were type A reactions and 23.8% (95% CI: 18.6, 29.0%) were type B reactions.

In-patient ADRs (ADRIn) and Admission ADRs (ARDAd) combined:

Incidence of ADRs - Serious ADRs (n=33 studies; 50,519 participants) 6.7% (95% CI: 5.2, 8.2); Fatal ADRs (n=16 studies; 46,625 participants) 0.32% (95% CI: 0.23, 0.41); All severity ADRs (n=39 studies; 62,480 participants) 15.1% (95% CI: 12.0, 18.1). Estimated number of hospital patients in 1994 with ADRs in thousands - Serious ADRs 2216 (95% CI: 1721, 2711); Fatal ADRs 106 (95% CI: 76, 137; All severity ADRs 4986 (95% CI: 3976, 5995).
Was any cost information reported?
No.

Authors’ conclusions
The incidence of serious and fatal ADRs in US hospitals was found to be extremely high. While our results must be viewed with circumspection because of heterogeneity among studies and small biases in the samples, these data nevertheless suggest that ADRs represent an important clinical issue.

CRD commentary
This is a clearly described study that uses an extensive literature search with defined search terms and well-defined inclusion criteria. Some relevant information may have been excluded however, as only studies with English language translations were assessed. The methods used to extract data from the included studies are described, but the authors fail to state how decisions were made about the relevance of the studies and their quality. Additional information in the results tables regarding the age of study participants, the study setting and length of the study period, would have been useful.

Heterogeneity is inevitable in this meta-analysis due to the all-inclusive inclusion criteria with regards to the type of participants and drug treatments studied. The authors describe the steps taken to reduce the heterogeneity including using a random-effects model and 95% CI intervals to highlight the issue. In view of these limitations and the results presented, the authors’ cautious conclusions would appear to be valid.

What are the implications of the review?
None stated.
Title: Computerised Advice on Drug Dosage to Improve Prescribing Practice

Authors: Walton R.T.
Harvey E.
Dovey S.
Freemantle N.

Authors’ objective
The authors’ stated objectives were:

To determine:
1. Whether there is clear evidence that computerised advice on drug dosage is beneficial and hence whether such advice should be more widely available.
2. What further research is required to assess the value of such advice in settings where it might be of use.”

Seven hypotheses were tested, of which number five and six were directly relevant to patient safety:
5. Decisions on drug dosage based on computer advice lead to fewer unwanted effects than conventional dose adjustment.
6. Computer advice given in real time is more effective than that given by delayed feedback.”

A further potentially relevant hypothesis was added during the course of the review:
“Computer advice reduces the cost of healthcare.”

Type of intervention
Organisation/management

Specific interventions included in the review
All comparative studies of computer advice on drug dosage, including studies where the computer directly administered the drug to the patient (e.g. as an infusion). Studies where computer-controlled infusion was not under the control of a clinician were excluded.

Participants included in the review
Any health professional (e.g. doctors nurses or pharmacists) with responsibility for patient care.

Patients receiving drug therapy based on:
1. Advice from a computer
2. Advice from any other source
3. Unassisted clinical judgement

Outcomes assessed in the review
The review included studies with any of six outcome measures, of which three were directly relevant to patient safety:
1. Proportion of patients where the therapeutic regimen is changed due to computer advice.
2. Proportion of patients with unwanted effects of drug therapy.
3. Proportion of patients with improved outcome from computer advice, such as reduced incidence of bleeding on warfarin.

Study designs of evaluations included in the review
The following study designs were included:
- Randomised controlled trials
- Interrupted time series analyses
- Non-equivalent group studies with pre and post measures (controlled before and after studies)

What sources were searched to identify primary studies?
The following electronic bibliographic databases were searched:
- Cochrane EPOC specialised register
- MEDLINE (1966-June1996)

Search terms were (“Computer Systems”[MESH] OR “Artificial Intelligence”[MESH]) AND (prescr* OR “drug therapy”[MESH] AND (“Comparative Study”[MESH] OR “Clinical Trials”[MESH]).

The journal “Therapeutic Drug Monitoring” was handsearched (1979-June1996), as were reference lists from primary articles, and experts in the field were contacted.

On what criteria was the validity of primary studies judged?
Methodological quality was assessed using published EPOC criteria.

How were decisions on the relevance of primary studies reached?
Papers were selected for inclusion by two authors independently. Disagreements were resolved by discussion.

How were judgements of validity made?
Methodological quality was assessed by two authors independently. Disagreements were resolved by discussion.

How was the data extracted from primary studies?
Data was extracted by two authors independently. Disagreements were resolved by discussion.

Number of studies included
A total of 15 studies met the inclusion criteria. This represented a total number of included patients of 1229.

The clinical disciplines represented by these studies were:
- Anaesthesia
- Internal Medicine
How were the studies combined?
Narrative synthesis

How were the differences between studies investigated?
Not Applicable

Results of the review
Comparison 1. Giving the health professional computer advice, or allowing the computer to administer drug directly, leads to a change in drug dosage. Studies reporting changes in dose were separated into three groups (initial dose, maintenance dose, and total amount of drug used):
  Four studies provided outcomes for the analysis of initial dose; initial doses tended to be higher with computer support.
  Eight studies provided data on maintenance dose; overall the pooled effect showed a tendency for maintenance doses to be higher in the computer groups, but this did not reach statistical significance.
Comparison 5. Decisions on drug dosage based on computer advice lead to fewer unwanted effects than conventional dose adjustment:
  Four studies that evaluated the impact of computer advice on toxic drug levels were included in this comparison; combined they showed a significant effect in favour of the computer group.
  Six studies assessed the effect of computer support on adverse reactions; again the results favoured the computer group.
Comparison 6. Computer advice given in real time is more effective than that given by delayed feedback:
  No outcomes were available for this comparison.

Was any cost information reported?
The hypothesis that computer advice on drug dosage reduced the cost of health care was examined. Both studies on computer support for aminoglycoside dosage reported economic data although neither conducted a full cost minimisation analysis. Both studies reported significant reduction in mean cost per patient associated with computer support. These cost savings resulted largely from reduced hospital stays.

Author’s conclusions
Implications for practice:
1. Computer support for dosage of drugs with a narrow ‘therapeutic window’ could help to reduce the numbers of patients with toxic levels and reduce the time taken to achieve therapeutic control. Benefits resulting from this include fewer adverse effects and shorter hospital stays. However more research is needed to evaluate risks and benefits.

2. The computer systems identified in our review were more accurate than clinicians at tailoring the dose to the individual patient. It is not certain that these benefits could be achieved with different computer systems in different clinical situations.

Implications for research:

1. Many studies so far have been too small to demonstrate clinically significant effects and most do not record sample size calculations. Adequate power is essential.

2. The studies that we identified usually randomised patients to treatment or control groups. This means that the same physician may be treating the intervention and control groups and hence there is a high likelihood of contamination. Study designs should be carefully chosen to avoid this effect.

3. To realise the full benefits of computer support for drug dosage, more studies must be conducted in primary care, where most prescribing takes place. Systems developed for secondary care will need modification and testing in the new setting.

4. Future studies should evaluate
   a. patient-based outcomes (unless there is definite evidence that control of dosage improves outcome)
   b. adverse effects of computer support (such as numbers of patients with toxic drug levels)
   c. economic effects of computer interventions
   d. potential barriers to implementation of systems
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