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

1 **ABSTRACT**

2 **Background**

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

6 **Objectives**

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

10 **Methods**

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

17 **Results**

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

25 **Conclusion**

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

31

32

## 33 Introduction

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

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

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

61

## 62 METHODS

### 63 Protocol Registration

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

### 68 Inclusion criteria

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

### 73 Exclusion Criteria

74 Studies were excluded if:

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

## 79   **Search strategy**

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

## 88   **Study selection**

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

## 96   **Data extraction and analysis**

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

## 110   **Critical Appraisal**

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

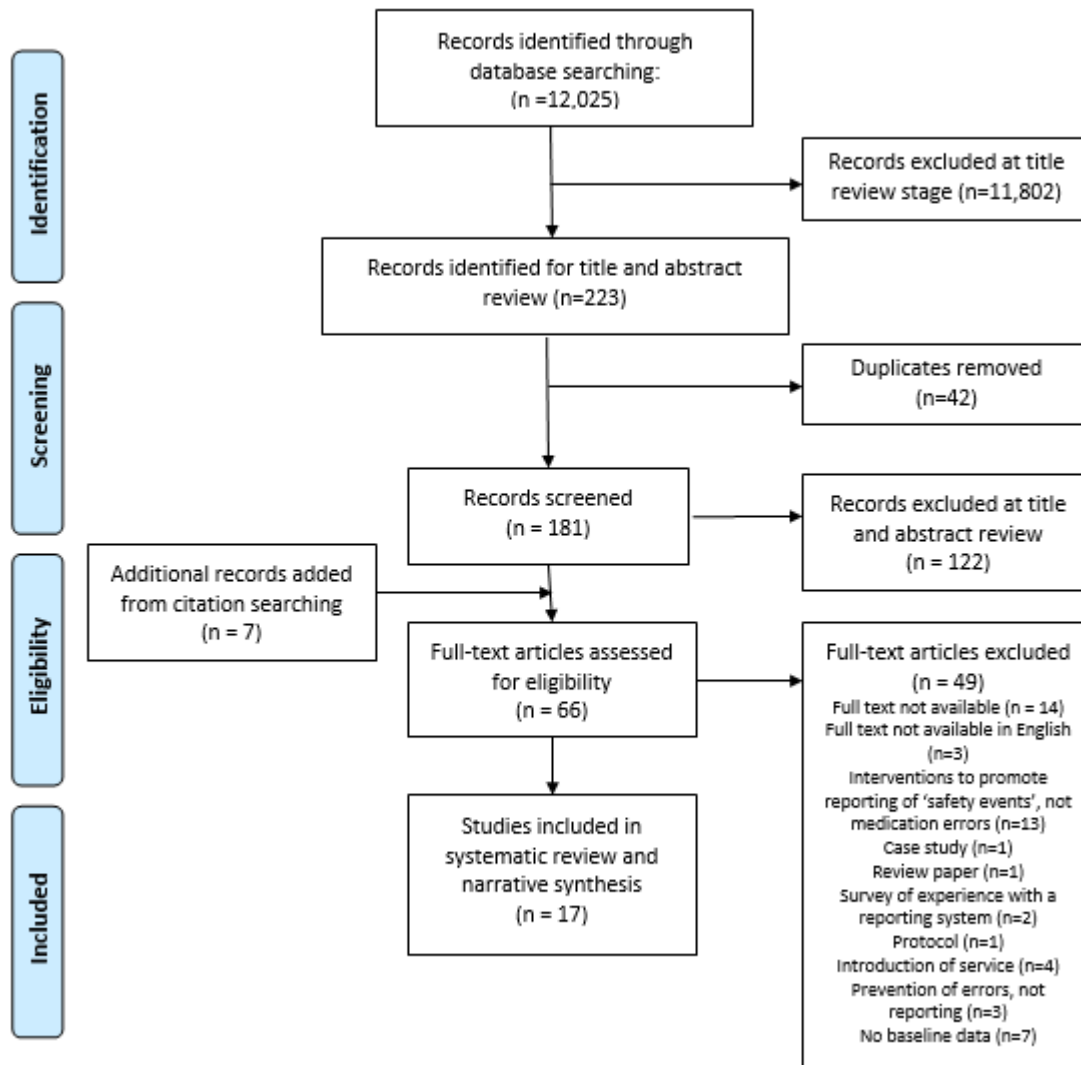
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119 RESULTS

120 Search results

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



126

127 Figure 1: PRISMA Flow Diagram

128

129 Characteristics of included studies

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

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

146 Fifteen of the studies were uncontrolled before versus after studies,<sup>28-33,35-37,39-41,43,44</sup> one was a non-  
147 equivalent group controlled trial,<sup>38</sup> and one was a survey.<sup>34</sup> Five studies carried out a single  
148 intervention<sup>31,34,35,40,44</sup>; the other twelve carried out multifaceted interventions.<sup>28-30,32,33,36-39,41-43</sup> The  
149 studies also varied in how the interventions were developed. Three studies held group strategy  
150 sessions,<sup>28,36,44</sup> two conducted focus groups,<sup>38,39</sup> and one used a survey to inform the development of  
151 the intervention.<sup>42</sup> The remaining studies either based their interventions on the literature,<sup>30,41</sup> or did  
152 not describe how the intervention was developed.<sup>29,31-35,37,40,43</sup> Data were gathered using a reporting  
153 form in each study, although the data gathered on the reporting forms varied across the studies.  
154  
155

Table 1a: Characteristics of Included Studies

Study Author (Year)	Setting	Study Design	Study Aim	Intervention	EPOC Intervention Subcategory
Abtoss <i>et al.</i> (2011) <sup>28</sup>	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 <i>et al.</i> (2011) <sup>29</sup>	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 <i>et al.</i> (2007) <sup>37</sup>	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 <i>et al.</i> (2007) <sup>38</sup>	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 <i>et al.</i> (2006) <sup>39</sup>	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 <i>et al.</i> (2003) <sup>40</sup>	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 <i>et al.</i> (2013) <sup>41</sup>	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 <i>et al.</i> (2011) <sup>42</sup>	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 <i>et al.</i> (2011) <sup>43</sup>	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 <i>et al.</i> (2007) <sup>44</sup>	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 <i>et al.</i> (2005) <sup>30</sup>	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 <i>et al.</i> (2005) <sup>31</sup>	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 <i>et al.</i> (2018) <sup>32</sup>	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 <i>et al.</i> (2009) <sup>33</sup>	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 <i>et al.</i> (2005) <sup>34</sup>	550 hospitals, USA	Survey	To evaluate the utility of an online ME reporting programme	New Reporting System	Critical Incident Reporting
Smith <i>et al.</i> (2006) <sup>35</sup>	University Medical Centre, USA	Uncontrolled before versus after study	To develop 'online ADR and ME reporting systems'	New Reporting System	Critical Incident Reporting
Stump <i>et al.</i> (2000) <sup>36</sup>	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
Abtoss <i>et al.</i> (2011) <sup>28</sup>	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 <i>et al.</i> (2011) <sup>29</sup>	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 <i>et al.</i> (2007) <sup>37</sup>	MEs	None provided	Yes	Mean 4.5 reports per month	Mean 27.3 reports per month
Evans <i>et al.</i> (2007) <sup>38</sup>	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 <i>et al.</i> (2006) <sup>39</sup>	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 <i>et al.</i> (2003) <sup>40</sup>	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 <i>et al.</i> (2013) <sup>41</sup>	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 <i>et al.</i> (2011) <sup>42</sup>	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 <i>et al.</i> (2011) <sup>43</sup>	Medication Events	MEs, near misses, and adverse drug reactions	Yes	Mean 1.4 reports per month	Mean 18.6 reports per month

Lehmann <i>et al.</i> (2007) <sup>44</sup>	Medication Events	None provided	No	Mean 19 reports per month	Mean 102 reports per month
Nakajima <i>et al.</i> (2005) <sup>30</sup>	Incidents	None provided	No	Mean 45 reports per month	Mean 177 reports per month
Nast <i>et al.</i> (2005) <sup>31</sup>	Patient Safety Events	None provided	Yes	8.5 reports per 1000 patient-days	25.3 events per 1000 patient-days
Ramirez <i>et al.</i> (2018) <sup>32</sup>	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 <i>et al.</i> (2009) <sup>33</sup>	MEs	None provided	Unclear	Mean 31.7 reports per month	Mean 75.4 reports per month
Savage <i>et al.</i> (2005) <sup>34</sup>	MEs	None provided	Unclear	Mean 32±47 reports per month	Mean 60±88 reports per month
Smith <i>et al.</i> (2006) <sup>35</sup>	ADRs and MEs	None provided	Unclear	Mean 6.7 reports per month	Mean 37.3 reports per month
Stump <i>et al.</i> (2000) <sup>36</sup>	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

154 **Critical appraisal**

155 Of the 17 included studies, 16 studies were found to be of moderate methodological quality.<sup>28–33,35–</sup>  
 156 <sup>42,44</sup> Fifteen studies were uncontrolled before versus after studies, which did not account for  
 157 confounders but used a valid and reliable data collection method.<sup>28–33,35–37,39–42,44</sup> These 15 studies  
 158 received a moderate score for selection bias and study design, a weak score for confounders, and a  
 159 strong score for data collection method, resulting in a global methodological quality rating of  
 160 moderate. The non-equivalent group-controlled trial carried out by Evans *et al.* reported  
 161 heterogeneity between the control at intervention groups at baseline resulted in a weak score for  
 162 confounders and a moderate quality overall.<sup>38</sup> The study carried out by Savage *et al.* used a survey to  
 163 measure changes in medication reporting, which had a low response rate, and was therefore deemed  
 164 to be methodologically weak.<sup>34</sup> The results of the critical appraisal are presented in **Table 2**.  
 165

166 *Table 2: Critical Appraisal*

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

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

168

## 169 **Interventions**

170 The interventions implemented in each of the studies were mapped to the EPOC taxonomy for  
171 healthcare interventions.<sup>25</sup> The most common intervention type was critical incident reporting, which  
172 was implemented in fifteen of the included studies,<sup>28,30,31,33,34,36-42,44</sup> followed by audit and feedback,  
173 which was implemented in seven studies.<sup>28-30,38,41-43</sup>

174 *Critical incident reporting:* Critical incident reporting interventions were implemented in 15 of the  
175 included studies.<sup>28,30,31,33,34,36-42,44</sup> Thirteen studies implemented a new reporting  
176 system,<sup>28,30,31,33,34,36,39-42,44</sup> while two studies made revisions to existing reporting systems.<sup>37,38</sup>

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

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

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

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

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

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

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

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

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

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

257

258 **Outcomes**

259 All studies reported an increase in the rate of reporting between the pre- and post-intervention  
260 periods (**Table 1b**). However, only one study compared a control group with an intervention group,  
261 therefore the effectiveness of the different intervention types could not be calculated. Evans *et al.*  
262 reported a significant improvement in reporting in the intervention group compared to the control  
263 group. In the control group, 54.5 incidents were reported per 10,000 occupied bed days (OBDs) at  
264 baseline, compared to 101.0 reports/10,000 OBDs post-intervention. The intervention group saw an  
265 increase from 82.8 reports/10,000 OBDs at baseline to 189.6 reports/10,000 OBDs post-  
266 intervention.<sup>45</sup> Two studies that compared one group pre- and post-intervention also reported  
267 significant increases in reporting. Savage *et al.* reported that the average number of MEs reported  
268 each month increased by 88% after implementation of the Medmarx system (60±88,  $p<0.001$ ), and  
269 the Lifesavers programme implemented by Force *et al.* was associated with a significant increase in  
270 ME reporting, from a mean monthly rate of 14.2 reports in the 12 months before the programme to  
271 72.5 in the 12 months after the programme ( $p<0.001$ ).<sup>34,39</sup>

273  
274 **DISCUSSION**

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

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

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



303 related to taking responsibility for a ME can be barriers towards reporting.<sup>51,52</sup> An anonymous  
304 reporting system could help to overcome these barriers.

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

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

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

327

## 328 **Limitations**

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

338

## 339 **Implications for Future Research**

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

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

354

## 355 CONCLUSION

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

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