Risk Evaluation of Drug Safety in the Emergency Treatment Process Using a Modified HFMEA-based Associated Matrix

Abstract: Error reduction is important for quality medical services and certification requirements. Patients have mostly complained of poor medical quality in the emergency care department. Therefore, the purpose of this study was to develop a risk assessment procedure for the emergency treatment process to ensure drug quality for patients. The associated matrix technique was proposed to improve the evaluation criteria of traditional Health Care Failure Mode and Effect Analysis (HFMEA). We used a medical center in Taiwan as a model to describe and validate the proposed process. Analysis revealed that most drug usage errors originate from prescription drugs and controlled substances. The results demonstrated the feasibility of a risk assessment procedure to identify emergency flow problems and thus improve drug safety management in hospitals.

Keywords: Emergency care; Healthcare quality; Medication error; Process analysis

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1. Introduction

Certain uncontrollable variations can cause the disruption of medical service flow. Therefore, devising effective measures to control variations is important for minimizing risks in quality medical management. The medical quality expected by patients includes the diagnosis of illness by doctors based on professional competence, accurate prescriptions, accurate verification, and dispensing of drugs. Medication error is a serious concern in drug therapy. According to statistics from the Joint Commission on Accreditation of Healthcare Organizations (TJC) in 2012, medication error ranks 9th among ten major medical sentinel events [1]. Furthermore, medication error ranks 1st among abnormal medical events, with an average incidence of approximately 30% according to the Taiwan Patient Safety Reporting System for 2012Q1–2013Q3 [2]. Medication error can result in incorrect treatment and patient distress if inappropriately handled; however, it is preventable.

Ferner and Aronson found that as many as 4% of patients develop adverse drug reactions because of incorrect drug prescription, dispensation, or administration [3]. Costa *et al*. assessed drug prescriptions in pediatric hospitals and found that the most common error was related to volume [4]. An analysis by Taxis and Barber in the 10 wards of two hospitals found that at least one error was made in 49% of cases [5]. Bower found 16-18 undetected errors in every 100,000 dispensing instances in a UK hospital. Approximately every 9 months, a pharmacist is fired because of errors in drug dispensing [6]. Spencer and Smith demonstrated that medication error was significantly higher in hospital pharmacies that did not verify prescriptions dispensed by pharmacists compared with those that did verify. Medication error, even with a small error, may considerably harm patients [7].

Hoff *et al*. pointed out that emergency, operating, and intensive care units are where adverse medical events are most likely to occur [8] because of their practical nature and unique environment. Emergency wards in Taiwan are characterized the factors more frequently associated with pressure, patients, public relations, and arguments and the factors less frequently associated with sickbeds, human resources, and salary. Every year, an average of over 6,000,000 patients are admitted to and discharged from emergency wards, resulting in a high occupancy of the emergency wards of each hospital throughout the year. Consequently, the turnover rate of medical care personnel engaged in emergency treatment is as high as 30% [9]. Hospitals in Taiwan estimate the demand for human resources according to 60–80 emergency treatment prescriptions processed by a single senior pharmacist on a daily basis [9]. Reportedly, the number of senior pharmacists is low at 181, 114, and

207 in the emergency wards of medical centers, regional hospitals, and district hospitals, respectively. Under these understaffed conditions, emergency departments occasionally have to deal with emergency patients and normal patients simultaneously; this decreases staff performance and increases the risk for inpatients. If a doctor gives an incorrect prescription, the senior pharmacist could misinterpret and dispense an incorrect drug, thus causing considerable harm. Therefore, appropriately prescribed and dispensed medication in emergency departments should be a priority.

Healthcare Failure Mode and Effect Analysis (HFMEA) is the most popular method of improving medical care flow. HFMEA effectively identifies high-risk factors and helps hospitals improve medical issues. Linkin *et al*. performed risk assessments in surgical units on the five major steps of disinfection and found that HFMEA was useful for increasing the awareness of problems that were not emphasized among hospital staff [10]. Van Tilburg *et al*. conducted high-risk harm analysis using HFMEA on the process of chemical medication in the oncology wards of pediatric departments and fourteen out of 61 failure modes were classified as high risk, 10 of which were sufficiently covered by current protocols [11]. Ouellette-Piazzo *et al*. used HFMEA to evaluate the risk of infections concerning the regimen of intravenous antibiotics and was able to decrease the occurrence of medical accidents [12]. Gilchrist *et al*. discovered 6 main flows, 67 sub-processes, and 217 failure modes and developed practical models for other medical service units as a reference [13]. Habraken *et al*. analyzed 13 medical processes with HFMEA and successfully applied the processes in the Holland health care system; however, HFMEA was found to be significantly time-consuming [14].

Many successful cases have demonstrated that HFMEA identifies risk factors in a medical process and provides preventive measures to decrease those risks. These few studies have addressed issues regarding emergency pharmacies in hospitals. Emergency treatment is unique under the National Health Insurance System in Taiwan. Therefore, this study proposed a modified HFMEA to develop a risk assessment procedure for safe patient medication in the treatment process of emergency pharmacies in Taiwan. Actual cases were used to describe and explore potential risks in the process of emergency pharmacies and to devise specific improvement strategies to ensure medical quality.

2. Methods

In practice, HFMEA is responsible for subjective scoring in the analysis of hazardous risks. In this study, an associated matrix was proposed to modify hazardous risk analysis, and a risk assessment was conducted on the emergency treatment process. The main concept involved integrating the failure mode, failure cause, and drug grade to obtain a risk ranking and determine the sequence for preventing failure causes. The modified HFMEA execution procedure is as follows:

- Step 1: To define the scope of the theme

Medical care processes with a high risk are typically selected for improvement following a specific criterion. First, selection should be made according to existing patient safety data in the medical institute or the preferred industry data. Second, selection should be made based on factors such as high complexity, high variation, non-standardization, operation with close interdependence, tight/relaxed intervals among operations, and strong dependence on human judgment.

- Step 2: To establish teams

An HFMEA team must include trans-department personnel. It is necessary to clarify the goals and required resources and time. The number of members should ideally be less than 10, and members need to meet for regular discussions. The main task is to complete HFMEA analysis and provide and execute suggestions for improvement.

- Step 3: To draw a flow diagram

For existing operations, draw a flow diagram following the actual steps of the procedure. For operations under planning, draw according to current thoughts. If the overall process is too extensive, the process must be classified into sub-processes, which should be expanded until a detailed process is achieved.

- Step 4: Hazard risk analysis based on associated matrix

Given the risk control on different drug grades is different, the core of risk analysis is to master the influence of the failure causes of different drug grades. Failure modes, effect analysis, and drug

grades are integrated to analyze hazard risks. The flow diagram in Step 3 is discussed by the team to complete the analysis of failure modes and failure causes. Personnel, equipment, drugs, and environment can be used to describe failure causes. If we assume there are i failure causes, A_1, A_2, A_3,…,A_i, and j failure modes, B_1, B_2, B_3,…,B_j, and that c_{ij} indicates the correlations between failure causes and failure modes, a larger value will lead to a stronger correlation. The associated matrix P between failure causes and failure modes on the basis of the above information is described below.

$$P = \begin{array}{c} \\ A_1 \\ A_2 \\ \vdots \\ A_i \end{array} \begin{array}{c} \begin{array}{cccc} B_1 & B_2 & \cdots & B_j \end{array} \\ \begin{bmatrix} c_{11} & c_{12} & \cdots & c_{1j} \\ c_{21} & \ddots & \cdots & c_{2j} \\ \vdots & \vdots & \ddots & \vdots \\ c_{i1} & \cdots & \cdots & c_{ij} \end{bmatrix} \end{array}$$

Next, establish the associated matrix between the drug grades and failure modes. Assuming that there are k drug grades, D_1, D_2,…,D_k, and j failure modes, B_1, B_2, B_3,…,B_j, and that e_{jk} indicates the correlation between failure modes and drug grades, a larger value will lead to a stronger correlation. The associated matrix Q between failure modes and drug grades according to the above information is described below.

$$Q = \begin{array}{c} \\ B_1 \\ B_2 \\ \vdots \\ B_j \end{array} \begin{array}{c} \begin{array}{cccc} D_1 & D_2 & \cdots & D_k \end{array} \\ \begin{bmatrix} e_{11} & e_{12} & \cdots & e_{1k} \\ e_{21} & \ddots & \cdots & e_{2k} \\ \vdots & \vdots & \ddots & \vdots \\ e_{j1} & \cdots & \cdots & e_{jk} \end{bmatrix} \end{array}$$

The associated matrix R between failure causes and drug grades can be obtained by multiplying the above P and Q matrices, with r_{ik} indicating the relevance value between the ith failure cause and k^{th} drug grade.

$$R = P \times Q = \begin{array}{c} \\ A_1 \\ A_2 \\ \vdots \\ A_i \end{array} \begin{array}{c} \begin{array}{cccc} D_1 & D_2 & \cdots & D_k \end{array} \\ \begin{bmatrix} r_{11} & r_{12} & \cdots & r_{1k} \\ r_{21} & \ddots & \cdots & r_{2k} \\ \vdots & \vdots & \ddots & \vdots \\ r_{i1} & \cdots & \cdots & r_{ik} \end{bmatrix} \end{array}$$

Given the practical execution and flexibility, assume the degree of importance of each failure cause as w_i, and define the risk index of this study as S_i. Sort all S_i in descending order to obtain a sequence for preventing proximate failure causes.

$$S_i = w_i \times \sum_{t=1}^{k} r_{it}$$

- Step 5: To determine actions and measure outcomes

According to the hazard risk index obtained through the analysis, classify the actions used to prevent failure causes as elimination, control, and acceptance. Increasing the devices or personnel or resetting the system without causing any issues related to failure modes fulfills elimination. Control is fulfilled from staff training, equipment adjustment, or increases in the control mechanism with the

failure modes within the allowable range of acceptance. Acceptance is fulfilled when problems cannot be removed or controlled by the former two approaches. Finally, propose corresponding action plans for improvement, determine a method or index for measuring the assessment, and allow senior directors to approve the preventive measures. During the improvement process, it is necessary to accurately record actual errors to determine if the preventive measures are achieved.

3. Analysis and Results

We used the emergency treatment process in a teaching hospital in Taiwan as a model to perform a risk assessment of drug safety using modified HFMEA. Regardless of day or night shift, only two pharmacists in the emergency wards were handling drug dispensing and verification, with one filling the drug prescription and the other dispensing and verifying.

In this study, the window of emergency pharmacies was defined as the demarcation point of error. The error found at the emergency pharmacies was named 'dispensing near-miss,' while that found at the patients' end was named 'dispensing error'. According to a 2010 report, the ratio of the dispensing error to the near-miss error was 8:1, indicating that the error rate associated with failure in verifying outgoing drugs was ultimately higher. The most common error made in emergency pharmacies at this stage was incorrect drug name (56.25%), followed by incorrect dosage (17.5%) and quantity error (16.25%). We discussed the analysis process and presented the details of the methods.

- Step 1: There was an issue because of the higher incidence rate of abnormal events and faults in the emergency treatment process of the hospital mentioned above in 2010, which lowered patient satisfaction and increased drug risk. Therefore, it was necessary to carry out a diagnosis process through systematic methodology to identify the causes.
- Step 2: HFMEA members included a senior professional consultant, seven professional pharmacists, and the research team leader.
- Step 3: In this study, emergency treatment provided by the teaching hospital was considered as the basis for process analysis. There were six stages in total: prescription through a computer, printing of drug bags, prescription, verification, dispensing of drugs, and guidance in drug medication. This process was conducted by a team that relied on professional and historical data, and it focused on the prescription, verification, and dispensing of drugs and guidance in medication.
- Step 4: Information on failure mode, cause, and influence were filled in a worksheet after brainstorming among HFMEA members.
- Step 5: Finally, suggestions were proposed for the prevention of key failure cause. Subsequently, the case hospital will aim to improve drug safety based on the suggestions.

Following preliminary analysis of the information obtained after one month of discussion, there were nine failure modes, including overlook of drug name, error in drug name, error in dosage, error in dosage form, error in marking, quantity error, technical error, incorrect drug dispensing to the wrong patient, and prescription of expired drugs. Furthermore, there were 10 failure causes; they were categorized as personnel (three reading and five verification, patient identification, and accuracy in prescription interpretation), equipment (cleaning and malfunction), drugs (drug mixture, similar appearance of drugs, and placement of drugs), and environment (space planning of the office, the dynamic line for prescription). Table 1 shows the associated matrix between failure causes and failure modes.

Table 1. The associated matrix between failure causes and failure modes

Failure causes		Failure modes	Overlook of drug name	Error in drug name	Error in dosage	Error in dosage form	Error in marking	Quantity error	Technical error	Incorrect drug dispensing to the wrong patient	Prescription of expired drugs
Personnel	1.	Three reading and five verification	5	5	5	5	0	5	3	0	3
	2.	Patient identification	0	0	0	0	5	0	0	5	0
	3.	Accuracy in prescription interpretation	0	5	5	5	0	5	5	0	0
Equipment	4.	Cleaning	0	0	0	0	0	0	3	0	0
	5.	Malfunction	3	3	0	0	0	3	0	0	1
Drugs	6.	Drug mixture	0	5	0	0	0	3	0	0	0
	7.	Similar appearance of drugs	0	5	5	5	5	0	3	0	3
	8.	Placement of drugs	0	5	5	5	0	0	3	0	0
Environment	9.	Space planning of the office	1	1	1	1	1	1	1	1	3
	10.	The dynamic line for prescription	5	3	1	1	5	5	0	0	1

According to historical data, Table 2 presents the results of the associated matrix between failure modes and drug grades. The most common errors involved prescription, controlled, over-the-counter, and high-alert drugs. The associated matrix between failure modes and drug grades was obtained by multiplying the two matrices.

Table 2. The associated matrix between failure modes and drug grades

Failure modes	Drug grades	Prescription drug	Controlled drug	Over-the-counter drug	High-alert drug
1.	Overlook of drug name	3	0	1	5
2.	Drug name error	5	5	3	5
3.	Error in dosage	3	5	0	0
4.	Error in dosage form	5	5	1	0
5.	Error in marking	3	0	0	0
6.	Quantity error	5	5	5	0
7.	Technical error	3	0	0	0
8.	Incorrect drug dispensing to the wrong patient	3	0	0	0
9.	Prescription of expired drugs	3	0	0	0

After the HFMEA team discussed and determined the degree of importance of each failure cause (w_i), the sequence for preventing key failure causes was obtained by ranking the calculated risk values. Table 3 shows the key failure causes according to risk values, including three reading and five verification, accuracy of prescription interpretation, similar appearance of drugs, placement of drugs, drug mixture, and the dynamic line for prescription.

Table 3. The associated matrix between failure causes and drug grades

Failure causes \ Drug grades	Prescription drug	Controlled drug	Over-the-counter drug	High-alert drug	w_i	S_i	Ranking
1. Three reading and five verification	123	100	50	50	4	1292	1
2. Patient identification	30	0	0	0	4	120	8
3. Accuracy in prescription interpretation	105	100	45	45	4	1180	2
4. Cleaning	9	0	0	0	2	18	10
5. Malfunction	42	30	27	30	1	129	7
6. Drug mixture	40	40	30	25	4	540	5
7. Similar appearance of drugs	98	75	20	25	4	872	3
8. Placement of drugs	74	75	20	25	3	582	4
9. Space planning of the office	39	20	10	10	1	79	9
10. The dynamic line for prescription	81	50	40	40	2	422	6

4. Discussion and Conclusions

In Taiwan, human resources restrict the emergency treatment process. Drug safety improvement has been an important topic that is related to medical quality in hospitals. In this study, a risk assessment was conducted on drug safety to establish an associated matrix. A modified HFMEA was proposed to determine the key risk factors of decreased drug safety. According to the results, in the Table 4 showed the suggestions for preventing key failure causes in Table 3, and demonstrated the feasibility of a risk assessment procedure to identify emergency flow problems and thus improve drug safety management in hospitals.

Table 4. The suggestions for preventing key failure causes

Failure causes	Suggestions
Three reading and five verification	1. Strengthen the number of staff trained, and perform regular checks 2. Actively promote the importance of patient drug safety, and increase staff awareness of patient safety 3. Design third reading of five pairs of standard processes to clarify steps
Accuracy in prescription interpretation	1. Improve individual judgment and training in the reading of prescriptions, and increase staff professional competence
Similar appearance of drugs	1. Strengthen control of high-risk drugs 2. Regularly check for errors, and add warning tags to drugs with the most errors. Highlight relevant units until the errors are decreased
Placement of drugs	1. Drug inventory should be regularly checked 2. Regularly check the placement of drugs
Drug mixture	1. The staff must re-confirm when drugs are placed in the machine box. 2. Strengthen checks of drug packaging
The dynamic line for prescription	1. Re-plan the movement route 2. Train staff to perform tasks by planning the dynamic line

In comparing the results of modified HFMEA and traditional HFMEA, the biggest difference lies in hazard risk analysis. In the original HFMEA, severity and incidence rate are considered as the evaluation criteria, and most evaluations are scored based on the experience of an expert [11,12,13,14]. Thus, the results are subjective. In this study, actual data and expert knowledge were combined, and risk assessment was conducted in a quantitative and qualitative manner. The failure causes determined in this study included the results of traditional HFMEA. Space planning and dynamic line for drug prescription were environmental failure causes and not covered by the original HFMEA.

In the three months after applying the suggested improvement strategies, the error rate was significantly decreased in a teaching hospital in Taiwan. Therefore, these results demonstrated the benefit of the derived assessment system for drug safety.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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