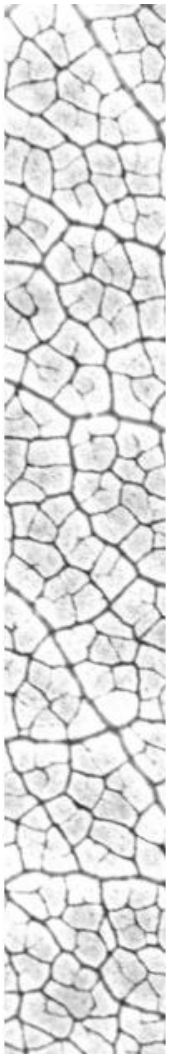

EurAsian Journal of BioSciences
Eurasia J Biosci 14, 3257-3261 (2020)

Application of Failure Mode and Effect Analysis (FMEA) report of medication processing a private hospital

Djazuly Chalidyanto [1*], Winda Easteria Kurniasari [1]

[1] Department of Health Policy and Administration, Faculty of Public Health, Universitas Airlangga, Surabaya, INDONESIA
*Corresponding author: djazulych@fkm.unair.ac.id

Abstract
Medication error is one of many adverse events that occur at a hospital, based on data from the Committee of Quality Improvement and Patient Safety in this hospital. This study aims to analyze failure modes and the effects of the medication process by using FMEA as a proactive risk reduction method in healthcare. The design of this study was cross-sectional. Data are obtained from incident reports and risk register of this hospital. In nature way, the writer analyzes the data descriptively. The FMEA process uses stages following JCI. For this activity, the FMEA produces failure modes, potential causes and potential effects. The highest Risk Priority Number (80) of failure modes is shown by the aspect of the lack of information about patients' allergic history in medical records. The rate of 60% of the proposed redesign process is implemented in this hospital, and it manages to lower Risk Priority Number 64 points from 80 to 16. Redesign Process using FMEA method can be used in reducing healthcare risk, and this research needs to be continued to observe the effectiveness of FMEA in reducing incident report in this hospital this year.

Keywords: FMEA, medication errors, medication process, patient safety and quality improvement, risk management storage

Chalidyanto D, Kurniasari WE (2020) Application of Failure Mode and Effect Analysis (FMEA) report of medication processing a private hospital. Eurasia J Biosci 14: 3257-3261.

INTRODUCTION

Medication errors are defined by WHO as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use"(Ahmed, et al. 2019).

The frequency of medical errors in Kuwait was found to be high at 60.3% ranging from incidences of prolonged hospital stays (32.9%), adverse events and life-threatening complications (32.3%), and fatalities (20.9%). In addition to these extraordinary casualties, medical errors also result in annual costs of USD 17 billion to USD 29 billion in the United States (Ahmed, et al. 2019). Furthermore, based on the results of research at John Hopkins University, medical errors rank third in the cause of death in the United States, with 250,000 cases recorded in 2013 (Hąbek, & Molenda, 2017).

Data at the research hospital in 2017 showed that 28% of all reports were related to the medication process. While in 2018, that number increased to 37% (Hąbek, & Molenda, 2017). Medication error placed first with yellow grading on the incident report. FMEA is one of the proactive efforts to prevent medication errors in health services by identifying potential failures of services before they occur (Setiasih, & Junadi, 2017). It identifies the failure mode of each medication process of which steps determined by JCI (Joint Commission International) (Ahmed, et al. 2019). Therefore, this study aims to analyze failure modes and the effects of the medication process by using FMEA as a proactive risk reduction method in healthcare.

MATERIAL AND METHOD

Research Design, Population Sample and Variable

The researchers use a cross-sectional research method. The population sample of this study is obtained from 2017-2018 incident report data at the research hospital. The researchers also observe the staff's activity in the pharmaceutical unit, an outpatient unit, emergency department and inpatient unit.

Received: March 2019
Accepted: March 2020
Printed: September 2020

Table 1. Failure Mode

NO	FAILURE MODE	HAZARD ANALYSIS				STAGES OF PROCESS
		IMPACT	PROBABILITY	CONTROL SYSTEM	RISK PRIORITY NUMBER	
1	The doctor did not record the patient's history of allergies on the Medical Records	5	4	4	80	Documentation
2	Wrong patient	5	4	4	80	Administering
3	Broken drug packaging	4	3	5	60	Dispensing
4	Empty column for allergies	5	2	5	50	Prescribing
5	Drug duplication	5	2	5	50	Transcribing
6	Wrong medication	5	2	5	50	Dispensing
7	Misread medication	5	2	5	50	Transcribing
8	Misread medication label	5	2	5	50	Transcribing
9	Wrong in dispensing	5	2	5	50	Dispensing
10	Misread medication instruction	5	2	5	50	Transcribing
11	Unreadable prescription	5	3	3	45	Transcribing
12	Wrong drug etiquette	4	2	5	40	Administering
13	Information received does not include a history of allergies	4	2	5	40	Documentation
14	Incorrect medication	3	4	3	36	Administering
15	Wrong dosage	5	3	2	30	Dispensing
16	Wrong amount	3	2	5	30	Dispensing
17	Wrong Medical Records	3	2	5	30	Other
18	Wrong medication	5	1	5	25	Transcribing
19	Did not ask about the history of illness	3	4	2	24	Subjective
20	Did not ask about the history of treatment	3	4	2	24	Subjective
21	Undetected expired drugs	3	2	4	24	Dispensing
22	Did not ask about the history of allergies	5	2	2	20	Subjective
23	Did not write about the history of allergies	5	2	2	20	Prescribing
24	The patient did not know the allergy	5	2	2	20	Subjective
25	Expired drug	3	2	3	18	Dispensing
26	Administration of prescription is incomplete	3	2	3	18	Prescribing
27	The doctor did not fill in the complete prescription (weight, allergy, diagnosis)	4	4	1	16	Prescribing
28	The nurse did not complete the supporting data in the prescription	4	4	1	16	Prescribing
29	Doctors did not write according to the standard	3	4	1	12	Documentation
30	The doctor did not record the patient's history of illness on the Medical Records	3	4	1	12	Documentation
31	Lost prescription	3	4	1	12	Prescribing
32	Long service	3	4	1	12	Other
33	Unavailable medication	3	4	1	12	Dispensing
34	History is not fully explored	3	3	1	9	Subjective
35	Doctor did not examine patients	3	2	1	6	Objective
36	Doctor is not thorough	3	2	1	6	Objective
37	Wrong diagnosis	3	2	1	6	Assessment
38	The doctor wrote the wrong prescription	5	1	1	5	Prescribing

Instrument

The research instrument includes eight steps of FMEA by JCI, that are: (1) Selecting a High-Risk Process and Assembling a Team, (2) Diagramming the Process and Brainstorming Potential Failure Modes, (3) Prioritizing Failure Modes, (4) Identifying Root Causes of Failure Modes, (5) Redesigning the Process, (6) Analyzing and Testing the Process, and (7) Implementing and Monitoring the New Process (Yousefian, et al. 2013; Assefa, et al, 2016).(Hashemi, et al. 2014).

Research Procedures and Analysis

This study uses the theory and standard of operational procedures applicable to the hospital to determine the flow of processes and sub-processes. To determine the failure mode, the researchers observe the staff's activity, also brainstorming between researchers and FMEA teams. In determining the value of the impact, probability and control systems, brainstorming is needed to be conducted by the team members, with each range of benefits of the impact, probability and control systems being 1-5. The Risk Priority Number (RPN) value is determined by multiplying the three components above. Then, the FMEA team members specify the steps of the redesign process and identify the person in charge of each new redesign process to be tested.

RESULT

The result of the FMEA analysis conducted by the researchers includes 38 failure modes, mostly in the process of dispensing and prescribing (**Table 1**).

This root cause analysis emphasizes on the nursing care model that uses a functional model that no longer recommended. In this model, the nurses do not know how to handle patients because the tasks are divided based on activities, not based on the patients. Hence the

Table 2. Recommendations from a priority failure mode summary

No	Critical / Priority Failure Mode	Root Cause	Recommendation	Short / Long Term
1	Wrong patient	No identification tool can minimize errors	- Identification sticker - Patient ID card with a barcode - Barcode reader - Same name sticker - Color-based Medical Records numbering - Revised registration SOP	Short
2	There is no information about the patient's allergy/ treatment/illness history	Information column about the history of allergy/treatment/previous disease is not detectable	- Revised Medical Records (includes a complete history of allergies, history of the disease, history of treatment) - Allergy stickers on the Medical Records cover - A particular column for drug allergy that detectable - Relevant SOP	Short
3	Error procedure in preparing medicine	Lack of staff	- Recruiting more pharmacists - Purchasing laminar airflow - Drug label stickers - Conducting double-check SOP - Other relevant SOP	Short
4	Error in interpreting the doctor's writing	Prescription drugs are still written manually. Not all doctor's writings are readable	- E- prescribing - E- medical record - Relevant SOP	Long
5	Error in medication administration to inpatients by nurses	The nursing care method still uses a team model	- Conducting double-check SOP in nursing - Changes in the nursing care model - Pharmacy and nursing training	Short

Table 3. Testing the Redesign Process

No	Critical / Priority Failure Mode	Recommendation	RPN	Reassessment Date	Likelihood	Severity	Detectability	New RPN
1	Wrong patient	- Identification sticker - Patient ID card with a barcode - Barcode reader - Same name sticker - Color-based Medical Records numbering - Revised registration SOP	80	August	2	3	1	6
2	There is no information about the patient's allergy/ treatment/illness history	- Revised Medical Records(includes a complete history of allergies, history of the disease, history of treatment) - Allergy stickers on the Medical Records cover - A particular column for drug allergy that detectable - Relevant SOP	80	August	2	4	2	16
3	Error procedure in preparing medicine	- Recruiting more pharmacists - Purchasing laminar airflow - Drug label stickers - Conducting double-check SOP - Other relevant SOP	60	August	4	3	5	60
4	Error in interpreting the doctor's writing	- E- prescribing - E- medical record - Relevant SOP	50	August	2	3	2	12
5	Error in medication administration to inpatients by nurses	- Conducting double-check SOP in nursing - Changes in the nursing care model - Pharmacy and nursing training	50	August	5	2	5	50

knowledge about patients is not comprehensive. The lack of pharmacists requires the nurses to do the additional job to complete the drug dispensing.

Non-compliance among the staff in identifying patients poses a risk for wrong patient identification. Doctors' behavior, for example, unreadable writing, writing the wrong dosage, amount, also contributed to medication errors. It makes it difficult for pharmacists to read drug prescriptions. The documentation process indicates the highest RPN score. It relates to the lack of information about patient allergies and insufficient space for the column of the history of diseases and treatment. The sign to distinguish the same names of patients is also unavailable.

Table 2 presents all the root problems, to result in process redesign plan inclusive of changes in man, method, material and machine. Several things can be implemented immediately, while some others must be planned for the long-term duration, including the addition of personnel, as well as e-prescribing and e-medical records. Testing for matters that can be implemented immediately is conducted for 2 weeks before being legally enforced.

The result of the implementation, which written in **Table 3**, suggests that after changes were made to the addition of the allergy column, the addition of stickers for patients with the same names, barcode reader and ID card with barcodes, identity stickers, and changes in

nursing care models. The new RPN has become lower than before.

DISCUSSION

There are four steps in medication system : (1) prescribing by the clinician (or self-prescribing), followed by transcribing; (2) preparing and dispensing by the pharmacist; (3) administering by the provider or consumer (self-care); and (4) monitoring for therapeutic and adverse effects (by the nurse, surrogate, or self). Each of these steps includes critical control points at which decisions and actions can contribute to safety or errors (Lago, et al. 2012; Khairurrijal, & Putriana, 2018).

A medication error is the most common type of medical errors (Khairurrijal, & Putriana, 2018; Roy, Gupta, & Srivastava, 2006).

Medication errors can occur in 4 phases, including prescribing error, transcribing error, dispensing error and dispensing-to-patients error (administration error) (Roy, Gupta, & Srivastava, 2006; Spath, 2003). In addition to examining the medication process, researchers also observe the patient examination include the subjective, objective, assessment and planning by the doctor as the factor that contributes to the failure mode in the medication process (Makeham, et al. 2016). It is under the research that the doctor examination and documentation also provide to medication errors (Roy, Gupta, & Srivastava, 2006).

The results of other studies suggest that the most common causes of medication errors vary, not specific in some processes only as of the obstacles in each hospital also vary (Khairurrijal, & Putriana, 2018).

(Duwe, Fuchs, & Hansen-Flaschen, 2005). The most common cause of medication errors in the treatment process and the examination factor; the overwhelming number of patients and lack of concentration (Spath, 2003; Hąbek, & Molenda, 2017). Professional nursing care model applied in the hospital changing the functional model (Fairbrother, Jones, & Rivas, 2010). This matter causes nurses to misinterpret their patients. This practical model still divides nurses based on assignments rather than on patients. The current model of nursing care uses the team method. The hospital needs to change nursing care into a team model (Tran, et al. 2010). The number of pharmacists in the research hospital is still far from the standards set by the Ministry of Health. The task of drug dispensing is always done by the nurses, which adds to their workload (Fairbrother, Jones, & Rivas, 2010; Tran, et al. 2010). The solution to this problem must be prepared, including recruiting more pharmacists.

LIMITATION OF THE STUDY

This research is not complete yet because not all the redesign process have been implemented. Additionally, the FMEA still results in a decrease in RPN/value of risk and does not reduce the incidence rate. Thus, further research is needed to find out whether this FMEA has had an impact on reducing the incidence of medication errors. The development of an interview approach to staff related to the medication process is also necessary.

CONCLUSION

FMEA produces many modes of failure in the medication process. However, it is a useful tool in reducing the risk of medication errors. It can be realized because of the implementation of systemic steps and redesigning the processes. The entire FMEA process takes around eight weeks and supported by a reliable and competent team.

ACKNOWLEDGEMENT

Thank you to all members of the FMEA team who assisted researchers in completing this FMEA process. These stakeholders allowed researchers to obtain data and analyze it for this article.

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