Application of Failure Mode and Effect Analysis (FMEA) to improve medication safety: a systematic review

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ABSTRACT

Medication safety is a phenomenon of interest in most healthcare settings worldwide. Failure Mode and Effect Analysis (FMEA) is a prospective method to identify failures. We systematically reviewed the application of FMEA in improving medication safety in the medication use process. Electronic databases were searched using keywords ((failure mode and effect analysis) AND (pharmacy OR hospital)). Articles that fulfilled prespecified inclusion criteria were selected and were then screened independently by two researchers. Studies fulfilling the inclusion criteria and cited in articles selected for the study were also included. Selected articles were then analysed according to specified objectives. Among 27€706 articles obtained initially, only 29 matched the inclusion criteria. After adding four cited articles, a total of 33 articles were analysed. FMEA was used to analyse both existing systems and new policies before implementing. All participants of FMEA reported that this process was an effective group activity to identify errors in the system, although time-consuming and subjective.

INTRODUCTION

Problems related to medicines are known as 'drug-related problems'[1] and includes both intrinsic toxicities and extrinsic toxicities. Intrinsic toxicity is the interaction of pharmaceutical, chemical and/or pharmacological qualities of medicines with the human biosystem and is also known as adverse drug reaction.[1] Extrinsic toxicity is the erroneous handling of medicines either by a healthcare professional or a patient and is also known as medication error.[1] WHO says medication errors occur if medicines are taken incorrectly, monitored insufficiently or if any accident or communication issue occurs.[2]

The treatment process also known as the medication use process includes prescribing, compounding, dispensing, drug administration and monitoring processes. Medication errors can occur in any stage of the medication use process and could be categorised into six main types: prescribing errors, prescription errors, transcription errors, dispensing errors, administration errors and 'across settings' errors.[3] Each of these medication errors could be further classified as wrong drug, wrong dose, wrong frequency, wrong route and wrong patient, or by severity of harm caused by the error.[4]

Patient safety and medication errors are major concerns in healthcare settings worldwide. Previous studies have shown that 10% of all inpatient admissions results in some degree of unintended patient harm, and 75% of them are preventable.[5] Medication errors can occur due to either human or system failures. However, research reveals that the majority of these errors are caused by system errors rather than individual errors.[6] Nevertheless, medication errors result in morbidity and mortality, increased healthcare costs and ultimately loss of patients' confidence in their respective healthcare systems.

There are a number of studies that show medication errors are a universal problem.[7] A study in the UK found that 12% of all primary care patients are affected by a prescribing or monitoring error over a year, and among them, 38% are 75 years and older, and 30% are receiving five or more drugs.[7] A study from Saudi Arabia reported that just under one-fifth of primary care prescriptions contained errors.[7] Another study in Mexico observed that 58% of prescriptions contained errors, with dosage regimen accounting for most cases (27.6%).[7] A systematic review reported a 3% error rate during the dispensing stage, and among them, 72% were due to failures in reviewing repeat medicines, 77% during outpatient recommendations to general practitioners and 43%–60% during transition of care, that is, discharge after hospitalisation.[7] Furthermore, WHO third Global Patient Safety Challenge (2017)[2] reveals that medication errors are a leading problem of worldwide healthcare settings.

Identification of these medication errors and preventing them from happening again are essential for improving patient safety. Promoting a safety culture in healthcare settings has been identified as the paramount means of ensuring patient safety. The goal of WHO third Global Patient Safety Challenge (2017) is also to attain global attention to reduce the medication errors by addressing system weaknesses in healthcare systems.[2] Creating an effective safety culture requires the appropriate procedures and systems to support it.[8] Researchers state that healthcare systems should change the 'blame and shame culture' since it prevents healthcare professionals from reporting errors and learning from errors.[9] Healthcare systems should move away from expecting error-free performances from individuals and should focus on establishing safer systems.[9]

A primary goal of healthcare is to avoid adverse events that could cause patient harm. Root cause analysis (RCA) is the conventional method used in health research to identify factors of harmful

consequences of past events. This method is used to prevent or minimise recurrent occurrences of failures which had already happened and is used in investigating and categorising the root causes of events. Importantly, RCA helps to search why an event occurred thereby supports to recommend corrective measures. RCA proceeds through data collection, causal factor charting, root cause identification and implementation of recommendations.[10]

In contrast, Failure Mode and Effect Analysis (FMEA) is a proactive, forward directed method to identify potential failures before they occur.[11] Aviation, aerospace, nuclear power and automotive industries frequently use FMEA as an important aspect of quality assurance. FMEA was first developed by the US military in 1949 and was then adopted by National Aeronautics and Space Administration in the 1960s.[11] Although the FMEA concept originated from other industries, it is now widely used in healthcare to analyse complex processes.[12] In 2001, the Department of Veterans Affairs (VA) National Centre for Patient Safety (NCPS) developed Healthcare Failure Mode and Effect Analysis (HFMEA) to proactively evaluate healthcare processes. FMEA has become extensively accepted since the US. Joint Commission on Accreditation of healthcare Organisations (JCAHO) expected its accredited hospitals to carry out an annual prospective study such as FMEA.[13] A number of frameworks for FMEA are available for use in different healthcare systems and have been developed by different organisations. The VA NCPS, Institute for Safe Medication Practices Canada (ISMP) and JCAHO are some organisations that developed their own FMEA frameworks.[13]

FMEA can be applied to analyse an existing process or a new process. Even though FMEA is a complicated and time-consuming procedure, it is well suited for many healthcare processes, including pharmacy and medication use.[11] FMEA is a systematic and stepwise procedure starting with selecting a clearly defined process to assess and assemble a multidisciplinary team. Afterwards, processes and subprocesses of the selected process are mapped using the team's collective knowledge and by focusing on key components of the process. After mapping the process, the team brainstorms to identify potential failure modes for each subprocess. Then, the team identifies the possible effects and causes of potential failure modes and enters the results into a spreadsheet. Professional knowledge and personal experience of team members and information from literature are useful in this step. The team then prioritises the potential failure modes, considering the severity, frequency and detectability of failure modes. Risk priority number (RPN) is calculated by multiplying those three parameters and calculated RPN is used to prioritise the failures. Finally, the team redesigns or modifies processes to avoid or minimise failures, followed by implementation and analysis of the effectiveness of the modified processes.[11] Figure 1 shows the steps of FMEA.

Since FMEA originated in other industries and was later adopted to healthcare systems, it would be useful to recollect ways in which this tool has been used in healthcare systems. Hence, the present study attempts to systematically evaluate the application of FMEA in improving medication safety in the medication use process, including composition of group members participating in FMEA procedures, outcomes/benefits of FMEA in healthcare settings and methods of analysing FMEA results. Furthermore, the present study reviews perceptions of researchers/participants on the application of FMEA for a defined healthcare process in order to improve medication safety.

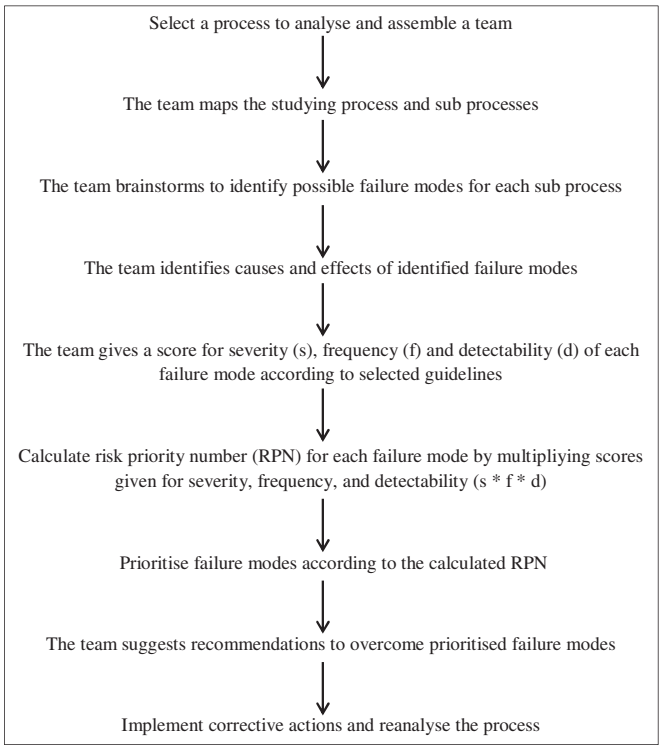

Figure 1 Steps of Failure Mode and Effect Analysis (FMEA). RPN, risk priority number.

METHODS

This systematic review was conducted using electronic databases, namely, PubMed, JSTOR, Emerald, SAGE, Wiley online, Oxford journals, Web of science, Scopus and Cochrane library. Databases were searched using keywords ((failure mode effect analysis) AND (pharmacy OR hospital)). Related articles published from January 2006 to December 2017 were selected by the first reviewer by reading the title and the abstract. Duplicate articles were removed using EndNote. The first reviewer read the full articles in the second round, to assess if articles were compatible with predetermined inclusion criteria. Articles published in English, on studies using a FMEA or HFMEA process to improve medication safety of the medication use process, having calculated a RPN or hazard score, and original research work which had been carried out through group discussions, were included in this review. FMEA or HFMEA procedures carried out by disciplines not related to medication use, systematic reviews and review articles were excluded. Articles, including the rejected ones, were reviewed again by a second reviewer to endorse the selection of articles according to the inclusion criteria. Any discrepancies were resolved through discussion among the two reviewers until 100% agreement was reached. Articles cited as references in the selected articles were also reviewed using the above procedure and same inclusion and exclusion criteria. Quality of all selected articles was checked using the Critical Appraisal Skills Programme (CASP) checklist for qualitative research[14] by both reviewers. Selected articles were iteratively and independently read by two researchers and variables for analysis were identified. Variables identified by the two researchers were then compared and discussed until 100% agreement was reached. The list of variables finalised for analysis were 'area of the medication use process FMEA was used', 'method of analysis of FMEA data', 'composition of the group who participated in FMEA', 'participants' perceptions on applying

FMEA for selected procedures' and 'outcomes or benefits of FMEA'. All selected articles were analysed using a predetermined datasheet with above variables.

RESULTS

A total of 27 706 articles resulted from the initial keyword search in stated databases. After reviewing titles and abstracts, 69 articles were selected for further analysis. After removing duplicates and articles which did not comply with inclusion criteria, 29 articles were selected for the study. Another four articles were selected from searching references of the selected articles. Finally, 33 articles were included in the systematic review (figure 2).

Area of medication use process for which FMEA applied

Among the 33 articles selected for review, 10 studies had focused on multiple steps of the medication use process in different inpatient settings. They had applied FMEA procedure to more than one process such as prescribing, transcribing of medication orders, dispensing, medication administering and monitoring. The remaining 23 studies had focused on a specific stage of the medication use process or had focused on a specific medication category. Seven studies applied FMEA/HFMEA on chemotherapy usage (N=7), five studies on the medication administration procedure by nurses in inpatient areas (N=5), two studies each were on new medication policy establishment (N=2), and the dispensing procedure in community pharmacies (N=2), and one study each were on, pharmacist-managed anticoagulation therapy in a community clinic (N=1), parenteral nutrition therapy (N=1), label reading of injectable medicine containers (N=1), patient safety in medicine shortages (N=1), medication handling process in operating room (N=1), infusion therapy (N=1), and outpatient antibiotic therapy (N=1). (Details are in online supplementary table.)

Study settings and geographical distribution of studies

There were 29 studies carried out in hospital settings and two in community pharmacy setting, one each in a community-based clinic and in a drug information service centre. Most studies were from USA (N=6) and UK (N=5). Spain, Canada, Switzerland and Iran had conducted and published three studies each. India, Italy, Taiwan, Netherlands, Egypt, Brazil, Germany, Serbia, Israel and China had reported one study each. (Details are in online supplementary table.)

Analysis of FMEA findings

Among the selected studies, 24 studies had used industrial FMEA method to assess their selected procedures and had used a RPN to prioritise failure modes. The RPN was calculated by multiplying the

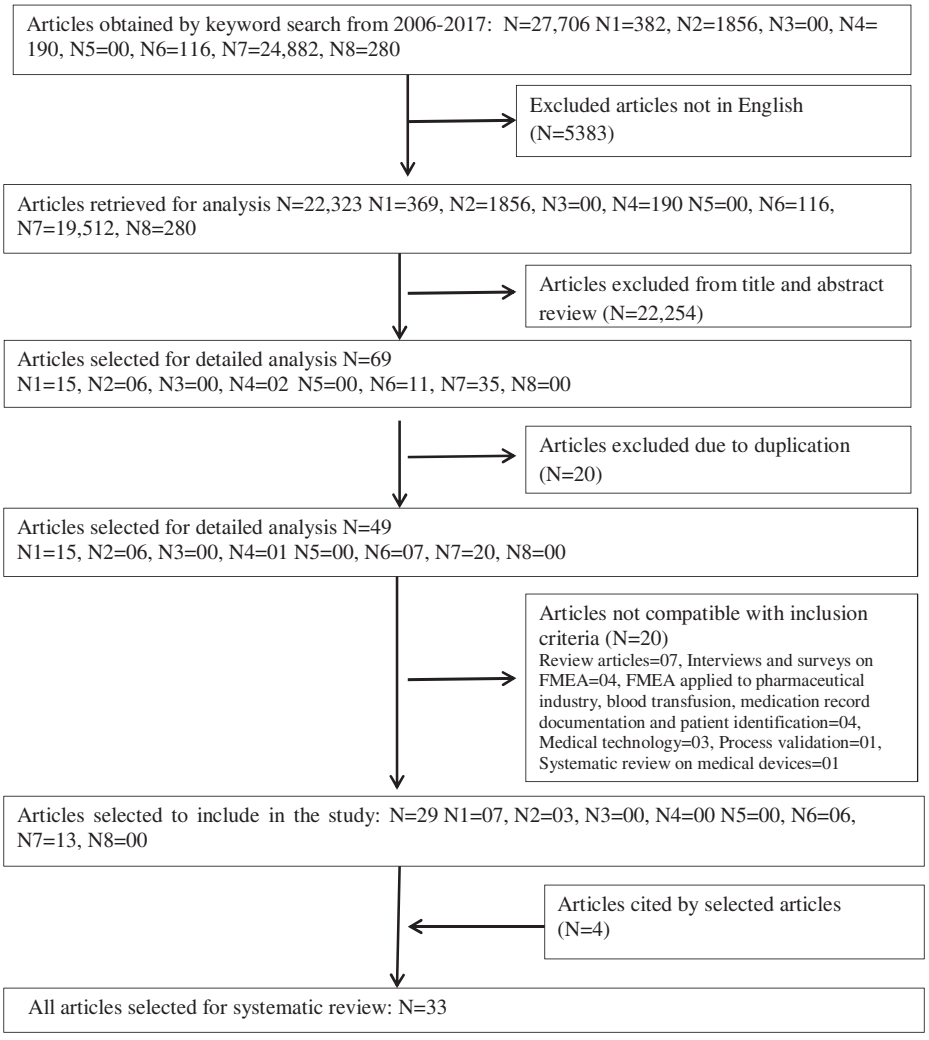

Figure 2 Flow chart of article selection for the systematic review.
N1=PubMed; N2=SAGE; N3=JSTOR; N4=Emerald; N5=Oxford Journals; N6=web of Science; N7=Scopus; N8=Cochrane library.

Table 1 Studies that used different scales for FMEA/HFMEA analysis of findings

	4-point scale	5-point scale	10-point scale
Used FMEA	15	16–20	21–30
Used HFMEA	31–37	38	

FMEA, Failure Mode Effect Analysis; HFMEA, Healthcare Failure Mode Effect Analysis.

three scores, severity, frequency and detectability, for each failure mode. Only nine studies had used HFMEA to assess their processes and had used a hazard score (severity × frequency) to prioritise the identified failure modes. A 4-point, 5-point or 10-point scales were used to score the severity, frequency and detectability according to the different guidelines used by authors (table 1).

Some other studies[13 39–43] had used mixed scales adopted from literature. One study had used the scale introduced by the ISMP, Canada,[44] which is also a mix of a 4-point scale and a 5-point scale.

Composition of group/s

In reviewing the participant composition, 29 studies had focus groups representing different professions, while four studies had participants from the same profession. Furthermore, 26 studies had managerial representatives in their groups. The minimum number of participants in a group was four while the maximum was 15. Thirty studies had conducted FMEA using one group. Two studies conducted their discussions using two groups, while one study used two groups meeting at two different times to best suit their working hours. The second study had two groups because they had ranked severity, frequency and detectability of failure modes through two groups of front-line staff while process mapping and brainstorming had been done by the research team. One study had five groups. (Details are in online supplementary table.)

Perceptions of FMEA participants

Most of the studies had reported on perceptions/feedback by participants regarding FMEA. They had reported both advantages and drawbacks of FMEA as shown in table 2.

Benefits/outcomes of FMEA

Among the reviewed studies, 31 had recommended corrective action. Ten of them were evaluated for the effectiveness of the recommended interventions which had resulted in a reduction in failures or reduction in RPN values. However, three studies had only proposed a methodology to assess the effectiveness of suggested corrective measures but had not implemented within the study period.

Table 2 Perceptions of participants on FMEA

Advantages of FMEA	References
FMEA method was useful in comprehensively analysing complex processes, gathering collective knowledge of participants and sharing their experiences.	16 23 28 30 33 42–45
FMEA improved the awareness of healthcare professionals on the risky nature of their profession and had led them to be more committed towards safety.	20 30 35 38 43 44 46
FMEA had prompted them to act on failures which were considered less serious and left unattended.	33
FMEA was simple to follow.	26 40 43
Drawbacks of FMEA	**References**
Results of FMEA are subjective, based on knowledge and experience of participants.	13 15 18 19 22 23 26 27 31 35 36 40 42 43
FMEA findings cannot be generalised to other institutions, even to the same stage of the medication use process.	16 17 19 22 27 36
FMEA is time-consuming.	16 21 24 28 30 35 41
Difficult to come to a consensus among different professions or different individuals of the same profession.	32
Difficult to precisely determine failures, causes and effects.	18

FMEA, Failure Mode Effect Analysis.

DISCUSSION

This systematic review is an attempt to comprehensively review the application of FMEA to improve medication safety in different steps of the medication use process in any healthcare setting. We reviewed 33 articles which resulted from the systematic procedure detailed above.

We found that FMEA is a valuable prospective analytical method that can be applied to most of the processes in healthcare. According to our study, FMEA can be successfully applied to evaluate the safety of existing procedures,[13 24 26 27 16-22 30–33 35 36 39–4244–46] process changes[43] and assess the implementation of new policies.[29] Furthermore, we encountered studies which employed FMEA to evaluate the impact of different situations such as drug shortages[25] and to select the best choice over two alternatives.[28] A large number of studies were carried out in different inpatient areas including paediatric units.[17 20 22–2427–-2940–42 44] A considerable number of studies were carried out to assess chemotherapy procedures including paediatric chemotherapy.[30 32–35 37 39]

Selected articles reported a reduction in errors[15 16 19 26 27 30] and increased detectability of errors[15] after implementing suggestions resulting from FMEA discussions. Most studies had successfully implemented corrective measures after having FMEA discussions.[13 15–3335–3739–4244–46] Although every single healthcare process has its own inherent risks, it is well known that areas such as chemotherapy, neonatology and paediatrics are areas that are more vulnerable to hazards. We learnt from the present systematic review that FMEA was effectively and widely used in such areas.[15–17 20 26 30 33–35 37 39–43]

Present healthcare systems are encouraged to concentrate more on safer systems rather than safer individuals.[9] FMEA focuses on systems and investigates system failures and not individual errors, which makes this method more suitable to analyse healthcare processes.[24] Additionally, some studies had appreciated the simplicity and quantitative nature as advantages of FMEA.[26 40 43] However, in contrast, Ashley *et al*[34] suggest that FMEA should be used as a qualitative method although it contains a numerical part (RPN). This is due to the subjective nature of scoring and high variability when scoring individually against team consensus.

FMEA procedure solely depends on the brainstorming of a limited number of individuals to identify failures, their effects, causes and for failure mode scoring. Hence, the procedure depends on experience and personal attitudes of individuals.

Scoring of failures was recommended to be done through team consensus, which was found to be more appropriate than considering a mathematical approach such as calculating an average of individual scores.[34] In the team consensus method, variability of individual scoring is clear and it can be resolved through discussions and agreement.[34] The successful completion of FMEA is highly dependent on commitment and agreement of group members.[16 21 41]

The composition of the FMEA team is a significant factor for successful conduction of FMEA. ISMP guidelines[9] suggest that the FMEA team should consist of three to eight people including front-line practitioners and management. Selected studies had also reported that incorporation of front-line staff in discussion groups is significant[24 44] as they have the best experience with practical issues. The minimum number of participants in a group

observed in this systematic review was four[21 43] while the maximum was 15.[13] However, large groups were divided into groups having less than 10 per each group. All studies had groups comprising of front-line staff while most also[13 16 18–25 27 29–38 41 42 44–46] had administrative or middle-level management in their groups. Some studies[13] had suggested that FMEA groups should also include end users of that particular service of interest. ISMP guidelines[9] too recommend FMEA teams to include patient representatives. As such, some studies[26 33 46] had incorporated patients or their family representatives in their respective FMEA group/s. Furthermore, it was found that having a large multidisciplinary group reduces biasness and the unavoidable subjectivity of FMEA.[13 16 18 22 26 30 33 37 42 43 46]

Many studies had identified communication issues and lack of knowledge/training as causes for errors. These causes were not confined to a specific area of medication use or to a specific region of the world showcasing the universal nature of communication issues in healthcare systems worldwide. Some studies on chemotherapy[35 37] had identified background distractions as a cause for some failures. Many studies from different countries of the world such as Spain,[31] UK,[23] Netherland,[33] Brazil,[45] Iran,[36] Serbia[19] and China[37] had mentioned understaffing and/or intense workload as a cause for errors. This reveals that shortage of healthcare professionals is a global issue. Mental lapses, unclear prescriptions and disorganised workspace were some other causes identified by different studies.

In order to overcome these identified issues, healthcare systems should work towards improving proper communication among healthcare professionals. Furthermore, healthcare professionals should practice professional communication among each other and with patients.[18 19 33 35 36] Moreover, continuous professional education and training is important in reducing possible failures in healthcare systems.[18 20 23 27 30 32 37 45] Developing standard guidelines was also a suggested recommendation for avoiding failures.[18 19 31 36 39 45]

Implementing new technology is an increasing trend in every field of work worldwide. As reported by researchers, introducing electronic prescribing, clinical decision support systems and bar code identification of patients could facilitate the reduction of medication errors.[18 19 23 36 44 45]

While most studies suggest FMEA as a useful tool to use in evaluating healthcare processes, some researchers have argued on the reliability of FMEA results. Nada *et al*[47] and others[48 49] (whose studies were not eligible to be included in this systematic review) had also questioned on the reliability of FMEA results with the exception of process mapping. Furthermore, they argue that the procedure of calculating RPN is mathematically questionable.[49] Due to this doubt on the mathematical accuracy of calculating RPN, it is recommended not to solely depend on RPN value when prioritising failure modes.[48 49]

There are some limitations in our review that needs to be acknowledged. Including articles from 2006 onwards may have missed some studies which were carried out during the time FMEA was introduced to healthcare in the 1990s. In addition, the electronic databases we used were limited to those we had access to. We may also have missed some articles related to other healthcare institutions such as private clinics due to the specific search terms we used.

CONCLUSIONS

FMEA showed a successful team attempt to prospectively evaluate high-risk procedures and had frequently used a multidisciplinary approach. This systematic review showed that most of the reported FMEA studies were carried out in inpatient settings. Furthermore, our findings revealed that participants of FMEA processes believed it to be an effective and useful method to assess possible failures of high-risk processes such as medication use, although the method encompasses some inevitable limitations like subjectivity, inability to extrapolate results to other settings and inability to reproduce results. Nevertheless, it is clear that FMEA is a useful tool to proactively assess the safety of any step of the medication use process and to develop corrective measures.

Self-assessment questions

1. FMEA is used to analyse effects and causes of past events. True or false?
2. FMEA was first developed by engineering and aerospace fields. True or false?
3. The process steps of FMEA differ according to the framework used. True or false?
4. FMEA process cannot be used to analyse chemotherapy processes. True or false?
5. The outcomes of the FMEA depend on the composition of the team. True or false?

Main messages

- FMEA is a structured prospective method recommended to analyse risky processes.
- FMEA has some inevitable limitations like subjectivity, inability to generalise and reproduce results.
- Present systematic review reveals that FMEA can be successfully used to improve medication safety by identifying possible failure modes before they occur.

Current research questions

- What are the different medication use processes that FMEA has applied?
- What are the advantages and drawbacks of FMEA according to the perceptions of FMEA participants (group members)?
- What are the effects and causes of identified errors in different healthcare settings of selected studies?

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Contributors JALA and NRS carried out the systematic review being reviewer 1 and reviewer 2. VR assisted in conducting the review. JALA wrote the manuscript in consultation with NRS and VR. All three authors discussed and contributed to fine-tune the final version of the manuscript. VR did the language editing.

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Answers

1. False
2. True
3. False
4. False
5. True