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Interventions to Improve Reporting of Medication Errors in Hospitals: A Systematic Review and Narrative Synthesis

ABSTRACT

Background

In 2017, the World Health Organisation pledged to halve medication errors by 2022. In order to learn from medication errors and prevent their recurrence, it is essential that medication errors are reported when they occur.

Objectives

The aim of this systematic review was to identify studies in which interventions were carried out in hospitals to improve medication error reporting, to summarise the findings of these studies, and to make recommendations for future investigations.

Methods

A comprehensive search of five electronic databases (PubMed, Medline (OVID), Embase (OVID), Web of Science, and CINAHL) was conducted from inception up to and including December 2018. Studies were included if they described an intervention aiming to increase the reporting of medication errors by healthcare providers in hospitals and excluded if there was no full-text English language version available, or if the reporting rate in the hospital prior to the intervention was not available. Data extracted from included studies were described using narrative synthesis.

Results

Of 12,025 identified studies, seventeen were included in this review - fifteen uncontrolled before versus after studies, one survey and one non-equivalent group controlled trial. Five studies carried out a single intervention and twelve studies conducted multifaceted interventions. The most common intervention types were critical incident reporting, implemented in fifteen studies, and audit and feedback, implemented in seven studies. Other intervention types included educational materials, educational meetings, and role expansion and task shifting. As only one study compared a control and intervention group, the effectiveness of the different intervention types could not be evaluated.

Conclusion

This is the first review to address the evidence on medication error reporting in hospitals on a global scale. The review has identified interventions to improve medication error reporting that were implemented without evidence of their effectiveness. Due to the essential role played by incident reporting in learning from and preventing the recurrence of medication errors more research needs to be done in this area.

Introduction

Medication errors (MEs), defined as '*any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer*', can occur at any stage in the prescribing, preparation, dispensing and administration of medicines.[1,2] A leading source of avoidable harm in healthcare worldwide, they are associated with an annual global cost of US$42 billion.[3] MEs are the 3rd leading cause of death in the United States of America (USA), after heart disease and cancer.[4] The scale of the problem is even larger in lower income countries, where patients experience twice as many disability-adjusted life years lost due to medication related harm than those in high income countries.[5]

In 2017, the World Health Organization (WHO) announced its third Global Patient Safety Challenge - 'Medication Without Harm' - which aspires to reduce the global rate of MEs by 50% in five years.[6] The nature of MEs makes it difficult to estimate their prevalence or the level of harm they can cause. The underreporting of MEs has been described, quantitatively and qualitatively, across various healthcare settings worldwide.[7–11] Several factors contribute to ME underreporting, including fear of reprisal, an impractical or burdensome reporting process and a lack of feedback on reported errors.[12–14] Along with ambiguity over the definition of an ME, healthcare providers may disagree over whether or not an error has occurred at all.[14]

In its landmark 1999 report, *To Err is Human*, the Institute of Medicine put forward that in order to learn from MEs and prevent their recurrence, an effective system for reporting these errors is essential.[15] It is now widely acknowledged that error reporting and analysis are key to improving patient safety, and high error reporting rates are considered indicative of a positive safety culture, rather than an unsafe healthcare environment.[13,14] In recent years, however, there has been debate over the effectiveness of incident reporting, with authors citing issues such as reporting bias, lack of feedback, and fear of blame as reasons why incident reporting has not led to a significant decrease in adverse events.[16–18] Despite the important role played by incident reporting in improving patient safety, no review has been carried out to date to address the evidence on ME reporting in hospitals on a global scale. The aim of this systematic review was to identify and summarise the studies investigating interventions to improve ME reporting in hospitals.

METHODS

Protocol Registration

This review was carried out in accordance with PRISMA guidelines.[19] A protocol for this review was registered in advance with the International Prospective Register of Systematic Reviews (PROSPERO): https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=116868 (registration number CRD42018116868).

Inclusion criteria

Studies were included in the systematic review if they investigated any intervention or strategy conducted in a hospital setting which aimed to increase the reporting of MEs, including randomised controlled trials, non-randomised controlled trials, controlled before versus after studies, and uncontrolled before versus after studies.

Exclusion Criteria

Studies were excluded if:

- No information was provided regarding the ME reporting rate in the hospital prior to the intervention.
- No full-text English language version of the study was available.
- The study was a conference abstract and no full-text version was available.

Search strategy

An electronic search was conducted using the following databases from inception up to and including December 2018: PubMed, Medline (OVID), Embase (OVID), Web of Science, and CINAHL. The search strategy focused on three concepts: medication errors, reporting, and the hospital setting. A search strategy was developed in PubMed around these concepts and appropriate Medical Subject Headings (MeSH) were used. For each of the remaining databases, the search strategy was modified to suit their specific search capabilities if necessary. A copy of the search strategy for each database is available in **Supplementary Data**. In addition, the reference lists of included papers were searched for potentially eligible studies.

Study selection

In the first stage of study selection, one reviewer (LG) screened the electronic search results to eliminate studies that were clearly not pertinent to our review. In the second stage, two reviewers (LG and KD) screened the titles and abstracts to identify potentially relevant studies. In the third stage, the full texts were independently assessed by both reviewers to determine their eligibility. Consensus on inclusion in the final two stages was reached by discussion between the two reviewers. Authors of five studies were contacted to request data;[20–24] however, no reply was received from any of the authors, and therefore these studies were not included.

Data extraction and analysis

Data were extracted using a dedicated extraction form, with the following headings: author, year, study design, setting, study aim, intervention type, and ME reporting rates before and after implementation of the intervention. The intervention types used in each study were mapped to the Effective Practice and Organisation of Care (EPOC) taxonomy, which is split into four main domains of interventions: *Delivery Arrangements*, *Financial Arrangements*, G*overnance Arrangements*, and *Implementation Strategies*.[25] Where possible, to allow comparison between the studies, the mean monthly reporting rate before and after the interventions were implemented was calculated for each study. Due to heterogeneity across the studies, a meta-analysis was not possible, therefore a systematic, narrative approach was adopted to synthesise the results. The Economic and Social Research Council (ESRC) Guidance on the Conduct of Narrative Synthesis in Systematic Reviews was followed in conducting the narrative synthesis.[26] The data from each study was tabulated to search for patterns and relationships across the studies; a primary synthesis was carried out to elucidate these patterns, which was then developed into a meaningful narrative.

Critical Appraisal

The Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for Quantitative studies was used to assess selection bias, study design, confounders, and data collection methods for the included studies.[27] Given the nature of the included studies, blinding of outcome assessors and study participants was not possible, and reporting of withdrawals and drop-outs was not applicable, therefore these criteria were not included in the critical appraisal. Each study was evaluated by two reviewers (LG and KD) and disagreements were resolved by consensus.

RESULTS

Search results

A total of 12,025 records were identified through electronic database searching. After the exclusion of records based on their titles and abstracts, as well as the removal of duplicates, sixty-six full texts were assessed for eligibility (including seven studies which had been identified by citation searching). Seventeen published papers were suitable for inclusion in the final review. A PRISMA flow diagram describes the flow of studies in the review (**Figure 1**).

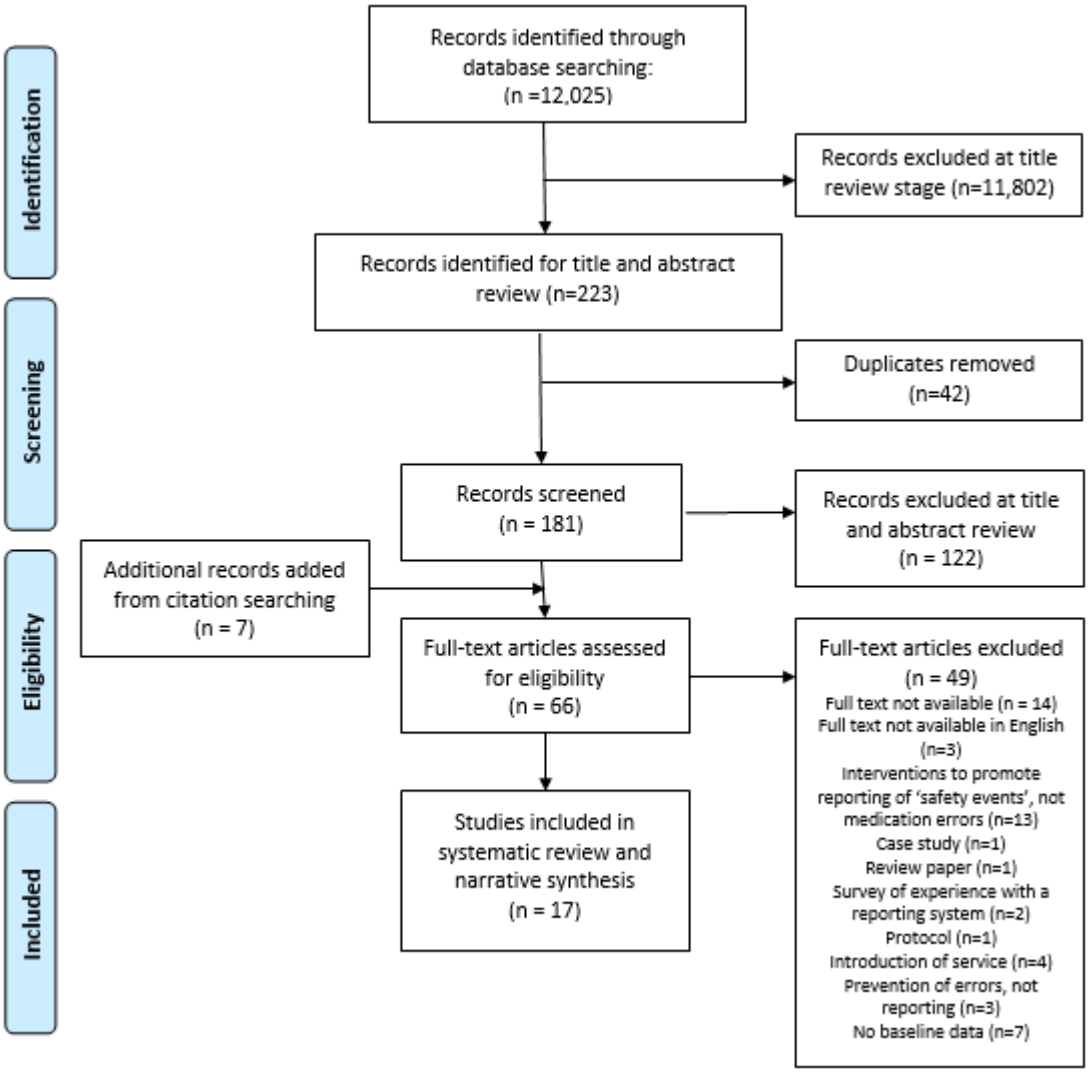


Figure 1: PRISMA Flow Diagram

Characteristics of included studies

The characteristics of the seventeen included studies are summarised in **Table 1a.**[28–44] Further characteristics and results of the interventions carried out in each study are provided in **Table 1b**.[28–44] Ten of the included studies were conducted in the USA,[37,39] two in Spain[32,41] and one each in Saudi Arabia,[29] Australia,[38] the United Kingdom (UK),[43] Japan,[30] and Ireland.[33] All of the studies were carried out at a single site, apart from one study which was carried out across 550 hospitals in the USA, and one which was carried out across 6 Australian hospitals.[34,38]

In terms of study aim, the included studies can be divided into two groups: (i) those that assessed the efficacy of interventions to improve ME reporting,[28,32,37–39,41] and (ii) those that described the implementation of a new system for reporting MEs.[29–31,33–36,40,42,43] Every study measured the rate of medication incident reporting before and after a change had been implemented, however some studies also measured the rates of medication incidents with harm,[28,29] or the level of harm caused by medication incidents.[31,37,43] Although what was reported in each study fell under the definition of MEs adopted by this review, the studies differed in terms of what was reported, and how this was defined. Most commonly reported were MEs which were measured in six studies,[28,33,34,37,39,41] medication events measured in two studies,[43,44] and so-called medication incidents measured in two studies.[29,30] Seven studies did not provide a definition for what was being reported.[30,31,33–35,37,44]

Fifteen of the studies were uncontrolled before versus after studies,[28–33,35–37,39–41,43,44] one was a non-equivalent group controlled trial,[38] and one was a survey.[34] Five studies carried out a single intervention[31,34,35,40,44]; the other twelve carried out multifaceted interventions.[28–30,32,33,36–39,41–43] The studies also varied in how the interventions were developed. Three studies held group strategy sessions,[28,36,44] two conducted focus groups,[38,39] and one used a survey to inform the development of the intervention.[42] The remaining studies either based their interventions on the literature, [30,41] or did not describe how the intervention was developed.[29,31–35,37,40,43] Data were gathered using a reporting form in each study, although the data gathered on the reporting forms varied across the studies.

Table 1a: Characteristics of Included Studies

Study Author (Year)	Setting	Study Design	Study Aim	Intervention	EPOC Intervention Subcategory
Abstoss *et al.* (2011) [28]	ICU, university children's hospital, USA	Uncontrolled before versus after study	To analyse the patterns in reporting rates of MEs and rates of MEs with harm in the context of medication safety interventions	Poster Tracking Days Since Last Error	Monitoring the performance of the delivery of healthcare
				Quality Improvement Channel	Educational Materials
				Quality Improvement Curriculum	Educational Meetings
				Medication Error Emails	Audit and Feedback
				Medication Manager' Programme	Role expansion or Task Shifting
				Patient Safety Report Form Revisions	Critical Incident Reporting
Arabi *et al.* (2011) [29]	Intensive care department, university-affiliated tertiary care centre, Saudi Arabia	Uncontrolled before versus after study	To describe the experience of implementing a Comprehensive Management System for incident reports	Comprehensive Management System	Critical Incident Reporting
				Feedback to staff	Audit and feedback
				Quality and Safety Forum	Communities of practice
Costello *et al.* (2007) [37]	Critical care centre, children's hospital, USA	Uncontrolled before versus after study	To study the effects of a pharmacist-led paediatrics medication safety team on the frequency and severity of MEs reported	New Reporting System	Critical Incident Reporting
				Clinical Pharmacist	Staffing Models
				Paediatric Medication Safety Team	Role expansion or Task Shifting
				Monthly Focus Groups	Communities of practice
Evans *et al.* (2007) [38]	Two regional hospitals, Australia	Non-equivalent group controlled clinical trial	To assess the effectiveness of an intervention package in order to improve incident reporting rates and change the types of incidents reported.	Educational Manual	Educational Materials
				Redesign of Reporting Systems	Critical Incident Reporting
				Feedback newsletters	Audit and Feedback
				Educational Sessions	Educational Meetings
Force *et al.* (2006) [39]	Community hospital, USA	Uncontrolled before versus after study	To build a non-punitive culture and to increase ME reporting	Medication Event Team	Role expansion or Task Shifting
				Lifesavers' project	Audit and Feedback
					Educational Materials
					Organisational Culture
					Educational Meetings
				New reporting system	Critical Incident Reporting
France *et al.* (2003) [40]	Paediatric chemotherapy pharmacy and inpatient	Uncontrolled before	To present the conceptual model of a Chemotherapy Incident Reporting and Improvement System	Chemotherapy Incident Reporting and Improvement System	Critical Incident Reporting

	paediatric oncology units, university hospital, USA	versus after study		Feedback	Audit and Feedback
Guerrero-Aznar *et al.* (2013) [41]	Paediatrics management unit, hospital, Spain	Uncontrolled before versus after study	To analyse the impact on error notification of the implementation of a decentralised multidisciplinary safety committee and a networked computer application for ME reporting.	New Reporting System	Critical Incident Reporting
				Safety Committee	Role expansion or Task Shifting
				Feedback to staff	Audit and Feedback
Guffey *et al.* (2011) [42]	Anaesthesia department, children's hospital, USA	Uncontrolled before versus after study	To implement a near miss reporting system	New Reporting System	Critical Incident Reporting
Haw *et al.* (2011) [43]	Psychiatric hospital, UK	Uncontrolled before versus after study	To describe the first 2 years of operation of an electronic system for reporting medication events in psychiatry.	New Reporting System	Critical Incident Reporting
Lehmann *et al.* (2007) [44]	University hospital, USA	Uncontrolled before versus after study	To 'develop monitoring systems to decrease the potential for drug harm'	New Reporting System	Critical Incident Reporting
Nakajima *et al.* (2005) [30]	University hospital, Japan	Uncontrolled before versus after study	To 'introduce a hospital-wide incident reporting system to collect data on variant practices, build an organisational structure for activities aimed at patient safety, and implement staff education and system oriented improvements'	New Reporting System	Critical Incident Reporting
				New organisational structure	Role expansion or Task Shifting
				Educational Seminars	Educational Meetings
				Feedback	Audit and Feedback
Nast *et al.* (2005) [31]	Cardiothoracic ICU and cardiothoracic post anaesthesia care units, university hospital, USA	Uncontrolled before versus after study	To 'evaluate a new mechanism for reporting and classifying patient safety incidents to increase reporting and identify patient safety priorities'	New Reporting System	Critical Incident Reporting
Ramirez *et al.* (2018) [32]	University hospital, Spain	Uncontrolled before versus after study	To assess which improvement actions were successful in reducing near-misses or adverse events	Training workshops	Educational Meetings
				Improvement Actions'	Continuous Quality Improvement
Relihan *et al.* (2009) [33]	University hospital, Ireland	Uncontrolled before versus after study	To develop an online ME reporting system	New Reporting System	Critical Incident Reporting
				Medication Safety Officer	Staffing Models
				Multiple Education and Training Initiatives	Educational Materials

Savage *et al.* (2005) [34]	550 hospitals, USA	Survey	To evaluate the utility of an online ME reporting programme	New Reporting System	Critical Incident Reporting
Smith *et al.* (2006) [35]	University Medical Centre, USA	Uncontrolled before versus after study	To develop 'online ADR and ME reporting systems'	New Reporting System	Critical Incident Reporting
Stump *et al.* (2000) [36]	University hospital, USA	Uncontrolled before versus after study	To implement a 'standardized, non-punitive medication use variance process'	New Reporting System	Critical Incident Reporting

ICU: Intensive Care Unit, ADR: Adverse Drug Reaction

Table 1b: Further Study Characteristics and Results of Interventions

Study Author (Year)	What was reported	How it was defined	Near Misses Included	Pre-intervention reporting rates	Post-intervention reporting rates
Abstoss *et al.* (2011) [28]	MEs	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer	Yes	3.12 reports per 10,000 doses dispensed	4.08 per 10,000 doses dispensed
Arabi *et al.* (2011) [29]	Incidents	An undesired event that might affect a patient, employee, family member, visitor, equipment, or property, and that was not consistent with standard operations or care. These events might cause actual injury, or might have the potential to cause injury, loss of function, or death.	Yes	Mean 27.4 reports per month	Mean 95.4 reports per month
Costello *et al.* (2007) [37]	MEs	None provided	Yes	Mean 4.5 reports per month	Mean 27.3 reports per month
Evans *et al.* (2007) [38]	Adverse Events	Unintended injury caused by healthcare management rather than the patient's disease	Yes	Control:54.5 reports per 10,000 OBDs Intervention:82.8 reports per 10,000 OBDs	Control:101.0 reports per 10,000 OBDs Intervention: 189.6 reports per 10,000 OBDs
Force *et al.* (2006) [39]	MEs	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.	Yes	Mean 14.3 reports per month	Mean 72.5 reports per month
France *et al.* (2003) [40]	Near Misses and Preventable ADEs	Medical error: the failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim, Adverse event: an injury or a laboratory abnormality that a patient experiences as a result of their medical management and not their underlying disease, Preventable adverse event: An adverse event attributed to medical error, near miss: a medical error that does not lead to an adverse event	Yes	53 reports in 657 admissions	93 reports in 818 admissions
Guerrero-Aznar *et al.* (2013) [41]	MEs	Any preventable incident that may harm the patient or result in the inappropriate use of a drug	Yes	Mean 1±1 reports per month	Mean 5±3 reports per month
Guffey *et al.* (2011) [42]	Near Misses	An event that did not cause patient harm, but had the potential to	Yes (near misses only)	Mean 1.33 reports per month	Mean 50 reports per month
Haw *et al.* (2011) [43]	Medication Events	MEs, near misses, and adverse drug reactions	Yes	Mean 1.4 reports per month	Mean 18.6 reports per month

Lehmann *et al.* (2007) [44]	Medication Events	None provided	No	Mean 19 reports per month	Mean 102 reports per month
Nakajima *et al.* (2005) [30]	Incidents	None provided	No	Mean 45 reports per month	Mean 177 reports per month
Nast *et al.* (2005) [31]	Patient Safety Events	None provided	Yes	8.5 reports per 1000 patient-days	25.3 events per 1000 patient-days
Ramirez *et al.* (2018) [32]	Patient Safety Incidents	An event during an episode of patient care that had the potential to or actually caused injury or harm to the patient.	Yes	Mean 20 reports per month	Mean 80 reports per month
Relihan *et al.* (2009) [33]	MEs	None provided	Unclear	Mean 31.7 reports per month	Mean 75.4 reports per month
Savage *et al.* (2005) [34]	MEs	None provided	Unclear	Mean 32±47 reports per month	Mean 60±88 reports per month
Smith *et al.* (2006) [35]	ADRs and MEs	None provided	Unclear	Mean 6.7 reports per month	Mean 37.3 reports per month
Stump *et al.* (2000) [36]	Medication Use Variance	Departure from clinical pathways	Yes	Mean 23.7 reports per month	Mean 31.4 reports per month

ADE: Adverse Drug Event, ADR: Adverse Drug Reaction

Critical appraisal

Of the 17 included studies, 16 studies were found to be of moderate methodological quality. [28–33,35–42,44] Fifteen studies were uncontrolled before versus after studies, which did not account for confounders but used a valid and reliable data collection method. [28–33,35–37,39–42,44] These 15 studies received a moderate score for selection bias and study design, a weak score for confounders, and a strong score for data collection method, resulting in a global methodological quality rating of moderate. The non-equivalent group-controlled trial carried out by Evans *et al.* reported heterogeneity between the control at intervention groups at baseline resulted in a weak score for confounders and a moderate quality overall.[38] The study carried out by Savage *et al.* used a survey to measure changes in medication reporting, which had a low response rate, and was therefore deemed to be methodologically weak. [34] The results of the critical appraisal are presented in **Table 2**.

Table 2: Critical Appraisal

Study Author (Year)	Selection Bias	Study Design	Confounders	Data Collection Method	Global Rating
Abstoss *et al.* (2011) [28]	Moderate	Moderate	Weak	Strong	Moderate
Arabi *et al.* (2011) [29]	Moderate	Moderate	Weak	Strong	Moderate
Costello *et al.* (2007) [37]	Moderate	Moderate	Weak	Strong	Moderate
Evans *et al.* (2007) [38]	Moderate	Moderate	Weak	Strong	Moderate
Force *et al.* (2006) [39]	Moderate	Moderate	Weak	Strong	Moderate
France *et al.* (2003) [40]	Moderate	Moderate	Weak	Strong	Moderate
Guerrero-Aznar *et al.* (2013) [41]	Moderate	Moderate	Weak	Strong	Moderate
Guffey *et al.* (2011) [42]	Moderate	Moderate	Weak	Strong	Moderate
Haw *et al.* (2011) [43]	Moderate	Moderate	Weak	Strong	Moderate
Lehmann *et al.* (2007) [44]	Moderate	Moderate	Weak	Strong	Moderate
Nakajima *et al.* (2005) [30]	Moderate	Moderate	Weak	Strong	Moderate
Nast *et al.* (2005) [31]	Moderate	Moderate	Weak	Strong	Moderate
Ramirez *et al.* (2018) [32]	Moderate	Moderate	Weak	Strong	Moderate
Relihan *et al.* (2009) [33]	Moderate	Moderate	Weak	Strong	Moderate
Savage *et al.* (2005) [34]	Moderate	Weak	Weak	Strong	Weak
Smith *et al.* (2006) [35]	Moderate	Moderate	Weak	Strong	Moderate
Stump *et al.* (2000) [36]	Moderate	Moderate	Weak	Strong	Moderate

Global ratings: Strong = No weak ratings, Moderate = One weak rating, Weak = Two or more weak ratings

Interventions

The interventions implemented in each of the studies were mapped to the EPOC taxonomy for healthcare interventions.[25] The most common intervention type was critical incident reporting, which was implemented in fifteen of the included studies,[28,30,31,33,34,36–42,44] followed by audit and feedback, which was implemented in seven studies. [28–30,38,41–43]

Critical incident reporting: Critical incident reporting interventions were implemented in 15 of the included studies. [28,30,31,33,34,36–42,44] Thirteen studies implemented a new reporting system,[28,30,31,33,34,36,39–42,44] while two studies made revisions to existing reporting systems.[37,38]

There was variability across the studies in terms of the format of the reporting system (i.e. web-based or paper-based), whether or not it was anonymous, and whether or not training was provided to hospital staff. Nine of the studies used a web-based reporting system,[28,30,33–35,40–43] and six used a paper-based system.[31,36–38,44] All web-based systems were accessible from a hospital computer, with the exception of the France *et al*. study, in which medication incidents could be reported using a handheld device.[40] Abstoss *et al*. revised their existing online reporting system from a multi-page form into a single quick submission form.[28] With regard to paper-based systems, Force *et al*. stored the reporting forms on a wall-mounted rack in nursing units in the study hospital.[39] Both Nast *et al*. and Stump *et al*. designed reporting forms that could be stored in a pocket or on a clipboard until they needed to be used.[31,36] In the study by Costello *et al*., completed forms were placed in a box, and reviewed each month.[37] Evans *et al*. reduced their three-page form to one page to reduce reporting burden, and also introduced a free telephone service where staff could report incidents at any time to a registered nurse.[38] Lehmann *et al*. did not give any details on their reporting form, other than the fact that it was paper-based.[44]

All but three reporting systems were anonymous.[35,39,43] In the study by Smith *et al*., staff using the online reporting system had to give their contact information for any necessary follow-up.[35] Similarly, in the study by Force *et al*., the person involved in the ME had to include their name, submit the medication event form and provide the form to their patient unit team leader to be signed off. It was felt that anonymous reporting would prevent 'valuable follow-up procedures' from being carried out.[39] In contrast, in the study by Haw *et al*., staff members completing the incident report was asked to give their names, but the staff member involved in the incident was not required to do so.[43] Stump *et al*. noted that a paper-based form was used to create a truly anonymous system, due to the possibility of tracing web-based reports.[36] This issue was acknowledged by Guffey *et al*., who implemented a 'secure' online reporting system in the paediatric anaesthesia department of a US hospital, however details were not provided on how the system was secured. [42]

Training was provided in how to use the new reporting system was provided to hospital staff in four of the studies.[36,39,43,44] Haw *et al.* provided staff with a guidebook on how to report errors and included an 'e-help function' in their web-based reporting system.[43] Lehmann *et al.* conducted a 'major education initiative' before the launch of their reporting system, which involved explaining the system to nurse managers.[44] Force *et al.* provided staff with ongoing education on how to complete incident forms and the importance of reporting errors.[39] In-service education programs were carried out by Stump *et al*. during implementation of their new reporting system.[36]

Two of the included studies encouraged use of their new reporting system by rewarding event reporting.[39,44] Lehmann *et al*. awarded the nursing unit that reported the greatest number of events with certificates of merit and educational materials.[44] Force *et al*. gave a personal 'thank-you' note and a gift card to staff who used the new reporting system.[39]

Audit and feedback: Seven studies used audit and feedback to encourage reporting and promote a non-punitive culture.[7,29,30,38,41,42] Abstoss *et al.,* Evans *et al*. and Guerrero-Aznar *et al*. sent out emails to staff containing summaries of recent reports and quality improvement actions.[28,38,41] Guffey *et al*. sent a summary report of all near misses to staff at regular intervals.[42] In the study by Haw *et al*., an analysis of reported errors was sent out to staff one year after the implementation of the new reporting system.[43] Arabi *et al*. provided feedback to staff at departmental meetings.[29] Nakajima *et al*. made feedback available to staff through newsletters, meetings, a seminars.[30]

Educational materials: Three studies used educational materials to promote a non-punitive culture and encourage further reporting.[28,38,39] Abstoss *et al*. displayed a 'quality improvement' channel on a television screen in the staff room, which included content such a performance metrics, lessons learned, and education on quality improvement and patient safety.[28] Evans *et al*. distributed a manual to staff to improve knowledge of reportable events.[38] Force *et al*. sent out newsletters and flyers with research-based information on a non-punitive culture.[39]

Educational meetings: Educational meetings were carried out in nine of the included studies.[28–30,32,33,36,37,39,45] Abstoss *et al*. held three 'mini-symposia' to provide frontline staff with information on medication safety and reporting.[28] Arabi *et al*. presented lectures about 'just culture' and high risk events to hospital frontline staff.[29] Costello *et al*. provided education to healthcare providers during patient rounds.[37] Evans *et al*. held educational sessions during existing departmental meetings.[38] Force *et al*. organised small group forums in which attending staff nurses and pharmacists could learn how MEs occur.[39] Nakajima *et al*. included educational seminars three times a year.[30] During the implementation of a new reporting system, Ramirez *et al*. performed ten training workshops with hospital staff on patient safety.[32] Stump *et al*. carried out in-service education programs for hospital staff, and Relihan *et al*. carried out 'multiple education and training initiatives' but did not give further details.[33,36]

Role expansion and task-shifting: Staff roles were expanded in six studies.[28–30,37,39,41] Arabi *et al.* set up a multidisciplinary 'Incident Reports Committee' to review, analyse and close incident reports, led by a physician, and including members from nursing and pharmacy.[29] Abstoss *et al.* set up a '*medication manager programme*' in which pharmacy technicians provided medication management services.[28] Force *et al.* created a medication event team that was responsible for analysing reports.[39] Costello *et al.* set up a paediatrics medication safety team.[37] Guerrero-Aznar *et al.* established a decentralised multidisciplinary safety committee which was responsible for analysing reports made to the new system and developing improvement strategies based on this analysis.[41] Nakajima *et al.* set up a new organisational structure for patient safety, comprised of (i) a clinical risk management committee, who analysed incident reports and develop improvement plans, (ii) a department of clinical quality management, which acted on the plans made by the committee, and (iii) an area clinical risk manager, who oversaw quality of care in their clinical area.[30]

Staffing Roles: Costello *et al.* introduced a clinical pharmacist to the paediatric critical care centre in which their study was carried out.[37] Relihan *et al.* appointed a medication safety officer during the study period; however, the responsibilities of this role were not detailed in the short report.[33]

Communities of Practice: Two of the included studies held regular forums with frontline staff at which ME reports were discussed.[29,37] Arabi *et al.* set up a weekly forum at which important feedback from incident reports was shared with frontline staff, and action plans were discussed and developed.[29] Costello *et al.* held monthly interactive focus groups to discuss the previous month's incidents, and to brainstorm methods to prevent future events.[37]

Outcomes

All studies reported an increase in the rate of reporting between the pre- and post-intervention periods (**Table 1b**). However, only one study compared a control group with an intervention group, therefore the effectiveness of the different intervention types could not be calculated. Evans *et al.* reported a significant improvement in reporting in the intervention group compared to the control group. In the control group, 54.5 incidents were reported per 10,000 occupied bed days (OBDs) at baseline, compared to 101.0 reports/10,000 OBDs post-intervention. The intervention group saw an increase from 82.8 reports/10,000 OBDs at baseline to 189.6 reports/10,000 OBDs post-intervention.[45] Two studies that compared one group pre- and post-intervention also reported significant increases in reporting. Savage *et al.* reported that the average number of MEs reported each month increased by 88% after implementation of the Medmarx system (60±88, $p<0.001$), and the Lifesavers programme implemented by Force *et al.* was associated with a significant increase in ME reporting, from a mean monthly rate of 14.2 reports in the 12 months before the programme to 72.5 in the 12 months after the programme ($p<0.001$). [34,39]

DISCUSSION

To our knowledge, this is the first systematic review to summarise the evidence on interventions to improve ME reporting in hospitals globally. Although our review found limited evidence to support the effectiveness of several interventions to improve ME reporting in hospitals, a variety of interventions were tested which, when considered alongside recent quantitative and qualitative research on ME reporting, may warrant further investigation.

The included studies that implemented a new reporting system were either paper-based or web-based systems, each of which carry advantages and disadvantages. Web-based systems avoid the shortcomings of paper-based systems, can be sent immediately to a hospital's risk management department, allow easy compilation and analysis of data, and can be accessed from any hospital computer or mobile device.[30,46] Although they did not meet the inclusion criteria for this review, recent studies by George *et al.* and de Vries *et al.* investigated the use of mobile telephone applications for ME reporting and found that they had the potential to increase reporting.[47,48] However, computers are often in high demand in a resource-scarce hospital setting, and it may be difficult to find a computer in a private location to fill out an incident report. Paper-based reporting forms can be placed at convenient locations throughout the hospital and can be designed to fit in a pocket so they can be filled in at any time.[31,36] However, paper-based reporting forms are less practical in terms of collection and analysis, are less environmentally friendly, are less secure and could easily be lost or mislaid. Two of the identified studies reduced the length of their reporting form to encourage reporting.[28,38] Reporting burden has been identified as a barrier to reporting in a number of studies.[12,49] Whether paper- or web-based, it is therefore important to design a succinct reporting form that will not put excess time pressure on busy healthcare professionals.

Anonymity is an important factor to consider when designing a reporting system.[14] An anonymous system implies a non-punitive reporting culture and may make hospital staff more likely to report errors.[50] However, as discussed by Force *et al*, anonymous reporting can prevent valuable follow-up procedures being carried out after a medication incident.[39] There is also the option of requiring the person reporting the incident to give their name, but not the name of the staff involved in the incident, as was done by Haw *et al*., however this may discourage the reporting of incidents that are not witnessed by another member of staff.[43] Qualitative research has shown that fear and concerns

related to taking responsibility for a ME can be barriers towards reporting.[51,52] An anonymous reporting system could help to overcome these barriers.

Educational interventions can improve healthcare workers' knowledge of how to report incidents, promote a non-punitive environment, and improve safety culture.[7,50,53] A lack of education about the reporting process has been identified as a barrier to reporting.[13] A mixture of formal educational meetings, such as lectures on patient safety, and informal educational meetings or materials, such as lunchtime educational sessions or an online tutorial on using a new reporting system, could be used to improve both error reporting and patient safety culture. This was demonstrated by Ramirez *et al*., who found a significant correlation between the number of staff attending patient safety training workshops and the rate of error reporting.[32]

Encouraging a non-punitive culture is an important factor in improving the reporting of MEs in hospitals. The fear of punitive action can be a significant deterrent to the reporting of MEs.[50–52] Rather than being considered an admission of fault, error reporting should be seen as an opportunity to learn from mistakes and improve systems to ultimately improve patient safety.[15] As the identified studies have suggested, a non-punitive culture could be encouraged using a variety of intervention types including educational meetings, educational materials, audit and feedback, and communities of practice.

Role expansion or task shifting could also be an effective strategy to improve patient safety culture and increase ME reporting. A significant amount of work is involved in collecting and analysing error reports and feeding this information back to frontline staff.[17] These responsibilities could be shared between a committee or taken on by a staff member with a dedicated safety role. Lack of support from management has been identified as a barrier to reporting.[13] Creating a safety committee or a safety-focused staff role demonstrates hospital management's commitment to patient safety, which could therefore have a positive impact on reporting rates.

Limitations

This review has a number of limitations. Ten of the identified studies were published over ten years ago. When assessed with the EPHPP Quality Assessment tool for Quantitative Studies, none of the studies identified in the review was found to be of high methodological quality.[27] There was heterogeneity between the studies in terms of what was reported, how it was defined, and how reporting rates were measured. As only one identified study tested an intervention group against a control group, it was not possible to determine the effectiveness of any of the interventions identified in this review. It was also not possible to determine whether any of the interventions used in the included studies are still in use. These factors to some extent limit the conclusions that can be drawn from this review.

Implications for Future Research

This review has identified interventions that have been implemented in healthcare organisations without clear evidence of their effectiveness. As many of the interventions highlighted in this review are resource intensive, and given the resource-scarce nature of healthcare systems, it is imperative that future interventions are developed and assessed appropriately. Apart from the two studies that used qualitative research to inform their intervention, a theoretical basis does not appear to have been used in the development of the identified interventions. The Medical Research Council guidance

for developing and evaluating complex interventions stresses the importance of developing a theoretical understanding of the likely process of change by drawing on existing evidence and theory.[54] Likewise, a suitable method must be used to assess the effectiveness of future interventions. No randomised controlled trials of interventions to improve error reporting were identified, and only one study that compared an intervention and control groups was identified.[38] Research of strong methodological quality in this area could have the potential to inform medication safety and quality improvement initiatives. Future research should focus on strengthening the evidence around the effectiveness of interventions to improve ME reporting.

CONCLUSION

The important role played by ME reporting in improving patient safety has been emphasised by several major organisations over the past two decades. Despite this, we have identified a lack of studies demonstrating the effectiveness of interventions to improve ME reporting. Although efforts to promote safety culture and improve error reporting in healthcare are to be encouraged, the authors recommend that future research in this area is carried out using appropriate methods to assess intervention effectiveness.

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