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Safety and Risk Management Interventions in Hospitals: A Systematic Review of the Literature

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The aim of this systematic review was (a) to synthesize the evidence on the effectiveness of detection, mitigation, and actions to reduce risks in hospitals and (b) to identify and describe components of interventions responsible for effectiveness. Thirteen literature databases were explored using a structured search and data extraction strategy. All included studies dealing with incident reporting described positive effects. Evidence regarding the effectiveness and efficiency of safety analysis is scarce. No studies on mitigation were included. The collected evidence on risk reduction concerns a variety of interventions to reduce medication errors, fall incidents, diagnostic errors, and adverse events in general. Most studies reported positive effects; however, interventions were often multifaceted, and it was difficult to disentangle their impact. This made it difficult to draw generic lessons from this body of research. More rigorous evaluations are needed, in particular, of continuous learning and safety analysis techniques.

INTRODUCTION

In 2000, the American Institute of Medicine (IOM) published a landmark report, *To Err is Human: Building a Safer Health System* (IOM, 2000). It was stated in the report that between 44 000 and 98 000 people die annually in U.S. hospitals as a result of medical errors. Since the publication of the report, patient safety has increasingly become a matter of interest to health care professionals, governments, policy makers, and researchers internationally (IOM, 2001, 2004). Many studies have been conducted to assess the prevalence, severity, and causes of adverse events (AEs) in hospitals as well as the effectiveness of efforts and approaches to enhance safety and to reduce risks. It seems that, on average, the most appropriate health care is delivered to just a little more than half of the patients (McGlynn et al., 2003; Scott et al., 2004). Retrospective record review studies in several countries have shown that 2.9% to 16.6% of patients in acute care hospitals experience one or more AEs (Baker et al., 2004; Davis et al., 2002; Vincent, Neale, & Woloshynowych, 2001; Zegers et al., 2009). In 4.5% to 20.8% of the AEs, the patient dies, and approximately 50% of the AEs are judged to be preventable. These figures indicate the importance of effective safety and risk management (SRM) in hospitals.

SRM encompasses activities or measures taken "by an individual or a health care organization to prevent, remedy or mitigate the occurrence or reoccurrence of a real or potential (patient) safety event" (World Health Organization World Alliance for Patient Safety, 2006, p. 8). A patient safety incident, moreover, is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient (Runciman et al., 2009). The potential array of SRM topics is extremely wide. It ranges from guideline compliance and information technology to human resource management and interinstitutional improvement initiatives.

Before going deeper into the details and the focus of our contribution, we will examine certain key concepts and a conceptualization of the relations between them.

Key Concepts From the International Classification for Patient Safety (ICPS)

A logical starting point for an attempt to collect and synthesize the evidence on effective SRM interventions is to make an inventory of key concepts. An understanding of the patient safety literature, however, has been compromised by the inconsistent use of language (Runciman et al., 2009). Similar patient safety concepts have different terms (e.g., *near miss*, *close call*), and identical terms are used to embrace several concepts (*medical error* for errors, violations, and system failures; see also Elder, Pallerla, & Regan, 2006; Runciman, 2006). To meet the need for clarification and standardization, the World Health Organization's World Alliance for Patient Safety has undertaken a project to develop an International Classification for Patient Safety. The ICPS is intended to define, harmonize, and group a standardized set of patient safety concepts—with agreed definitions and labeled with preferred terms—into an internationally acceptable classification in a way that is conducive to learning and to improving patient safety across time and borders (Sherman et al., 2009). The current conceptual framework consists of three categories that are linked by several semantic relations. Two of the categories affect the clinically meaningful categorization of an incident (based on incident types and patient outcomes) and descriptive information about the context of the incident, including patient characteristics, incident characteristics, contributing factors/ hazards, and organizational outcomes. The third category, "proactive and reactive system resilience," affects the activities and measures belonging to the area of SRM. Within the ICPS, a distinction is made between detection, mitigating factors, ameliorating actions, and actions taken to reduce risk (Figure 1; for more information on the categories and the classes, see Table 1). The current study addresses this third category of the conceptual framework.

[FIGURE 1]

[TABLE 1]

New Contribution

There is a substantial body of research in the area of patient safety. It is an ongoing challenge to keep track of the growing literature and to categorize study findings and their implications in an orderly way. In their systematic review, Hoff, Jameson, Hannan, and Flink (2004) examined the relation between system features and safety outcomes. They addressed the evidence available on associations between organizational dynamics, medical errors, and patient safety. Their contribution involved an exploration of the relevance of, among others, culture, organizational structure, teams, feedback, opinion leaders, board leadership, educational programs, and information technology. Only a small number of studies confirmed a relation between system components and errors or safety. This is an important finding. Still, a possible explanation might be that the distance between system features and medical errors and safety events as investigated by Hoff et al. (2004) is too large. A complementary perspective is that the field of organizational dynamics indeed covers important conditions but that the association between conditions and safety outcomes depends on the successful implementation of specific SRM interventions. In other words, interventions, and not the organizational features, are linked more directly to patient safety. The effectiveness of such interventions, implemented within hospital organizations, is the main focus of our systematic review. Furthermore, given the nature of the international taxonomy debate and the gradual progress that is being made with regard to the development of a conceptual framework (Figure 1), we apply our review on the effectiveness of SRM interventions from a system resilience perspective.

The concept of resilience in the context of the ICPS is defined as "the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents" so that an organization can "bounce back" to its original ability to provide core functions (Sherman et al., 2009, p. 5). We underline the notion that together, detection and mitigation can impede the progression of an incident from reaching and/or harming a patient. However, we choose to refrain from placing undue emphasis on the effectiveness of ameliorating actions in the sense of responses to harm, that is to say, unless a direct influence of reactive damage control actions on the dependent variable (e.g., number and severity of medical errors, AEs, events reported, or hazards/root causes identified) is assessed. The primary study objective is (a) to

synthesize the evidence on the effectiveness of detection, mitigation, and actions to reduce risks in hospitals and (b) to identify and describe the components of interventions that are responsible for effectiveness.

DATA AND METHODS

Databases

To identify empirical studies, electronic searches were performed in PubMed, PsycINFO, EMBASE, the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, the Health Technology Assessment Database, the NHS Economic Evaluation Database, the Cumulative Index to Nursing & Allied Health Literature, King's Fund database, World Health Organization Library & Information Networks for Knowledge Database, Sociological Abstracts, and Web of Science. Searches were conducted in May and June 2008.

[TABLE 2]

Search Terms

The search strategy was based on a combination of several search terms—*safety management* or *risk management* together with *medical errors*, *adverse events*, *incidents*, or *near misses*—and were restricted to *hospitals* (see Table 2). An incident is an "event or circumstance that could have resulted, or did result, in unnecessary harm to a patient" (Runciman et al., 2009). AEs are "occurrences during clinical care that result in physical or psychological injury or harm to a patient or harm to the mission of the organization" (Battles & Lilford, 2003). Near misses are "events in which the unwanted consequences were prevented because there was a recovery by identification and correction of the failure, either planned or unplanned" (Van der Schaaf, 1992). Terms were used in singular and plural form, with medical subject headings (MeSH) if the database supported this option (i.e., safety management, risk management, medication errors, and hospitals).

Inclusion Criteria

As this review is on the effectiveness of interventions, stringent inclusion criteria were adopted concerning the study design. First, only systematic reviews, randomized controlled trials (RCTs), controlled-before-and-after studies (CBAs), and interrupted time series (ITSs) were included. As this limitation excluded too many potentially interesting studies, during the literature search phase, it was decided to include uncontrolled-before-and-after studies (UBAs) as well. To ensure that evaluation studies with the preferred design were included, a methodological search filter developed by the Cochrane Effective Practice and Organisation of Care Group (EPOC) was added to the search terms. Second, studies were excluded if no intervention or a clinical intervention was described. Third, exclusion took place if outcomes measures were not related to the quantity or quality of (reported/identified) incidents, risks, errors, AEs, near misses, root causes, and so on. A fourth exclusion criterion was that interventions had to be implemented in a hospital setting. In addition, studies not published in English were excluded.

Screening

Screening took place in different stages. During the first round, two reviewers independently screened articles retrieved on title and abstract or, if needed, the full text, based on the inclusion criteria. For the articles to be found appropriate in the screening phase, one author (MD) checked the full text of the article to confirm eligibility. Next, data were extracted using prestructured forms by four independent reviewers, each handling an equal number of articles. The data extraction was checked for completeness and correctness by an independent second reviewer. A third reviewer was consulted in those instances in which discrepancies were found.

In the case of systematic reviews (of reviews), the topic, setting, search period, data sources, number of included studies, main SRM outcomes, and conclusions were described. For nonreview articles, the study setting and the nature of the intervention were described. With regard to the main outcomes, a differentiation was made as to whether the intervention affected the number of reported or identified events,

the willingness to report, changes in patient safety outcomes and risks (occurrence, severity), safety culture or staff satisfaction, efficiency benefits, or other types of outcomes.
A general hierarchy of evidence classification was applied (the first being the strongest): systematic reviews of reviews, systematic reviews, RCTs, CBAs, ITSs, and UBAs. For all included articles, an indication of the methodological quality of the study was reported, based on EPOC criteria for reviews, RCTs, CBAs, and ITSs (The Cochrane Collaboration; criteria are summarized in the appendix). The classification on methodological quality was based on two rules, which are described below.
(a) If zero to two of the criteria were not fulfilled or reported unclear in the case of an RCT, CBA, or ITS, the study was considered strong. Study designs with half or less of the criteria not fulfilled or reported unclear were labeled moderate. Designs were considered weak if more than half of the criteria were not fulfilled or reported.
All UBAs were considered weak as they do not meet most of the criteria. (b) An additional weight was given to fundamental characteristics of different studies: Critical aspects of the methodological quality must be guaranteed. RCTs and CBAs were rated moderate if comparability of control groups was not met or unclear.

Studies Included

A total of 3,772 references to studies were found in the various literature databases.
Application of the methodology filter to further reduce this number in preparation for the first screening round helped decrease the total to 1,872 studies. Approximately 65% of the studies were provided by PubMed. After the total number of studies was checked for duplicates, the abstracts of 1,645 unique studies were examined using the inclusion criteria. After abstract screening and full text confirmation, 146 articles were found to be eligible. Two reviewers assessed these articles in full text and included 38 studies: 3 systematic reviews, 6 RCTs, 4 CBAs, 9 ITSs, and 16 UBAs. Two of the RCTs were taken from a Cochrane review on fall prevention (Gillespie et al., 2003), which contained two studies about interventions in a hospital setting (Donald, Pitt, Armstrong, & Shuttleworth, 2000; Tideiksaar, Feiner, & Maby, 1993). All included studies were given a quality rating, ranging from strong to weak (see Tables 3 and 4).
The design of four studies was considered strong (Berner et al., 2006; Paoletti et al., 2007; Schneider et al., 2006; Walsh et al., 2008) and the design of seven studies moderate (Kozer, Scolnik, MacPherson, Rauchwerger, & Koren, 2005; Leape et al., 1999; Lehmann et al., 2007; Schwendimann, Buhler, De Geest, & Milisen, 2006; Simon, Lee, Cooke, & Lorenzetti, 2005; Snijders, van Lingen, Molendijk, & Fetter, 2007; Voeffray et al., 2006). The remainder (25 studies) were of weak methodological quality. Major limitations of the reviews were the absence of studies with strong designs and unclear descriptions of review procedures. In the case of RCTs, CBAs, and ITSs, uncertainty often existed about the extent to which a perceived change was independent of other changes. The authors of most RCTs and CBAs could not guarantee the absence of contamination of interventions (the possibility that the intervention reached the comparison groups). ITSs were rarely examined with appropriate statistical techniques, and the reliability of the outcome measure of many UBAs was unclear.
In general, interventions were multifaceted but poorly specified.
More than half of the material came from the United States. The other studies were conducted in the United Kingdom, Australia, Canada, the Netherlands, and Switzerland. The studies focused on acute care, medical wards, ambulatory care, general internal medicine, pediatrics, cardiology, surgery, geriatrics, intensive care, and chemotherapy. Some studies made no distinction in the specialty or the types of patients treated.

RESULTS

Discussion of the evidence on SRM interventions is organized into three subsections: detection, mitigation, and actions to reduce risks.

Detection

Detection was defined as an action or circumstance resulting in the discovery of an incident. Approximately one quarter of the included studies evaluated detection approaches. Studies could be divided into two categories: incident reports (Table 3) and analysis techniques.

Incident reports. Six studies address the effectiveness of reporting systems as an organizational instrument to detect safety incidents. All six report positive effects on the quality and/or quantity of reported incidents. Two systematic reviews focused on the effectiveness of incident reporting systems and their characteristics. Simon et al.
(2005) assessed the effectiveness of hospital incident reporting systems in improving hospital and clinic performance in terms of patient safety, clinical outcomes, costs, and operations. The main findings were that incident reporting and chart review detection were effective but less reliable than direct observation. This was also a conclusion in the second review. Snijders et al. (2007) narrowed the scope to characteristics of incident reporting systems in neonatal intensive care units in relation to type, etiology, outcome, and preventability of incidents. Medication incidents were most frequently reported. The total error rate was much higher in studies using voluntary reporting than in a study using mandatory reporting. Multiinstitutional reporting identified uncommon but important errors. A substantial number of incidents were potentially harmful.
The four other studies all described positive detection effects of voluntary or nonpunitive reporting systems. Harris et al. (2007) compared the introduction of a new voluntary paper card–based event reporting system with existing online tools.
In both systems, nurses submitted the majority of the reports (nurses, 67.1%; physicians, 23.1%; other reporters, 9.5%). However, with the paper-based system, the greatest increase in reporting was experienced with physicians. Lehman et al.
(2007) discovered a significant increase in the number of reports and a change in the type of errors after the hospital-wide implementation of a revised medication event reporting policy in 2005. This was preceded by strategy sessions with the senior management about nonpunitive reporting in the autumn of 1999 and smallscale implementation 1 year later. Plews-Ogan et al. (2004) evaluated the implementation of clinician-based near miss/AE voluntary reporting, coupled with systems analysis and redesign as a model for continuous quality improvement.
Effects on AE reporting were positive. Stump (2000) found a substantial increase in reported events within 1 year of redesigning the medication-error reporting process (see Table 3 for details).
In addition to reporting systems, other interventions to enhance incident reporting have been evaluated. Evans et al. (2007) described a significant improvement in reporting in inpatient areas and emergency units after implementation of an intervention package (Table 3). Sim and Joyner (2002) linked an increase in the reporting of medication variances to the introduction of a multidisciplinary team initiated to address medication-related patient safety initiatives. Silver and Antonow (2000) reported on how a Breakthrough Series model was applied to optimize medication error reporting.[1] Teams consisting of medical, pharmacy, and quality improvement staff attended seminars and acquired knowledge to enhance error reporting.
In summary, all retrieved studies on incident reporting, regardless of the quality of their design and the differentiation in interventions, describe ways to enhance incident reporting.
Analysis techniques. Extensive literature is available on different analysis techniques.
Woloshynowych, Rogers, Taylor-Adams, and Vincent (2005) described the nature and characteristics of different methods in industry and health care such as the Australian incident monitoring system, the critical incident technique, comparison with standards, failure mode and effect analysis (FMEA), organizational accident causation model, root cause analysis, and significant event auditing. Positive aspects are that these methods contribute to priority setting, emphasize the system and not the individual, and localize weak spots and risks in the organization of care.
Negative aspects are that they are sometimes highly time-consuming or complex, their outcomes depend on the level of available expertise, and a comprehensive answer is not always guaranteed. Although relevant, this and other studies addressing reactive (e.g., critical incident technique) or proactive (e.g., FMEA) analysis techniques could not be included in this review. They do not focus on effects or effectiveness. Two examples of studies that address the results of FMEA show that it enables the monitoring of changes. Bonnabry et al. (2005) compared an old and a new pediatric parenteral nutrition process to quantify the improved safety of the new process and to identify major residual risks. The FMEA was performed by a multidisciplinary team following a series of process steps: (a) prescription, (b) transmission to pharmacy, (c) pharmaceutical validation, (d) label production, (e) compounding, and (f) quality control. Several changes were implemented: new prescription software, direct recording on a server, automatic printing of the labels, and creation of a file used to pilot an automatic compounder. In the new process, the sum of the

criticality indices of all identified failure modes was reduced by 59% compared with the old process. Robinson, Heigham, and Clark (2006) also conducted a FMEA to identify risks in chemotherapy with the aim of implementing appropriate improvement strategies. Analysis results helped them implement changes in prescribing, dispensing, and administration. Based on this assessment (detection), an improvement in the potential prescribing error rate, dispensing error rate, and administration error rate was deemed feasible. The main conclusion to be drawn with regard to different analysis methods and techniques is that despite an abundance of descriptive material, information on their reliability and accuracy is limited. Studies comparing the effectiveness of analysis techniques were not found.

[TABLE 3]

Actions to Mitigate

Mitigating factors have been defined as actions or circumstances that moderate the progression of an incident toward harming the patient. Mitigating factors are designed to minimize the harm to the patient after the error has occurred and has triggered damage control mechanisms (Table 1). We did not identify studies that fit in this category.

Actions to Reduce Risks

The remainder of the included studies do not address interventions aimed at mitigation but at reducing risks. Actions taken to reduce risk concentrate on preventing the reoccurrence of the same or similar safety incidents and on improving system resilience (Table 1). The studies included are listed in Table 4. Main patient outcome categories were medication errors, fall incidents, diagnostic errors, human simulation training, and AEs and safety risks.

Medication errors. With 17 studies, interventions to reduce medication errors were by far the largest intervention category, and 10 different types of interventions were distinguished. Four studies evaluated the effectiveness of (a) computerized physician order entry implementation (CPOE). One of these was a systematic review conducted by Shamliyan, Duval, Du, and Kane (2008). They tested the hypothesis that with regard to pediatric and adult patients, medication errors and adverse clinical events decrease with CPOE compared with handwritten physician orders, independent of patient and provider characteristics. The main conclusion was that the CPOE implementation was associated with a significant reduction in medication errors. However, effects were possibly overestimated because of the use of nonrandomized uncontrolled interventions. Moreover, implementation of CPOE was not associated with a substantial improvement in patient safety, and the studies did not allow broad generalizability. Two other studies also reported positive effects of CPOE (King, Paice, Rangrej, Forestell, & Swartz, 2003; Voeffray et al., 2006). The authors of a fourth study, involving CPOE in pediatric inpatient care, concluded that CPOE was not as effective in reducing medication errors in the pediatric setting as it is in adult inpatient care (Walsh et al., 2008). Two studies described how (b) pharmacist participation in physician/postadmission rounds led to lower rates of preventable adverse drug events (ADEs; Leape et al., 1999) and enhanced the accuracy of medication history (Fertleman, Barnett, & Patel, 2005). The effectiveness of (c) education tools was examined in three studies with mixed results. Simpson (2004) concluded that the impact of a combined risk management/clinical pharmacist–led education program on medication errors occurring in a neonatology intensive care unit was significantly positive. This was identical to the assessment by Schneider et al. (2006) on the influence of an interactive CD-ROM program on the rate of medication administration errors made by nurses. Nevertheless, this second approach did not contribute to a significantly reduced administration error rate. Manning et al.
(2007) pointed out that the introduction of a Web-based educational tool was also not accompanied by a reduction in self-reported error rate. Berner et al. (2006) evaluated the effectiveness of a (d) clinical decision support system on a personal digital assistant. The intervention group with this decision support tool revealed a significantly lower mean proportion of cases per physician with unsafe prescriptions.
Two other studies dealt with the effectiveness of (e) bar code technology.
Paoletti et al. (2007) described the implementation of a multidisciplinary approach to systematically decrease medication errors through, among others, bar-codedmedication administration (Table 4). The medication error rate decreased significantly in one of the two intervention groups and was unchanged in the other. In the second study (Poon et al., 2006), bar-code technology resulted in a significant decrease in

dispensing errors and potential ADEs. Cohen et al. (2005) focused on a possible reduction of ADEs by (f) an organization-wide safety program. The positive effects (a significant reduction of ADE rate, proportion of patients with ADEs) were attributed to the program that included several measures (Table 4). Larsen, Parker, Cash, O'Connell, and Grant (2005) conducted a study to determine whether combining standard drug concentrations with (g) smart-pump technology reduced reported medication-infusion errors. They found that the significant reduction in the number of reported errors was associated with continuous medication infusions. Kozer et al.
(2005) concluded that a (h) structured order sheet was effective in reducing the incidence of medication errors in pediatric emergency departments. The intervention group used a new structured order sheet instead of the regular blank order sheets.
The (i) Breakthrough Series evaluation by Silver and Antonow (2000) was mentioned previously in the detection subsection. The authors reported a significant decrease in overall error frequency and a significant increase in error detection and prevention. The (j) FMEA conducted by Robinson et al. (2006) was also described in the previous section. After the implementation of improvement strategies, following from the analysis, improvements were realized in the potential prescribing error rate, actual dispensing errors, and actual administration errors. The use of preprinted standard order sets increased.
Fall incidents. Five of the seven studies addressing interventions to reduce the number and/or severity of fall incidents were multicomponent fall prevention programs.
Positive effects were reported by Dempsey (2004) and Donoghue, Graham, Mitten-Lewis, Murphy, and Gibbs (2005). Dempsey reported that because of the program, the number of falls was reduced between 1995 and 1996 by 55%. In 2001, however, the rate of patient falls had exceeded preresearch levels. Donoghue et al.
(2005) examined whether a companion observer program helped prevent high-risk inpatients in an acute aged care ward from falling. Patients at high risk were accompanied in a room staffed by volunteer companion observers (Table 4). The fall rate decreased significantly. A third program, evaluated by Williams et al. (2007) proved effective in reducing the number though not the severity of falls. In this systematic, coordinated approach, patients were classified according to three levels of risk (low, medium, high). Appropriate interventions in three categories (environment, mobility, elimination) were developed for each risk level on a fall care plan for each patient. In the two remaining studies, the intended decrease in falls was not detected.
Schwendimann et al. (2006) examined an interdisciplinary falls prevention program (activities are described in Table 4). After the implementation, a nonsignificant decrease in falls was observed. Lane (1999) evaluated the effectiveness of a falls prevention program in reducing the patient fall rate. The complete program contained a range of activities, although changes in fall rate and injury were insignificant.
Two other studies, dealing not with a fall prevention program but with other interventions, were extracted from the fall prevention interventions review by Gillespie et al. (2003). Donald et al. (2000) compared two flooring types—carpet and vinyl—in hospital bed areas and modes of physiotherapy—conventional therapy and additional leg strengthening exercises—in avoiding falls. No significant effect was found for either intervention. Tideiksaar et al. (1993) examined the clinical efficacy of a bed alarm system in reducing falls from beds in a geriatric evaluation and treatment unit. The system functioned properly. However, although there was a clinical trend toward reduced falls in the experimental group, no statistical difference in bed falls was found between the experimental and control groups.
Diagnostic errors. Two studies involving reminder systems were included, both reporting significant improvements. Ramnarayan et al. (2006a) examined the impact of a Web-based diagnostic reminder system on clinicians' decisions in an acute pediatric setting during assessments characterized by diagnostic uncertainty.
After the introduction of the computerized decision support system, the percentage of unsafe diagnostic workups decreased significantly. Ramnarayan et al. (2006b) assessed the impact of a diagnostic reminder system on the quality of clinical decisions made by various grades of clinicians during acute assessment. The mean count of diagnostic errors of omission decreased significantly, whereas the diagnostic quality score increased. Moreover, the number of irrelevant diagnoses increased but did not result in a corresponding increase in the number of irrelevant or deleterious tests and treatments.
Adverse events and risks. Four studies fit within this broad final category. In the institutional reporting systems review by Simon et al. (2005), the authors also assessed the effectiveness of reporting systems as

an SRM intervention to improve safety and reduce risks. The majority of the included studies (7 out of 11) reported no reduction in medical errors and AEs after implementation of incident reporting systems. The three other studies dealt with different interventions. Reported effects are mainly positive. Fraenkel, Cowie, and Daley (2003) report mostly positive effects of a computerized clinical information system implemented in an intensive care unit. Jain, Miller, Belt, King, and Berwick (2006) evaluated a combination of different interventions (Table 4), implemented one by one, over a 12-month period.
In a third study, the number of patient attendances associated with an AE decreased significantly when, again, a combination of interventions (Table 4) was implemented after a retrospective screening of patient files (Wolff & Bourke, 2002).
Simulated survival. A study by DeVita, Schaefer, Lutz, Wang, and Dongilli (2005) could not be categorized in any of the prior categories. DeVita et al. (2005) confirmed that simulated survival rates improved significantly after a human simulation training to develop multidisciplinary team skills. Course components are described in Table 4.
Overall, the studies addressing actions to reduce risks deal with many different types of interventions. Most of the reported safety improvement and risk reduction effects are positive: 11 of the 17 evaluated medication error reduction strategies are considered effective, whereas 4 appear partly effective, and 2 are ineffective; of the 7 fall rate intervention studies, 2 report positive effects, 2 are partly effective, and 3 are ineffective. Both diagnostic interventions are found to be effective, like the simulated survival training evaluation. Finally, 3 of the 4 studies, falling within the broad category of AEs and risks, present positive effects. The fourth study, a systematic review, points primarily to the ineffectiveness of reporting systems as a risk reduction intervention.

[TABLE 4]

DISCUSSION

The primary study objective of this review was (a) to synthesize the evidence on the effectiveness of detection, mitigation, and actions to reduce risks in hospitals and (b) to identify and describe the components of interventions that are responsible for effectiveness. The collected studies were categorized within different SRM activities as part of the ICPS framework (Figure 1 and Table 1).
The first activity is detection. All included studies dealing with incident reporting (i.e., incident reporting systems, intervention package, Breakthrough Series, and efforts by a multidisciplinary team) indicate some positive effect of the interventions studied on the quality and/or quantity of reports. Most of the research addresses reporting systems. When it comes to identifying their effective components, one finding is that voluntary incident reporting may lead to underreporting (Plews-Ogan et al., 2004). The total error rate seemed to be higher in studies using voluntary reporting than in a study using mandatory reporting (Snijders et al., 2007). In practice, nurses report considerably more events than do physicians (Harris et al., 2007; Simon et al., 2005). Feedback to the reporter is seen as a condition to guard the willingness of staff to continue to report incidents and near misses (Simon et al., 2005). Snijders et al. (2007) found, in the case of neonatology, that multiinstitutional reporting identified uncommon but relevant errors. Moreover, Harris et al. (2007) concluded that paper-based reporting sometimes works better than a Web-based tool.
The effective components of the other interventions to advance reporting are part of a larger intervention package. This makes it impossible to disentangle their effective components.
A second detection activity concerns analysis methods. Despite the large number of articles devoted to this subject, research addressing the effectiveness and efficiency of safety analysis is scarce (see also Vincent, 2004). There are indications that analysis techniques are effective in identifying potential risks or root causes and in monitoring changes. One study (weak design) shows positive effects of FMEA application, although information about which method works best in which circumstances in terms of effectiveness, efficiency, accuracy, and reliability cannot be provided.
No studies on mitigating factors were identified. The majority of the studies, also those with the strongest study designs, dealt with actions to reduce risk. The collected evidence contributes to the knowledge about what works in reducing the number and severity of medication errors, fall incidents, diagnostic errors, and AEs in general.

Unfortunately, however, it often remains unclear what the effective component was and why it worked. In reality, SRM interventions are embedded in the structure and process of health care organizations. Furthermore, the diversity of the collected material combined with the limited evidence per topic makes it difficult to draw generic conclusions or to conduct a quantitative meta-analysis.

Resilience is the degree to which a system continuously prevents, detects, mitigates, or ameliorates hazards or incidents so that an organization can bounce back to its original ability to provide core functions (Table 1). Within the context of resilience, SRM can be linked to implementation science and concepts like continuous quality improvement, cyclical quality management systems, and organizational learning. Improving safety and risk reduction, based on collected information about incidents and risks or analysis results, requires some sort of learning or feedback mechanism.

The study by Robinson et al. (2006) is an example of a case in which analysis results were used as input for improvement. Simon et al. (2005), however, concluded that many of the studies in their review on institutional reporting systems suffered from a flaw—namely, that they are based on the assumption that incident data will automatically improve safety performance by directing system or institutional interventions and by having an impact on health provider knowledge and skills via feedback. In many of the studies included in our review, the chronological or repetitive relation between detection, mitigation, and risk reduction actions could not be verified. A general conclusion is that the initiation of reporting systems is likely to contribute to an increase in the number of reports. The real challenge, however, is not related to the quantity or quality of reports but to the degree to which professionals or organizations use the collected information for the sake of improvement. Feedback is considered a sine qua non for learning and, thus, for continuous SRM. Still, its practical feasibility must be considered with some reservations.

There is limited evidence with regard to effective forms of safety feedback within health care (Benn et al., 2009), and a Cochrane review of audit and feedback, which included more than 100 trials, showed a very modest improvement in professional performance overall (Jamtvedt, Young, Kristoffersen, O'Brien, & Oxman, 2006).

Limitations

There are reasons to view the study findings with caution or to question their usefulness in initiatives to translate them to new settings. First of all, it seems highly probable that the published research on SRM has a substantial publication bias.

Almost 90% of the studies included in our review reported positive results. Second, more than two thirds of the included studies were of a low methodological quality.

The available research mainly comprises uncontrolled observational evaluations. In many of the studies, the sample size was relatively small, and details were described poorly, limiting the ability of the researchers to determine whether patients with particular characteristics (e.g., age, morbidity) were more or less likely to respond, for instance, to fall incident or medication safety interventions. In particular, the effects reported in the UBAs should be interpreted with caution.

Third, interventions were often embedded in multifaceted intervention packages or programs. In these instances, it was not possible to isolate the impact of specific components from other activities and conditions. This is not necessarily a problem but does make it difficult to determine what exactly caused an effect or lack thereof.

Fourth, most studies provided limited information on the costs relating to the intervention. Without this information, policy makers, program designers, managers, and/or professionals cannot make informed decisions about the costs and benefits of improvement schemes.

Finally, by taking the term *safety and risk management* as a starting point in our review, we have identified research that has been linked to this term in the literature.

Such an open approach gave us the opportunity to obtain a general sense of reference and guidance instead of directly focusing on specific applications. It is an explorative approach, in which the term itself defines the directions in which to look.

However, because of this, not all the safety research performed in the context of quality improvement has been included. We recommend extending the search strategy of future literature studies by using key phrases from the evolving ICPS framework.

Our decision to select studies with strong research designs follows from the study goal, but as a result, relevant information from studies not meeting this threshold was excluded. This is why only a selection of safety items were presented in this review, whereas highly relevant items like infection control were omitted.

Future Research

By linking our review to the ICPS framework, we have the opportunity to locate lacunae in the international literature on SRM. Most of the evidence discussed in this review affects detection and risk reduction measures. Researchers must feel encouraged to proceed with the evaluation of the effectiveness of these and other detection interventions. In particular, we recommend the further assessment and comparison of analysis techniques (and their role as a window on the system; Vincent, 2004). It is important to learn more about their effectiveness, efficiency, accuracy, and so forth. One way of exploring this tentatively is to have experts—having practical experience with particular analysis methods—analyze the same incident (in the case of causes) or process (in the case of failure modes) and study (a) whether their findings are similar, and if so (b) whether differences found can be attributed to the method or to the way in which the analysis was conducted. In this manner, one can perhaps decide whether the result of an applied risk analysis method depends on the type of analysis or on the presence of specific conditions during the implementation. Likewise, the impact of analysis techniques may be studied best in combination with safety improvement interventions.

Next, the low availability of material on mitigation is interesting, but it is in the area of continuous SRM and resilience where we perceive the highest need for original and system-oriented evaluations of effectiveness. How do SRM interventions contribute to continuous learning? Testable hypotheses can be formulated with regard to positive influences of various SRM approaches and conditions within hospitals, such as the application of integrated safety frameworks, organizational culture, safety culture, leadership styles, guidelines, performance management, continuous quality improvement techniques, multidisciplinary teams joining a quality improvement collaborative, and so on. Although high expectations are often raised, given the discourse in different branches of the social and organizational sciences, no evidence with regard to these topics was found in relation to SRM outcomes in the current review. This finding reflects that of other studies: for instance, the research evidence concerning collaboratives (Schouten, Hulscher, van Everdingen, Huijsman, & Grol, 2008) as well as the low number of studies found by Hoff et al. (2004) verifying the relation between organizational features and patient safety. Compared with the review by Hoff et al. (2004), which focused on conditions, our emphasis on interventions resulted in relatively many examples of studies describing positive effects on safety and risk outcomes. Nevertheless, the possibilities for future research are enormous. There is currently a substantial body of research on organizational changes in health care settings, but quality and safety systems have seldom been studied in rigorous evaluations, and therefore, their effectiveness remains unproven (Wensing, Wollersheim, & Grol, 2006). Authors of studies in this review have pinpointed the importance of follow-up measurements and the issue of sustainability (Dempsey, 2004; Kozer et al., 2005), and sustainability of implementation outcomes and changed practices is indeed a highly relevant research area (Greenhalgh, Robert, Bate, Macfarlane, & Kyriakidou, 2005; Grol, Bosch, Hulscher, Eccles, & Wensing, 2007). We strongly recommend that research on the improvement of patient safety links to and builds on the large and rich world of quality improvement research and implementation science (Grol, Berwick, & Wensing, 2008). For instance, it is not clear whether and how knowledge about the success and failure of the implementation of SRM interventions is used in dissemination decisions locally, nationally, or even internationally (in the case of effect studies published in international journals). Dissemination without a good understanding of the idiosyncrasies of a particular innovation may be a waste of time or may even be counterproductive.

A general conclusion drawn from this review is that it is surprising—given the international attention being given to patient safety—that the evidence base for SRM in a hospital setting is so limited. SRM should be approached like any intervention in health care in the sense that it should prove its effectiveness and costeffectiveness before wide implementation is promoted. At this point, the number and quality of published studies on the effectiveness of SRM interventions is too small to support conclusions regarding effectiveness in a systems perspective. In this sense, a substantial expansion and improvement in the research on SRM is extremely welcome.

Appendix

Reviews: (a) eligibility was scored by at least two authors; (b) authors used inclusion and exclusion criteria; (c) designs were judged using predefined criteria (EPOC, Jahad, etc.); (d) findings were scored by at least two authors; and (e) authors used data extraction forms.

Randomized controlled trial (RCT): (a) protection against selection bias, (b) protection against contamination (e.g., randomizing organization/professionals rather than individual patients), (c) protection against exclusion bias, (d) follow-up of patients or episodes of care, (e) comparability of baseline measurements, (f) protection against detection bias (blinded assessment of primary outcomes), and (g) reliability of primary outcome measures.

Controlled-before-and-after studies (CBA): (a) protection against contamination, (b) protection against exclusion bias, (c) follow-up of patients or episodes of care, (d) comparability of baseline measurements, (e) protection against detection bias, (f) characteristics for studies using second site as control, and (g) reliability of primary outcome measures.

Interrupted time series (ITS): (a) intervention is independent of other changes, (b) data were analyzed appropriately (ARIMA or time series regression), (c) reason for the number of points preintervention and postintervention given, (d) shape of the intervention effect was specified, (e) intervention unlikely to affect data collection, (f) protection against detection bias, (g) completeness of data set, and (h) reliability of outcome measures.

Uncontrolled-before-and-after studies (UBA): (a) reliability of outcome measures.

Note

1. Within Breakthrough Series, different multidisciplinary teams are trained simultaneously to apply plan–do–study–act cycles and to answer three questions: (a) What are we trying to accomplish? (b) How will we know that a change is an improvement? and (c) What change can we make that will result in an improvement? (Berwick, 1998; Langley et al., 1996). Teams receive organizational support and training, work under time pressure, and have to test several interventions while measuring outcomes.

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TABLES

Table 1
Ten Classes Within the Conceptual Framework for the ICPS (as Depicted in Figure 1)

Clinically meaningful incident categorization

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

Descriptive information providing context for the incident

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

System resilience (proactive and reactive risk management)

- The concept of resilience in the context of the ICPS is defined as the degree to which a system continuously prevents, detects, mitigates, or ameliorates hazards or incidents so that an organization can bounce back to its original ability to provide core functions.
- Actions taken to reduce risk concentrate on steps taken to prevent the reoccurrence of the same or similar patient safety incident and on improving system resilience. Actions taken to reduce risk are those actions taken to reduce, manage, or control any future harm, or probability of harm, associated with an incident. These actions may be directed toward the patient (provision of adequate care, decision support), toward staff (training, availability of policies/protocols), toward the organization (improved leadership/guidance, proactive risk assessment), and toward therapeutic agents and equipment (regular audits, forcing functions). Detection, mitigating factors, and ameliorating actions all influence and inform the actions taken to reduce risk.
- Detection is defined as an action or circumstance that results in the discovery of an incident. For example, an incident could be detected by a change in the patient's status, or via a monitor, alarm, audit, review or risk assessment. Detection mechanisms may be informally developed or built into the system as official barriers.
- Mitigating factors are actions or circumstances that prevent or moderate the progression of an incident toward harming the patient. Mitigating factors are designed to minimize the harm to the patient after the error has occurred and triggered damage control mechanisms. They can be directed to the patient (patient education/explanation, apology), staff (good supervision/leadership, effective communication, relevant persons educated), organization (effective protocol available, device management, and availability), an agent (infection control strategies implemented), or other.
- If the incident does result in harm, ameliorating actions can be introduced. Ameliorating actions are those actions taken or circumstances altered to make better or to compensate any harm after an incident. Ameliorating actions apply to the patient (clinical management of an injury, apologizing) and to the organization (staff debriefing, culture change, and claims management).

Source: Sherman et al., 2009; Thomson et al., 2009
Note: ICPS = International Classification for Patient Safety.

Table 2
Search Terms

Search Term
1 "Risk management" (all fields, if available MeSH)
2 "Safety management" (all fields, if available MeSH)
3 2 OR 3
4 "Medical error(s)" (all fields, if available MeSH)
5 "Incident(s)" (all fields)
6 "Adverse event(s)" (all fields)
7 "Near miss(es)"
8 4 OR 5 OR 6 OR 7
9 "Hospital(s)" (all fields, if available MeSH)
10 3 AND 8 AND 9
11 EPOC methodological filter
12 10 AND 11

Note: MeSH = medical subject heading.

Dückers, M., Faber, M., Cruijsberg, J., Grol, R., Schoonhoven, L., Wensing, M. Safety and risk management interventions in hospitals: a systematic review of the literature. Medical Care Research and Review: 2009, 66(6 suppl.), 90s-119s

Table 3
Characteristics of Studies Addressing Incident Reporting

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"[a]	Intervention	Outcome Measure(s)	Effective
Reporting systems				
Harris et al. (2007)	ITS, weak; none	New voluntary paper card–based event reporting system compared with an existing Web-based reporting system	Reporting of medical errors	Yes
Lehmann et al. (2007)	ITS, moderate; 3,4,6,8	Implementation of a hospital-wide nonpunitive reporting system and CPOE to decrease the potential for drug harm	Number and type of reported errors	Yes
Plews-Ogan et al. (2004)	UBA, weak; none	Voluntary near miss/adverse event reporting (combined with system analysis and redesign)	Clinical-based near miss/adverse event reporting	Yes
Simon, Lee, Cooke, and Lorenzetti (2005)[b]	Review, moderate; 2,3	Institutional medical incident reporting systems	Quality and quantity of incident reports	Yes
Snijders, van Lingen, Molendijk, and Fetter (2007)	Review, moderate; 1,2	Characteristics of incident reporting systems in neonatology (multiinstitutional, voluntary vs. mandatory, nonpunitive)	Type, etiology, outcome, and preventability of incidents	Yes
Stump (2000)	ITS, weak; none	Changing the traditional, multitiered incident-reporting system into a standardized, nonpunitive process with central pharmacy department receiving report within 48 hours; unified database; near misses can be captured in every process stage; structured check box reports, instead of handwritten free text; staff involved in reviewing data	Number of reported medication events	Yes

Dückers, M., Faber, M., Cruijsberg, J., Grol, R., Schoonhoven, L., Wensing, M. Safety and risk management interventions in hospitals: a systematic review of the literature. Medical Care Research and Review: 2009, 66(6 suppl.), 90s-119s

Table 3 (continued)

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"[a]	Intervention	Outcome Measure(s)	Effective
Other interventions				
Evans et al. (2007)	CBA, weak; 1,4,5	Intervention package: education, a range of reporting options, enhanced report management, and feedback	Number and type of reported errors	Yes
Silver and Antonow (2000)[b]	UBA, weak; none	Breakthrough Series: teams, improved information access, standardized and simplified medication procedures, restricted access to potentially lethal drugs, educating clinical staff, enhanced error reporting	Perceived number of reported medication errors: all errors* and error reaching patient	Yes No*
Sim and Joyner (2002)	UBA, weak; none	Multidisciplinary team addressing medication-related patient safety initiatives (number of variance reports)	Number of variance reports	Yes

Note: ITS = interrupted time series; UBA = uncontrolled-before-and-after studies; CBA = controlled-before-and-after studies; CPOE = computerized physician order entry.

a. See appendix.

b. Also included in Table 4 (study addresses risk reduction).

* refers to the outcome measure mentioned in column 4.

Dückers, M., Faber, M., Cruijsberg, J., Grol, R., Schoonhoven, L., Wensing, M. Safety and risk management interventions in hospitals: a systematic review of the literature. Medical Care Research and Review: 2009, 66(6 suppl.), 90s-119s

Table 4
Characteristics of Studies Addressing Actions to Reduce Risks

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"ª	Intervention	Outcome Measure(s)	Effective
Medication errors				
Berner et al. (2006)	RCT, strong; 1,3,4,5,6	Clinical decision support system on a personal digital assistant (PDA) compared with using a PDA without decision support	Proportion of patients with unsafe prescriptions	Yes
Cohen et al. (2005)	ITS, weak; 4,7	Organization-wide safety program, including formation of a patient safety council, assigning a full-time safety specialist, implementing an event reporting system, introducing drug protocols, weekly medication profile audits, and order standardization	ADE rates, proportion of patients with ADE, and number of ADEs associated with patient harm per total dose delivered	Yes
Fertleman, Barnett, and Patel (2005)	UBA, weak; none	Pharmacist participation on postadmission ward rounds (pharmacist added to posttake medical team)	Accuracy of medication history (detected accuracy)	Yes
Kozer, Scolnik, MacPherson, Rauchwerger, and Koren (2005)	RCT, moderate; 1,2,3,4,6	New structured order sheet instead of the use of regular blank order sheets, plus orientation during research, staff meetings, and a pilot study	Incidence of errors	Yes
King, Paice, Rangrej, Forestell, and Swartz (2003)	CBA, weak; 2,3,4	Computerized physician order entry system, interfaced with the laboratory system but not with the pharmacy computer, compared with handwritten medication errors	Overall medication error rate, potential ADEs, and ADE rate*	Yes No*
Larsen, Parker, Cash, O'Connell, and Grant (2005)	UBA, weak; none	Combining standard drug concentrations with "smart-pump" technology and human-engineered medication labels replacing pharmacy-generated labels	Reported continuous-medication-infusion error rate	Yes

(continued)

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Table 4 (continued)

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"[a]	Intervention	Outcome Measure(s)	Effective
Leape, Lawthers, Brennan, and Johnson (1993)	CBA, moderate; 2,3,4,5,7	Pharmacist participates in physician rounds (each morning) and stays in the unit for consultation and assistance to the nursing staff during the rest of the morning and is available on call throughout the day (compared with situation in which pharmacist is available but does not participate in rounds)	Rate of ADEs and preventable ADEs	Yes
Manning et al. (2007)	RCT, weak; 1,3,5,6	New Web-based education tool compared with a standard education tool	Number of self-reported errors	No
Paoletti et al. (2007)	CBA, strong; 2,3,4,5,6,7	Observation methodology and deployment of electronic medication administration records with bar code technology compared with usual care	Medication error rate and accuracy rate of medication administration	Yes/No
Poon et al. (2006)	UBA, weak; none	A bar code–assisted storage and retrieval system implemented in three configurations (in two, all doses were scanned once during the dispensing process, and in one configuration, dose was scanned if several doses of the same medication were being dispensed)	Dispensing error rate and potential ADE rate	Yes
Robinson, Heigham, and Clark (2006)	UBA, weak; none	Use of failure mode and effects analysis to identify risk and to use for implementing strategies	Prescribing, dispensing, and administration error rate	Yes
Schneider et al. (2006)	RCT, strong; 1,2,3,4,5,6	Interactive educational CD-program for nurses "Basic Medication Administration" compared with usual care	Deviation from safe administration practices error rate, preparation, and administration error rate* and error rate of deviation from prescribed therapy*	Yes No*

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Table 4 (continued)

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"[a]	Intervention	Outcome Measure(s)	Effective
Shamliyan, Duval, Du, and Kane (2008)	Review, weak; 4	Computerization of physician orders compared with handwritten physician orders	Prescription errors	Yes
Silver and Antonow (2000)[b]	UBA, weak; none	Breakthrough Series: teams, improved information access, standardized and simplified medication procedures, restricted access to potentially lethal drugs, educating clinical staff, enhanced error reporting	Number of errors observed: all errors, medication ordering,* transcription and verification, dispensing and delivery,* medication administration;* respondent indicating errors were discovered and prevented	Yes No*
Simpson (2004)	ITS, weak; 1	Combined risk management program, including clinical pharmacist–led education	Medication error rate	Yes
Voeffray et al. (2006)	ITS, moderate; 1,3,4,5	Computerized physician order entry system; junior doctor prescription validated by senior doctor online before being processed; after validation, automatic order transfer to nursing staff and pharmacy; correction on initial prescription is transmitted to all professionals involved	Prescription error rate	Yes
Walsh et al. (2008)	ITS, strong; 1,2,3,4,5,7	A commercial computerized physician order entry system using a weight-based dosage calculator to check medication dosage, with alert function (compared with former situation with paper-based nursing medication records and in which only the pharmacy used an automated check system for drug–drug interaction and allergies)	Errors in general, serious errors, nonintercepted serious interactions, preventable ADEs, rate of dosing errors, and administration errors	No

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Table 4 (continued)

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"[a]	Intervention	Outcome Measure(s)	Effective
Shamliyan, Duval, Du, and Kane (2008)	Review, weak; 4	Computerization of physician orders compared with handwritten physician orders	Prescription errors	Yes
Silver and Antonow (2000)[b]	UBA, weak; none	Breakthrough Series: teams, improved information access, standardized and simplified medication procedures, restricted access to potentially lethal drugs, educating clinical staff, enhanced error reporting	Number of errors observed: all errors, medication ordering,* transcription and verification, dispensing and delivery,* medication administration;* respondent indicating errors were discovered and prevented	Yes No*
Simpson (2004)	ITS, weak; 1	Combined risk management program, including clinical pharmacist–led education	Medication error rate	Yes
Voeffray et al. (2006)	ITS, moderate; 1,3,4,5	Computerized physician order entry system; junior doctor prescription validated by senior doctor online before being processed; after validation, automatic order transfer to nursing staff and pharmacy; correction on initial prescription is transmitted to all professionals involved	Prescription error rate	Yes
Walsh et al. (2008)	ITS, strong; 1,2,3,4,5,7	A commercial computerized physician order entry system using a weight-based dosage calculator to check medication dosage, with alert function (compared with former situation with paper-based nursing medication records and in which only the pharmacy used an automated check system for drug–drug interaction and allergies)	Errors in general, serious errors, nonintercepted serious interactions, preventable ADEs, rate of dosing errors, and administration errors	No

(continued)

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Table 4 (continued)

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"[a]	Intervention	Outcome Measure(s)	Effective
Fall incidents				
Dempsey (2004)	UBA, weak; none	Falls prevention program, consisting of an assessment tool, an alert graphic, and education for patient and staff	Fall rate	Yes
Donald, Pitt, Armstrong, and Shuttleworth (2000)	RCT, weak; 3,4,6	Comparison of carpet and vinyl flooring types in bed areas and two modes of physiotherapy	Number of fallers and fractures	No
Donoghue, Graham, Mitten-Lewis, Murphy, and Gibbs (2005)	UBA, weak; none	Companion observer program, based on 128 volunteer observers accompanying patients at high risk for falling on weekdays from 08:00 to 20:00 hours; primary objective: to observe patients for increasing agitation or risky behavior and, if needed, to reassure patient or to contact a nurse; observers were also involved in other activities, like conversation, playing cards, reading out loud, assistance in finding belongings, and meal setup	Fall rate	Yes
Lane (1999)	UBA, weak; none	Fall prevention program, including identification of patients at risk for falling and establishing guidelines for interventions promoting patient safety for patients at risk	Fall rate and injury rate after fall	No
Schwen-dimann, Buhler, de Geest, and Milisen (2006)	ITS, moderate; 2,4,5,7,8	Interdisciplinary fall prevention program: screening all patients at admission for risk of falls, examination of patients considered at risk, interventions for all patients to provide safety, intervention in patients considered at risk for falling, reassessment of patients who fell	Inpatient fall rate, proportion of major and minor injuries	No

(continued)

Table 4 (continued)

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"[a]	Intervention	Outcome Measure(s)	Effective
Tideiksaar, Feiner, and Maby (1993)	RCT, weak; 3,4	Bed alarm system	Number of patients sustaining falls from beds,* number of patients sustaining other falls	Yes No*
Williams et al. (2007)	UBA, weak; none	Systematic, coordinated approach: patients were classified according to three risk levels (low, medium, high); appropriate interventions (environment, mobility, elimination) were developed for each risk level on a fall care plan for each patient	Number and severity* of falls	Yes No*
Diagnostic errors				
Ramnarayan et al. (2006a)	UBA, weak; none	Computerized decision support system: Web-based diagnostic reminder system for clinical decision making	Number of diagnostic errors of omission	Yes
Ramnarayan et al. (2006b)	UBA, weak; none	Computerized decision support system: Web-based diagnostic reminder system for clinical decision making	Proportion of "unsafe" diagnostic workups following system consultation	Yes
Adverse events				
Fraenkel, Cowie, and Daley (2003)	ITS, weak; none	Clinical information system, replacing paper-based charts of patient observations, clinical records, results reporting, and drug prescribing	Medication incidents, intravenous incidents, ventilation incidents, pressure ulcers,* and other incidents	Yes No*
Jain, Miller, Belt, King, and Berwick (2006)	UBA, weak; none	Combination of interventions: physician-led multidisciplinary rounds, daily bed flow meetings to access bed availability, implementation of evidence-based practices related to quality initiatives, culture change with a forum on team decision making	Adverse events per ICU day, ventilator-associated pneumonia rate, bloodstream infection rate, nosocomial urinary tract infection rate, mortality rate	Yes

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Table 4 (continued)

Reference	Study Design, Overall Quality of Design; Individual Quality Items Scoring "Done"[a]	Intervention	Outcome Measure(s)	Effective
Simon, Lee, Cooke, and Lorenzetti (2005)[b]	Review, moderate; 2,3	Institutional medical incident reporting systems	Medical errors and adverse events	No
Wolff and Bourke (2002)	UBA, weak; none	Combination of interventions: retrospective medical record screening and clinical review followed by appropriate quality improvement actions	Relative risk and number of patient attendances associated with adverse events	Yes
Simulated survival				
DeVita, Schaefer, Lutz, Wang, and Dongilli (2005)	UBA, weak; none	Human simulation training/educational environment to develop multidisciplinary team skills, including Web-based presentation and pretest before the course, brief reinforcing didactic session on course day, three of five different simulated scenarios each followed by debriefing and analysis with the team	Simulated survival rates	Yes

Note: RCT = randomized controlled trial; ICU = intensive care unit; ITS = interrupted time series; ADE = adverse drug event; UBA = uncontrolled-before-and-after studies; CBA = controlled before and after studies.

a. See appendix.

b. Also included in Table 3 (study addresses incident reporting).

[a] refers to the outcome measure mentioned in column 4.

FIGURES

Figure 1
Conceptual Framework for the International Classification for Patient Safety