

Article Review

Healthcare Failure Mode and Effect Analysis (HFMEA) in Reducing Patient Safety Incidents Risk at Hospital: Literature Review

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ABSTRACT

Patient safety is a priority in hospital services, but patient safety incidents such as adverse events frequently occur in hospitals. Healthcare Failure Mode and Effect Analysis (HFMEA) is one of the hospital's strategies to reduce patient safety incident risks through risk management. This study aims to describe the use of the HFMEA method in various countries and its role in reducing patient safety incident risks. This study began with searching data using four databases and selecting scientific article sources using the Preferred Reporting Items for Systemic Reviews and Meta-Analysis (PRISMA) method, where 15 articles were found that met the research objectives, inclusion, and exclusion criteria. The result shows that HFMEA has been applied in hospital services and management in various countries. HFMEA reduced the risk of failure and patient safety incidents in the hospital. However, this can be effective if the hospital implements all steps of HFMEA and routine monitoring and evaluation of interventions to prevent the occurrence of patient safety incident risk.

Keywords: *Healthcare Failure Mode and Effect Analysis (HFMEA), Patient Safety, Risk Management, Literature Review*

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INTRODUCTION

Healthcare tends to develop rapidly with the development of science and technology. Therefore, hospitals are competing to provide better, high-quality, and modern health services to increase patient satisfaction and win the competition between hospitals ¹. However, hospitals must ensure patient safety and security amid the possible risk of incidents from various advanced technologies, complex diagnostic procedures, and hospital therapeutic service².

Patient safety is a priority in hospital services and has become a patient need in healthcare ¹. Patient safety incidents can cause death and disability. Harm to patients due to unsafe hospital care is a major and growing global public health challenge, which is one of the leading causes of death and disability worldwide. Patients are harmed and even dead every year due to medication error and unsafe

healthcare. They are major contributors of high burden of death and disability worldwide, especially in middle and low-income countries, namely around 2.6 million deaths yearly. The Ministry of Health summarized that Indonesia patient safety incident reports show 1489 incidents in 2018 and increased to 7465 incidents in 2019. Incidents included 38% near misses, 31% non-injury incidents and 31% unexpected incidents (adverse event) ³. However, recent national patient safety incidents reports are not publicly available and difficult to access.

From a financial and economic perspective, the cost of handling patient safety incidents is quite high. The annual cost of medication error estimated by WHO is around US\$ 42 billion ⁴ Public confidence and trust in the local health system are often diminished when incidents are publicized. The health workers involved also suffer psychological impact and feeling guilty.

The world's seriousness towards patient safety is again proven by the establishment of the Global Patient Safety Action Plan 2021-2030 by the World Health Organization (WHO) in August 2021, which the aim is to achieve the maximum possible reduction in harms that can be avoided due to unsafe healthcare globally ⁵. Patient safety strategies in hospitals are expected to minimize the risk of unexpected medication errors, events (adverse event), minimize conflicts between officers, avoid lawsuits, and legal processes as well as allegations of malpractice in hospitals ⁶. Identifying and managing potential risks of patient safety incident is one of strategy that can be applied. Risk identification is divided into proactive and reactive assesment. Proactive risk assessment is applied by determining risks that have the potential to occur so that risks not occur such as healthcare failure mode and effect analysis (HFMEA) ⁷.

HFMEA is a development of the Failure Mode and Effect Analysis (FMEA) method which is a systematic process to help identify a risk of failure in the process before the failure occurs. FMEA is one of the methods widely used in the automotive, industrial and aviation fields for proactive risk assessment ⁸. In 2001, The Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS) adopted the FMEA for healthcare implementation ⁹.

HFMEA helps health services to identify potential failures, their impact and calculate the magnitude of the impact through the severity and likelihood of the risk occurring ¹⁰. The Joint Commission (JCI) requires JCI accredited hospitals to regularly perform risk assessment using the HFMEA method for 18 months ⁶. Indonesian Ministry of Health Accreditation Standards 2022 Edition shows that HFMEA is required to be carried out by the hospital at least once in 1 year ⁷.

In previous studies showed that HFMEA used to analyze risks in the medical service process ¹¹, nursing ¹², laboratory ^{13,14}, radiology ^{15,16}, hemodialysis ^{17,18}, inpatient ¹⁹, ICU ²⁰, surgery ^{21, 22}, anesthesia ²³, blood transfusion procedure ²⁴, chemotherapy ^{25,26}, radiotherapy^{11,27}, medication management ^{28,29}, and medical waste management ³⁰. In addition, several studies using systematic literature review methods related to FMEA and HFMEA discussed their role in the quality of service in hospitals ^{14,19}. Reviewing previous studies, no

published studies discuss the role of HFMEA as a strategy to reduce the risk of patient safety incidents in hospitals. Hence, this study focuses on describing the application of HFMEA in hospitals of various countries and its role in reducing the risk of patient safety incidents.

METHOD

This study was literature review which began with determining the questions and research objectives as the main focus of the research. PRISMA tools applied in this article to improve the reporting of literature review. Articles were collected from Pubmed, Science Direct, SpringerLink, and Taylor & Francis Online databases. Articles searched by suitable keywords due to reach specific studies such as *healthcare failure mode and effect analysis*, HFMEA, healthcare, failure mode and effect analysis, FMEA, patient safety incident, risk, and hospital. Keywords combined using Boolean or AND.

Selection of scientific article sources using the PRISMA method (Figure 1) adapted to the research objectives, inclusion and exclusion criteria. Filtered scientific articles by the language, publication period, free full text, journal article type, and open access journal. Inclusion criteria such as publication period around 2013 to 2023, language in English, hospital as studies population area, and journals academic as type of publication. Exclusion criteria such as grey literature and systematic literature review publication.

RESULTS

The search was conducted through four databases and 627 scientific studies (Figure 1). Sixty-two publications screened and 565 excluded that did not meet the inclusion criteria such as other than English language, publication period above ten years, and review studies. 58 publication assessed for full text eligibility. 15 scientific articles were obtained which were determined by researchers as research sources.

Relevant data extracted by author, year, country, research topic and unit area, and research objectives and conclusion. Due to facilitate reader on highlighting differences on each selected articles, data synthesize by monitoring evaluation of HFMEA and impact HFMEA of patient safety of every included

studies.

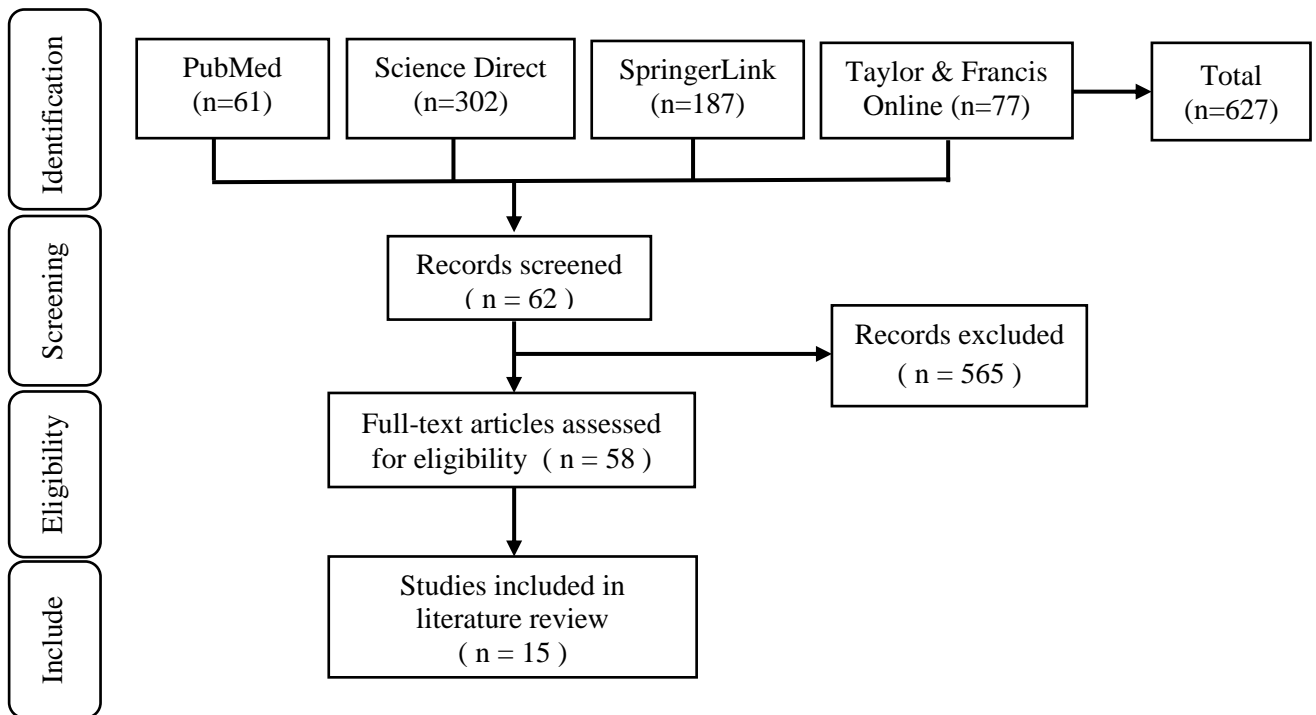


Figure 1. PRISMA Flow Diagram

Selected scientific articles discuss the use of HFMEA in hospital risk management in United States of America, Ethiopia, Belgium, Iran, Israel, Italy, Sierra Leone, Sri Lanka, China, Jordan, Spain, New Zealand, Seoul, and Sweden.

Hospitals applied HFMEA by every step on HFMEA process such as define the HFMEA topic, assemble team, risk identification, assessment, analysis, decide

intervention to prevent patient safety incident risk, monitor, and evaluate of the outcome after implemented intervention. Previous studies result (Table 1) show gaps on the last steps of HFMEA, which some hospitals unimplemented the monitoring and evaluation of the outcome of intervention. Therefore, uncomplete process affected the impact of HFMEA on patient safety incident.

Table 1. Data extraction

No	Author (Year)	Country	HFMEA topic	Monitoring & Evaluation	HFMEA impact on patient safety incident
1	Fanny Ofek et al. (2016)	Israel	A change in hospital policy: switching of KCl infusion solution to KCl ready to use solutions	Monitoring & evaluation of interventions based on HFMEA results have been completed. Routine monitoring with one-day survey method (every 3 to 4 months)	Before interventions implemented, several adverse events or unexpected events were reported that related to the highest risk score. However, after the intervention was applied for 2 years,

No	Author (Year)	Country	HFMEA topic	Monitoring & Evaluation	HFMEA impact on patient safety incident
					no adverse event founded
2	Zhila Najafpour et al. (2017)	Iran	Blood transfusion	Monitoring & evaluation of interventions based on HFMEA results have been completed. Corrective actions are evaluated after 6 months implementing the intervention	Error rates in blood transfusions decreased and adverse events not occur after the implementation of risk prevention interventions
3	Andy Yuanguang Xu et al. (2017)	United States	Gamma Knife radiosurgery	Monitoring & evaluation of the intervention unimplemented	Unanswered because monitoring and evaluation unimplemented
4	J.A.L. Anjalee et al. (2021)	Sri Lanka	Drug dispensing	Monitoring & evaluation of the intervention unimplemented	Unanswered because monitoring and evaluation unimplemented
5	Viviane Van Hoof et al. (2022)	Belgia	POCT blood gas analysis (BGA)	Monitoring of interventions based on HFMEA results have been completed by using key performance indicators (KPI) to monitor corrective actions in order to prevent risks from occurring. But evaluation unimplemented yet	Unanswered because monitoring and evaluation unimplemented
6	M.A. Rosen et al. (2014)	Sierra Leone	Testing new device : The Universal Anesthesia Machine (UAM)	Monitoring & evaluation of the intervention unimplemented	Unanswered because monitoring and evaluation unimplemented
7	Clemente Ponzetti et al. (2016)	Italia	Administrative risk of subcutaneous and intravenous therapies	Monitoring & evaluation of the intervention unimplemented	Unanswered because monitoring and evaluation unimplemented
8	Berhanetsehay Teklewold et al. (2023) Ethiopia	Etiopia	Admission of asymptomatic Covid-19 patients to the adult emergency department	Monitoring & evaluation of the intervention unimplemented	Unanswered because monitoring and evaluation unimplemented

No	Author (Year)	Country	HFMEA topic	Monitoring & Evaluation	HFMEA impact on patient safety incident
9	Jiuling Shen et al. (2019)	China	Application of Helical Tomotherapy – Total Marrow Irradiation (HT-TMI)	Monitoring of interventions based on HFMEA results have been completed by conducting HFMEA after 1 year of implementing the intervention and plan-do-check-action (PDCA) cycle after the second FMEA intervention was implemented	In the second HFMEA, the highest 5 risk score in the first HFMEA decreased and didn't being the highest score. However, the impact on patient safety incident risks related to FMEA 1 and 2 is unexplained
10	Anas Haroun et al. (2021)	Jordan	The nursing blood sampling process	Monitoring and evaluation of interventions based on HFMEA results have been completed after 3 months of implementing the intervention	There was a significant reduction of 58% of the the risk assessment result and incidents of blood sampling errors was reduced by 70% after the intervention was implemented.
11	Maria Dolores et al. (2017)	Spain	Hemodialysis process	Monitoring & evaluation of the intervention unimplemented	Unanswered because monitoring and evaluation unimplemented
12	XuXia Yu et al. (2020)	China	HFMEA for improving the qualification rate of disinfection quality monitoring process	Monitoring and evaluation of HFMEA results have been completed from July 2017 to March 2018	The overall qualification rate in disinfection quality monitoring increased from 16.5% to 78.7% ($p < 0.001$). However, the impact on patient safety incident is unexplained
13	Ehsan Ullah et al. (2022)	New Zealand	Use of Rapid Response System (RRS)	Monitoring & evaluation of the intervention unimplemented	Unanswered because monitoring and evaluation unimplemented
14	Howard Lee et al.(2023)	Seoul	Clinical trials	Monitoring & evaluation of interventions based on HFMEA results have been completed	A significant reduction of 80% in post-intervention risk assessment results was performed.

No	Author (Year)	Country	HFMEA topic	Monitoring & Evaluation	HFMEA impact on patient safety incident
					However, the impact on patient safety incident was unexplained
15	Claudia Sabate Martinez et al. (2023)	Sweden	Protein drug supply chain	Monitoring & evaluation of the intervention unimplemented	Unanswered because monitoring and evaluation unimplemented

DISCUSSION

Risk identification and assessment

HFMEA processes begin with determining the topic and establishing a multidisciplinary team. The team consists of functional and managerial hospital workforce related to the selected topic. Some hospitals involved representatives from the hospital quality team to lead the HFMEA process^{12,24,31}. The next step is to clearly describe and identify the process and sub-process flow of the topic selected. Hospitals need competent HFMEA team members who are proficient in selecting topics and HFMEA concepts. The HFMEA team needs to hold regular meetings in several times until the overall risk has been identified. Based on the selected articles, discussion take around 3 to 6 months to identify, assess and define risk interventions^{32,33}. This process will take much time, resources and requires organizational commitment, but it is effective for identifying and prioritizing potential risks of blood transfusion service process in China hospitals²⁴

HFMEA conducted in a Sri Lanka hospital has proved successful in identifying and prioritizing the potential risks that may occur in the drug dispensing process²⁹. The HFMEA method help hospitals in identifying hazards and implementing mitigation strategies in order to establish emergency hospitals during the COVID-19 pandemic³⁴. Potential risks in the use of universal anesthesia machines occur due to the availability and conditions of the tools, drugs, environmental factors, workload and knowledge of health workers²³.

The next process is causes and impacts analysis of risks. The highest risk ranking can be determined from the scoring results obtained from severity, frequency, and impact of those risks which help hospitals to prioritize the failure mode. Risk identification to risk

assessment is carried out in several discussions to determine the risk list from the process and sub-process flows of the selected topic. In gamma knife radiosurgery procedures in the United States, which found 86 potential risks, the risk assessment helped hospitals prioritize the 9 highest risk scores²⁷.

In addition, the HFMEA process involving team collaboration has succeeded in forming and increasing understanding and awareness of strengths and weaknesses on a healthcare process among the healthcare workforce^{29,35}. Increasing patient safety and potential risks awareness of pharmacists, apothecarist, and intensive care unit staff who involved in HFMEA process^{29,14}. This is in line with Simamora's theory³⁶ which states that education and training for staff can increase and strengthen good performance as well as improve poor performance.

Intervention to prevent patient safety incident risk

The next step is determining the action or intervention of the highest risk in order to prevent the risk from occurring. Development of action plans from selected studies show various plan that hospital implemented, such as developing protocol or standard operating procedure (SOP)³⁷, education and training for hospital workforce^{12,31}, supervision³⁸ redesign dispensing area with patient waiting facilities, reorganize the dispensing process²⁹, increasing internal and external audit³³, increase communication with patients, and advocate for additional human resources²³.

Interventions are not always affordable, but hospitals had their own consideration of their ability to carry out interventions both in terms of human resources and costs. Intervention cost were estimated lower than the social cost of patient harm which can be valued at US\$ 1 to 2 trillion a year⁵. In addition,

interventions can be considered based on previous research showing significant error reduction.

Monitoring and evaluation of risk prevention

The HFMEA process does not end at the intervention steps, routine monitoring and evaluation of the intervention implementation of the intervention are needed. Monitoring is carried out to monitor the implementation of interventions. Meanwhile, evaluation requires data from monitoring process to find out whether the specified intervention is successful and effective in reducing risk. The risk reduces, reducing patient safety incidents shown on patient safety incidents report. Therefore, HFMEA will provide maximum results.

Following step after determining intervention is monitoring and evaluating of interventions to prevent risks from occurring. Based on the 15 selected articles, 5 studies conducted monitoring and evaluation of risk prevention interventions, 2 studies each conducted monitoring but did not evaluate, while the other 8 not conducted monitoring and evaluation.

Monitoring and evaluation can be measure in the form of a plan-do-study-action (PDSA) method³⁵, plan-do-check-action (PDCA) and key performance indicators (KPI)¹¹. KPI aims to evaluate whether the objectives for performance are met. KPIs were used to monitor interventions routinely through KPIs from laboratory units and staff³⁹. KPI is also used to reduce clinical laboratory pre-analytic errors⁴⁰.

Studies of Fanny Ofek et al show that interventions from 6 potential risks have been carried out, since it was implemented for 2 years, adverse events were not found³¹. The error rate in blood transfusions decreased after the intervention in preventing the risk of errors in patient blood transfusion procedures. If necessary, the HFMEA can be repeated in the following year to monitor if the risk score has decreased as was done in the study by Jiu Ling et al.,¹¹.

The application of HFMEA followed by consistent monitoring and evaluation which can reduce patient safety incidents. It also bring impact on improving the quality of hospital services in quality dimensions of safety, effectiveness and efficiency¹⁴. Studies in hospital operating rooms states that HFMEA

can improve service quality in the quality dimensions of safe, effective, efficient, fair, timely, patient-centered, and integrated⁴¹.

Impact of HFMEA implementation in reducing patient safety incidents

Applying the HFMEA method requires long process and cost for interventions, but by doing so resulting in cost effective, quality improvement, medication safety, health worker safety, and patient safety. The integration of the Value Stream Map with HFMEA in improving the specimen handling processes as found that the application of HFMEA was able to reduce specimen rejection cases from 0.92% to 0% in 2010–2013⁴². In oncology and hematology cases, subcutaneous injection is better than intravenous injection because it can reduce the risk of medication errors in patients. From the hospital perception, it shows cost and resource savings⁴³.

Several studies have shown the role of HFMEA in reducing the risk of nursing care in pre-surgery³⁷. The impact of reducing adverse event of blood sampling errors reduced by 70% and no adverse events after intervention in the use of ready-to-use KCl solutions and blood transfusions^{12,24}. Thus, proactive method of risk management use to identify potential risks that cause errors or failures in the process and useful in improving patient safety²⁹.

CONCLUSION

Based on 15 articles that have been reviewed, HFMEA application has an impact on reducing patient safety incident risk. However, the hospital requires commitment and precision to apply each steps in the HFMEA process. HFMEA is a continuous and multiphase proactive risk assessment method, which if implemented optimally at every step and supported by competent human resources and hospital commitment, it will lower the risk of patient safety incidents occurring in the hospital. Apart from being a form of learning and routine monitoring in the context of reducing patient safety incident, the application of HFMEA is effectively applied in hospital services to create effectiveness and efficiency by maximizing existing resources in the hospital, avoiding waste, and increasing efficiency in the healthcare service process. In addition, it can reduce the cost of handling a relatively high patient safety incident.

Conflicts of Interest: The authors declare no conflict of interest.

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