

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

Abstract: It is important to reduce errors in the quality of medical services and certification requirements. Emergency care is the department with the most complaints of poor medicinal quality from patients. The purpose of this paper was to develop risk assessment mechanisms in the emergency process to ensure drug quality for patients. The associated matrix technique was proposed to improve the evaluation criteria of traditional HFMEA. We used a medical center in Taiwan as an example to explain and validate the proposed process. The analysis shows that most drug usage errors originate from prescription drugs and controlled substances. These research results provide a risk assessment procedure to identify emergency flow problems, improving drug safety for hospital management.

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

1. Introduction

Some uncontrollable variations causing the current medical service flow was limited. Therefore, devising measures to effectively control variations for minimal risk is important for quality medical management. The medical quality expected by patients includes the determination of the status of an illness by doctors on the basis of professional competence, accurate prescriptions, accurate verification and dispensing of drugs. Medication error is a serious concern in drug therapy. According to the Joint Commission on Accreditation of Healthcare Organizations (TJC) statistics of 2012, medication error ranks 9th among ten major medical sentinel events [1]. Medication error ranks first among abnormal medical events, with an average incidence of approximately 30% according to Taiwan Patient Safety Reporting System for 2012Q1–2013Q3 [2]. Medication error can result in incorrect treatment and patient distress if handled inappropriately. However, it is preventable.

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

Hoff *et al.* pointed out that emergency, operating and intensive care units are where adverse medical events are most likely to occur [8], given the practical nature and special environments. Emergency wards in Taiwan are characterized by ‘four mores’—more pressure, more patients, more public relations and more arguments and ‘three less’—fewer sickbeds, less human resources and less salary. Every year, an average of over 6,000,000 patients are admitted to and discharged from emergency wards, resulting in full occupancy in 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 evaluate the demand for human resources by 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 risk inpatients. When the doctor writes an incorrect

prescription, the senior pharmacist misinterprets and dispenses an incorrect drug, causing considerable harm. Therefore, appropriately prescribed and dispensed medication in emergency departments should be given considerable attention.

Healthcare Failure Mode and Effect Analysis (HFMEA) is the most popular method of improving medical care flow. HFMEA effectively discovers high-risk factors and helps the hospital improve medical issues. Linkinet *et al.* performed risk assessments in surgical units and five major processes of disinfection and found that HFMEA was useful for increasing the hospital staff's awareness of problems that were not emphasized[10]. Van Tilburg *et al.* conducted HFMEA high-risk harm analysis for the process of chemical medication in the oncology wards of pediatric departments[11]. Ouellette-Piazzoet *et al.* identified risks using HFMEA to evaluate the risk of infections concerning the regimen for intravenous antibiotic administration and decreased the occurrence of medical accidents[12]. Gilchrist *et al.* discovered six main flows, 67 sub-processes and 217 failure modes and developed practical models for other medical service units as a reference[13]. Habrakenet *et al.* analyzed 13 medical processes with HFMEA and successfully applied the processes in the Holland health care system. However, they found HFMEA significantly time-consuming[14].

Many successful cases have shown HFMEA identifies risk factors for medical process and provides preventive measures to decrease those risks. These few studies have addressed the issues regarding emergency pharmacies in hospitals. Under the National Health Insurance system, emergency treatment is unique in Taiwan. Therefore, this study proposed the modified HFMEA to develop a risk assessment procedure for safe patient medication in the process of emergency pharmacies in Taiwan. Real cases were used to explain and explore potential risks in the process of emergency pharmacies and to devise specific improvement strategies to achieve the goals of medicinal quality.

2. Methods

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

- Step 1: To define the scope of the theme

Usually, processes with a high risk are selected for improvement. The criterion for selecting medical care processes with a high risk includes the following: First, selection should be made according to the safety data of the existing patients in the medical institute or preference industry data; Second, selection should be made by factors such as high complexity, high variation, non-standardisation, operation with close interdependence, tight/relaxed intervals among operations and strong dependence on the human judgment.

- Step 2: To establish teams

An HFMEA team must include trans department personnel. It is necessary to clarify the goals and necessary 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 the HFMEA analysis and put forward and execute suggestions for improvement.

- Step 3: To draw a flow diagram

For the existing operations, draw a flow diagram according to the actual steps of the procedure. For operations under planning, draw according to the present 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 drugs of different grades is different, the core of risk analysis is to master the influence of the causes of failure of drugs of different grades. This study integrates failure modes, effect analysis and grade of drugs to analyze hazard risks. The flow diagram in step 3 is discussed by teams to complete the analysis of failure mode and failure causes. The personnel, equipment, drugs

and environment can be used to describe the failure causes. If we assume there are i -failure causes, $A_1, A_2, A_3, \dots, A_i$ and j -failure modes, $B_1, B_2, B_3, \dots, B_j$ 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.

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

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

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

The associated matrix R between failure causes and grade of drugs can be obtained by multiplying the above P and Q matrixes, with r_{ik} indicating the relevance value between the i -th failure cause and k -th grade of drug.

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

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 the sequence of preventing proximate failure causes.

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

- Step 5: To determine actions and measure the outcomes

According to the hazard risk index obtained through analysis, classify the actions used to prevent failure causes into elimination, control, and acceptance. Increasing devices or personnel or resetting the system without causing any issue related to failure modes realizes elimination. Control is released from staff training, equipment adjustment or increase in the control mechanism with the failure modes within the allowable range of acceptance. Acceptance is realized when problems can't be removed or controlled by the former two ways. Finally, put forward corresponding action plans for

improvement, determine the method or index of measuring the assessment and allow senior directors approve the preventive measures. During the improvement, it is necessary to record actual errors accurately to determine if the prevention targets are achieved.

3. Analysis and Results

Consider an example of the emergency treatment process in a teaching hospital in Taiwan for presenting the risk assessment of medication safety using the modified HFMEA. Regardless of day shift or night shift, only two pharmacists in the emergency wards handle drug dispensing and verification, with one filling the drug prescription and the other dispensing and verifying.

In this paper, the window of emergency pharmacies is taken as the demarcation point of error definition. The error found at the emergency pharmacies is named 'dispensing near-miss,' while that found at the patients' end is named 'dispensing error.' According to the 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 the outgoing drugs is eventually higher. The most common error made in emergency pharmacies at this stage is incorrect drug name (56.25%), followed by incorrect dosage (17.5%) and quantity error (16.25%). Next, we discuss the analysis process of putting forward the details of methods.

- Step 1 : The issue has occurred 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 is necessary to carry out a process diagnosis through the systematic methodology to identify the causes.
- Step 2 : HFMEA members include a senior professional consultant, seven professional pharmacists and the research team leader.
- Step 3 : In this study, emergency treatment provided by the teaching hospital is considered the basis for process analysis. There are six stages in total: prescription through a computer; printing of drug bags; prescription; verification; dispensing of drugs; and guidance in drug medication. This process is conducted by a team that relies on professional and historical data, and it focuses on prescription, verification and dispensing of drugs and guidance in medication.
- Step 4 : Fill the failure mode, cause and influence into the worksheet after brainstorming among HFMEA members.
- Step 5 : Finally, proposed the suggestions for the prevention of key failure cause. The table 4 shows the first six key failure causes from the table 3. Next, the case hospital will base on the suggestions to improve drug safety.

According to the preliminary analysis of information obtained after one month discussion, there were nine failure modes, including overlooking the 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 categorised as personnel (three reading and five verification, patient identification and accuracy in prescription interpretation), equipment (cleaning and malfunction), drugs (drug mixture, the similar appearance of drugs and placement of drugs) and environment (space planning of the office, the dynamic line for a prescription). Table 1 shows the associated matrix between failure causes and failure modes.

172

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

Failure causes \ Failure mode		overlooking 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

173

174

175

176

177

178

179

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

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

Failure mode		Drug grades			
		prescription drug	controlled drug	over-the-counter drug	high-alert drug
1.	overlooking 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

180

181

182

183

184

185

186

187

188

189

190

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

191

Table 3. The associated matrix between failure causes and 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

192

193

Table 4. The suggestions for major failure

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

194

4. Discussion and Conclusions

195

196

197

198

199

200

201

202

203

204

In Taiwan, human resources restrict emergency treatment process. The improvement of medication safety has been an important topic related to medical quality in the hospital. In this study, a risk assessment was conducted on medication safety to establish an associated matrix. A modified HFMEA was proposed to determine the key risk factors for decreased medication safety.

Incomparing the results of modified HFMEA and traditional HFMEA, the biggest difference lies in hazard risk analysis. In the original HFMEA, the severity and incidence rate are considered the evaluation criteria and most evaluations scored by the experience of the expert. Therefore, the results are subjective. In this study, actual data and knowledge of experts are combined, and risk assessment conducted in a quantitative and qualitative manner. Failure causes determined in this study included the results of traditional HFMEA. Space planning and dynamic line for drug prescription belong to

environmental failure causes and are not covered by the original HFMEA.
In the three months after applying the suggested remedies, the error rate decreased significantly.
Therefore, these results show the derived assessment system for medication safety has a specific benefit.

References

1. The Joint Commission on Accreditation of Healthcare Organizations. National Patient Safety Goal, **2012**.
2. Gau CS, Shih CI, Liao HH, Yang HC, Wung C. Analysis of Medication Events in Taiwan Patient-Safety Reporting System. *Formosan Journal of Medicine*. **2007**, 11(5), 546-555.
3. Ferner RE and Aronson JK. Medication errors, worse than a crime. *Lancet*. **2000**, 355, 947-948.
4. Costa LA, Valli C, Alvarenga AP. Medication dispensing errors at a public pediatric hospital. *Rev Latino-am Enfermagem*. **2008**, 16(5), 812-817.
5. Taxis K, Barber N. Ethnographic study of incidence and severity of intravenous drug errors. *BMJ*. **2003**, 326(7391), 684.
6. Bower AC. Dispensing error rates in hospital pharmacy. *Pharm J*. **1990**, 244, R22-3.
7. Spencer MG, Smith AP. A multicentre study of dispensing errors in British hospitals. *Int J Pharm Pract*. **1993**, 2, 142-6.
8. Hoff T, Jameson L, Hannan E, Flink E. A review of the literature examining linkages between organizational factors, medical errors, and patient safety. *Med Care Res Rev*. **2004**, 61(1), 3-37.
9. Pan HN. Integration HFMEA and Relation Matrix for Patients Drug Safety of Risk Assessment. Ming Chi University of technology. Unpublished master's thesis. **2010**.
10. Linkin DR, Sausman C, Santos L, Lyons C, Fox C, Aumiller L, Esterhai J, Pittman B, and Lautenbach E. Applicability of healthcare failure mode and effects analysis to healthcare epidemiology: evaluation of the sterilization and use of surgical instruments. *Clinical Infectious Diseases*. **2005**, 41(7), 1014-9.
11. Van Tilburg CM, Leistikow IP, Rademaker CMA, Bierings MB, and Van Dijk ATH. Health care failure mode and effect analysis: a useful proactive risk analysis in a pediatric oncology ward. *QualSaf Health Care*. **2006**, 15(1), 58-63.
12. Ouellette-Piazza K, Asfaw B, and Cowen J. CT healthcare failure mode effect analysis (HFMEA): the misadministration of IV contrast in outpatients. *Radiol Manage*. **2007**, 29(1), 36-44.
13. Gilchrist M, Franklin BD and Patel JP. An outpatient parenteral antibiotic therapy (OPAT) map to identify risks associated with an OPAT service. *J Antimicrob Chemother*. **2008**, 62(1), 177-183.
14. Habraken MMP, Van Der Schaaf TW, Leistikow IP and Reijnders-Thijssen PMJ. Prospective risk analysis of health care processes: A systematic evaluation of the use of HFMEA™ in Dutch health care. *Ergonomics*. **2009**, 52(7), 809-819.