

Original Paper

# Risk Assessment of Clinical Care in Emergency Departments by Health Failure Modes and Effects Analysis



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## ABSTRACT

**Introduction:** Medical errors are among significant health system problems. The best method to detect errors is to identify the root and systemic causes of errors.

**Objective:** This study aimed to investigate the failures of clinical care in emergency departments using the Healthcare Failure Modes and Effects Analysis (HFMEA).

**Materials and Methods:** This was an analytical and cross-sectional study. The required data were collected qualitatively and quantitatively using focus group discussions in emergency departments. The study population consisted of all emergency department nurses. Study samples were selected by purposive sampling technique. By the HFMEA method, Risk Priority Number (RPN) was calculated to reach failure modes and those with RPN >216 were identified as the most frequent and risky errors.

**Results:** A total number of 67 failure modes were identified for 26 clinical care processes. The errors with the highest RPN were “the lack of oxygenation during airway suctioning” and “the lack of airway suctioning during ventilator weaning process”; they related to the respiratory system care with RPN=336. The error with the lowest RPN was “the lack of signing verbal orders by two nurses”; related to the general practice with RPN=8.

**Conclusion:** Investigating the causes and effects of these errors, controlling, and suggesting measures indicate the high efficiency of the HFMEA method. It also suggested the preventability of these errors by increasing the knowledge and awareness of the training staff by providing training courses.

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## Highlights

- Errors in clinical care processes account for a significant percentage of complaints, injuries, and even deaths.
- The Healthcare Failure Modes and Effects Analysis (HFMEA) is valid for detecting human errors in clinical care processes.
- By the HFMEA method, we take advantage of the available resources for implementing corrective and preventive measures.

## Plain Language Summary

Errors in clinical care processes highly impact treatment-related problems, such as decreased patient safety, service quality complaints, physical injuries, and death. Accurate identification of clinical care processes and detection of failures and analysis of the effects of these failures and executing corrective measures can reduce the incidence of medical errors of service providers and their related issues. Given the importance of emergency services and the nature of clinical care processes, this study aimed to fully identify the processes, tasks, sub-tasks, and possible error modes in service delivery and their effects in the emergency department. In the risk assessment phase of detected errors, the three indices of occurrence, severity, and detection were scored by experts, and through focus group discussions, the errors with a risk priority number >216 were considered with risk priority. The highest risk priority scores in the respiratory system care category were related to the lack of suctioning and attention to oxygenation. Controlling the risks associated with clinical care in the emergency department plays a crucial role in reducing treatment costs, dissatisfaction, and complaints related to medical errors.

## Introduction

**P**reventing medical errors in the health sector is highly essential. As a result, the quality of health care services is considered as error-free delivery of health services, at the right time, by the right person and with the use of fewest resources. Increasing awareness of the number, causes, and consequences of medical errors indicates the need to improve knowledge about this problem and to provide practical and strategic solutions to its prevention [1]. The emergency department is among the most critical, sensitive, and risky wards of hospitals [2-4].

Clinical care and its associated adverse events are the major health problems and of international concern [5]. Approximately one in every four people admitted to the hospital experiences an adverse event; about half of which is preventable. Moreover, nearly one-third of the events harm the patient, causing adverse effects, varying from increased stay duration to death [6, 7]. Studies suggested that the human error in medical care, in addition to causing death and disability, can increase the healthcare sector costs [8]. It is estimated that almost 5-10% of healthcare costs are due to unsafe clinical services that can harm patients [9].

Among the official statistics of medical error rate among the medical staff, 42-53 related to complaints, 22-42 to deaths, 35% to adverse events, and 27% to physical injuries [10]. The best approach to prevent medical errors is to identify errors and their root and systematic causes [5].

Systematic thinking has been introduced in identifying and treating health sector errors; accordingly, applying various risk management techniques have been frequently used to improve patient safety in this sector [11]. There are various methods to assess risk. Healthcare Failure Modes and Effects Analysis (HFMEA) is the most common method in this regard [8]. It is a systematic tool to manage, execute, and document the activity of identification, evaluation, prevention, elimination, or control of the causes and effects of potential errors in a service system before a final product or service is delivered to the customer [12, 13].

Unlike many other risk assessment tools, this method does not require complicated statistical analysis [14]. The HFMEA technique, which is implemented with a preventive, team-based approach, increases employee's precision and focuses on functional defects and strives to eliminate them. The primary purpose of HFMEA is to identify and correct potential failures. It is

among the most accurate tools for evaluating and eventually managing risk [13]. Applying the HFMEA method in the health care system establishes systematic thinking for the safety of the patient care process [6].

There are two phases in HFMEA. The first phase relates to failure detection and its effects. The second phase analyzes critical points to determine the severity of each failure by ranking them. The method consists of 5 steps. In the first step, after selecting the process, activities are listed using focus group discussions and through meetings and individual interviews. In the second step, the potential failure modes of each listed activity are determined using focus group discussions as well as team members' brain storming.

Then, after agreeing and reaching a common conclusion by all members, it is recorded in the final worksheet and the potential failure mode column. The immediate and direct effect of failure on the patient's treatment process also recorded. In the third step, each identified failure mode is prioritized based on the Risk Priority Number (RPN). RPN results from multiplying three factors; occurrence, detection, and severity. Next, in the fourth step, the causes of the failure modes with a high RPN are identified.

In the fifth step, the proposed coping strategies for failure modes with high RPN in each selected process are presented. The advantages of this approach include the existence of multi-tasking teams, involving patients, and improving the understanding of current processes, ease of understanding, lower cost of implementation, and ability to run it by necessity [5, 13].

Using HFMEA is effective in all sectors of the healthcare system. Furthermore, studies have revealed that HFMEA is useful for detecting errors and improving patient safety [15-18]. Petrillo et al. concluded that implementing HFMEA can significantly reduce errors. With the precautionary approach, HFMEA can reduce costs, help the hospital deliver quality services, and provide satisfaction [11, 19]. Shahrami et al. argued that HFMEA could be a reliable and efficient approach to reduce emergency department costs and increase its revenue [20].

The patient evaluation process, as the source of many risk management issues, is highly essential in the emergency department. Thus, this study aimed to use the HFMEA method to identify and prevent emergency department failures.

## Materials and Methods

This analytical and cross-sectional study was conducted in the emergency department of a hospital in Rasht City, Iran, in 2015 (May-June). The study population consisted of all nursing staff of the emergency department. Qualitative data were collected using the Focus Group Discussion (FGD). Purposive sampling technique was used for selecting the FGD members. The average required the number of participants for FGD is 4-12 people.

Therefore, in this study, the FGD consisted of nine members; one was in charge of education and eight were the nurses working at the emergency department. The studied nurses were selected by the matron and ward supervisors based on their work experience. We aimed to familiarize the FGD members with applying the human error risk assessment method and its scoring. Moreover, we familiarized them with the teamwork principles as a feature of the HFMEA method. Therefore, a retraining program was implemented by the permission of the Continuing Education Secretariat and in collaboration with university faculty members.

To collect the required qualitative data, all clinical care processes of the emergency department were identified with the presence of the researcher. Then, using Hierarchy Technique Analysis (HTA), the tasks and sub-tasks of nurses in providing emergency clinical care services were analyzed. The main processes of the emergency department were listed using a literature review, interviewing with nurses, direct observation, and checking patient records. The processes were ranked by the FGD members, given the severity of the impact of errors on patients and the need to resolve their problems on a 5-point Borg scale from 0 to 10. Score 10 was assigned to a process with the highest priority for error detection. Thus, all processes with scores >9 were selected for the study. Next, potential hazards and human errors were identified by FGD members through group discussion and brain storming.

Additionally, among all identified hazards, hazardous processes with potential harm to the patient were identified and entered into the standard HFMEA worksheet. Consequently, the research was conducted in 5 steps. In the first step, after the process selection, related activities were prepared using the work book and group discussion by the FGD members. In the second step, the potential errors of each listed activity were determined and recorded in the final worksheet. The immediate and direct effect of the error on the patient's treatment process was also recorded.

In the third step, to obtain quantitative data, each error was prioritized based on RPN, obtained for each error mode by multiplying occurrence, detection, and severity indices. Based on the error severity index, team members assigned scores 10 and one to processes with the most severity, and without an effect, respectively. According to the error occurrence index, scores 10 and one were assigned to errors that certainly occur and highly unlikely to occur during the clinical process, respectively. Based on the error detection index, scores 1 and 10 were assigned to detectable and undetectable errors, respectively.

Thus, the team members rated the errors identified by group discussion and brain storming using a table containing three indices. In this regard, for these severity index of  $\geq 6$  (very severe, but compensable), occurrence index of  $\geq 6$  (1 in 80 cases), and detection index of  $\geq 6$  (low chance of error detection), the errors with  $RPN \geq 216$  were considered as high priority risks (at 65% confidence level).

In the fourth step, the probable causes of error modes with high RPN were identified using Root Cause Analysis (RCA). It is a structured survey to identify the real causes of a problem and suggests solutions to eliminate them. Finally, in the fifth step, the proposed coping strategies for high RPN error modes in each selected process were presented.

## Results

The FGD members had a Mean  $\pm$  SD age of  $30 \pm 6.78$  years and a Bachelor's degree. They reported mean work experience of  $12.96 \pm 5.80$  years. Their average work experience in the emergency department was 7 years; 6 of them had experience of  $>10$  years. In the first stage, 67 main processes of clinical care in the emergency department were identified in 10 general categories. Of these, 26 processes in 7 categories were selected based on a Borg scale.

A total number of 66 potential error modes were listed and recorded in the worksheet. Of these, 5 were related to general measures; 6 to infection control and wound care; 15 to medication orders; 3 to laboratory tests; 4 to nervous system care; 15 to cardiovascular system care; and 19 to respiratory system care (Table 1). After obtaining the RPN number of each error mode, a total number of 13 errors with  $RPN \geq 216$  were identified as high-risk and unacceptable (Table 2).

## Discussion

The present study evaluated emergency department clinical care errors by the HFMEA method. The error with the highest priority in the "general practice" cat-

egory in our study was the failure to record clinical practice as an examination and practical error. According to Mazlom et al. a physician's failure to provide verbal instructions was among the most common errors [5]. Attar Jannesar Nobari et al. categorized delays in initiating the patient care process and failure to follow physician's orders, as high priority errors [6].

Delayed care by the nurse, forgetting to execute orders or executing erroneous instructions, physician's refusal to provide orders via phone, failing to execute the order, and writing wrong instructions in the patients' medical records were the results of providing poor quality clinical services to patients. The emergency department is among the crowded hospital wards. It is somewhat uncontrollable and increases the workload and fatigue of nurses, resulting in increased odds of errors.

In the "infection control and wound care" category, the most common errors were non-compliance with the aseptic technique during wound dressing and insufficient attention to the wound site (considered as practical errors). According to Attar Jannesar Nobari et al. poor dressing quality and wound suture were categorized as functional errors but not considered as high priority errors [6]. This may be due to differences in the study settings, considering the type of admitted patients.

In our study, due to the high admission rate of traumatic patients requiring wound care, proper clinical practice in the area of infection control and wound care was critical. Amini et al. suggested that most nurses were not adequately aware of nosocomial infections [21]. Failure to properly perform dressing can lead to complications, like an infection. Consequently, it might cause increased treatment costs and a lack of proper treatment provided for patients.

In the category of "executing medication orders" the most frequent errors were the lack of attention to the blood transfusion speed and drug expiration date, the use of inappropriate drug dosage for the patient, and failure to observe intravenous line replacement time. Dehnavieh et al. investigated blood transfusion errors and reported that most errors occurred in the early stages of the transfusion [22].

Blood transfusion speed must be considered when transfusing blood. Transfusion of blood products should take place within a specified time, and prolonged transfusion could cause complications for the patient. Similar to our study, Kermani et al. reported the lack of attention to the drug expiration date and the use of inap-

**Table 1.** Processes, failure modes, and their RPN

Clinical Care	Process	Failure Mode	RPN
General practice	Medication control	Failure to record clinical practice	324
		Failure to follow medication	54
	Preparation for Para clinical procedures	Physician's failure to write the prescription	180
		Not training the patient properly	24
		Failure to examine the patient for necessary preparations	200
Infection control and wound care	Changing wound dressing	Non-compliance with the aseptic technique during wound dressing	320
		Insufficient attention to the wound site	320
		Failure to properly wash the wound	180
	Amputation care	Improper wound dressing	126
		Not paying attention to the stump wound	180
Executing medication orders	Executing oral medications	Failure to apply a sterile dressing over the stump wound	180
		Failure to correctly identify the patient	108
		Giving the wrong drug	150
	Medication by gavage	Use of inappropriate drug dosage form for the patient	240
		Not paying attention to the drug expiration date	243
		Inappropriate patient positioning	160
	Intravenous line care	Failure to wash the nasogastric tube	96
		Failure to observe intravenous line replacement time	224
		Injection of wrong blood type (blood group mismatch)	40
	Blood transfusion	Not paying attention to the blood transfusion speed	256
		The lack of monitoring of vital signs	210
		Injecting inappropriate blood bag	108
		Injection in the wrong place	105
		Failure to perform the injection correctly	126
		Failure to disinfect injection site	192
Laboratory sampling and sending samples to the laboratory	Heparin subcutaneous injection	Wrong dose injection of the drug	120
		Intravenous blood sampling	Failure to correctly perform intravenous sampling
	Arterial blood sampling to analyze blood gases from a closed system	Inadequate sampling	98
		Blood glucose test	Error in measuring blood glucose with a glucometer
	Closing of the cervical collar	(E) Nervous system care	
		Improper closing	80
	Control of consciousness level	Not paying attention to the patients' airway	80
		The lack of precise control	90
Neurological and vascular status control	Failure to control	72	

Clinical Care	Process	Failure Mode	RPN	
Cardiovascular system care	Pulse control	Incorrect pulse counting	105	
		Not paying attention to the volume and rhythm of the pulse	105	
	Blood pressure control	Inaccurate measurement of blood pressure	200	
		Blood pressure device not working properly	144	
	Help with central venous catheter insertion	Poor dressing of central venous catheter site	180	
		Incorrect ECG lead connection	160	
	Right ventricular Electrocardiography (ECG)	Not setting a ECG machine	84	
		The lack of control of consciousness and heart rhythm	36	
	Cardiopulmonary Resuscitation (CPR)		The lack of control of vital signs	36
			Inappropriate CPR	36
			Improper positioning during CPR	28
			Improper connection of defibrillator leads	100
			Delay in CPR	100
			Failure to discharge defibrillator properly during CPR	50
			Defibrillator malfunctioning during CPR	50
Respiratory system care	Respiration control	Not paying attention to the number, depth, and breathing sounds	63	
		Failure to comply with the sterile technique in the placement of a chest tube	210	
	Chest tube care	Inappropriate dressing of chest tube	210	
		Failure to control vital signs during placement of chest tube	240	
		The lack of attention to the function of the drainage system	240	
	Oxygen therapy	Poor oxygen therapy	105	
		Improper suction function	112	
	Endotracheal suctioning	The lack of control of vital signs during suctioning	160	
		The lack of attention to oxygenation during suctioning	336	
		Airway suctioning for a long time	112	
	Weaning of adult patients from the ventilator		The lack of control of vital signs and arterial blood gas during the ventilator weaning process	108
			The lack of consciousness control during the ventilator weaning process	108
			The lack of airway suctioning during the ventilator weaning process	336
			Not paying attention to the signs of intolerance for ventilator weaning	160
			Failure to provide ventilation support during ventilator weaning	96
Ventilator alarm not working			320	
Ventilator malfunction			80	
Connecting the ventilator to the patient	Failure to match device setting with physician order setting	180		

**Table 2.** The highest potential errors of clinical care identified in the emergency department

No.	Failure Mode	Severity	Occurrence	Detection	RPN*
1	The lack of oxygenation during airway suctioning	7	6	8	336
2	The lack of airway suctioning during the ventilator weaning process	7	6	8	336
3	Failure to record clinical practice	9	9	4	324
4	Non-compliance with the aseptic technique during wound dressing	8	5	8	320
5	Ventilator alarm not working	8	8	5	320
6	Error in measuring blood glucose with a glucometer	9	5	7	315
7	Insufficient attention to the wound site	7	6	7	294
8	Not paying attention to the blood transfusion speed	8	8	4	256
9	Not paying attention to the drug expiration date	9	3	9	243
10	Failure to control vital signs during placement of chest tube	8	6	5	240
11	The lack of attention to the function of the drainage system of chest tube	8	6	5	240
12	Use of inappropriate drug dosage form for the patient	6	5	8	240
13	Failure to observe intravenous line replacement time	8	7	4	224

\* Risk Priority Number (RPN)

appropriate drug dosage form as the most critical medical errors [23]. Poor Aghaee et al. reported medication prescription with inappropriate speed, wrong dose prescription, adverse medication effects, and drug interactions, as identified low-risk errors [24].

The incidence of these clinical errors in the emergency department can be increased due to the high workload and overcrowding of patients. According to Farzi et al. reducing the workload of nurses can be useful in reducing the incidence of such errors [25]. Another error was a failure to observe intravenous line replacement time which can have some consequences, including phlebitis, not receiving a proper amount of serum and the lack of providing proper treatment for the patient. Adjusting the intravenous line replacement protocol in each department and having more control over it at the beginning of each work shift can be effective in reducing it.

In this study, factors, such as improper equipment or failure of medical devices and equipment, were the causes of errors, including the malfunction of the ventilator alarm and errors in measuring blood glucose level with a glucometer. Poor Aghaee et al. reported the use of non-calibrated devices, as medium risk errors [24]. Rezaee and Salehi reported the malfunction and misuse of equipment as the reasons for the damages caused by medical equipment; they can reduce patients' safety [26]. Therefore, it is vital to educate staff on how

to check the proper functioning of the devices before using them. Defects in equipment and incorrect use of them can impose substantial financial losses and irreparable injuries.

In the category of "respiratory system care", the most frequent errors were the lack of oxygenation during endotracheal suctioning, and lack of airway suctioning in weaning adult patients from the ventilator. Khalili et al. recognized oxygenation failures as high-priority errors [27]. Identifying such processes as high-risk in this study and other studies and its clinical consequences in patients are observed in the form of dyspnea, reduced arterial oxygen saturation and the lack of suction tolerance. Such matters indicate the importance of oxygenation during the patient suction process and the need for error reduction.

The lack of airway suctioning during ventilator weaning can have some consequences, including the aspiration of secretions, shortness of breath, and patient's intolerance during weaning. No study investigated such failure mode. Valencia et al. and Kesieme et al. found airway suctioning critical [28, 29]. Suctioning may reduce airway resistance. Therefore, attention to airway suctioning and its appropriateness can improve respiratory function and make the weaning process tolerable.

Regarding errors in respiratory system care, results reported that failure to control vital signs during the placement of a chest tube and the lack of attention to the function of the chest tube drainage system had high-risk priorities. One of the causes of this clinical error was the lack of awareness to understand the importance of drainage system care. Based on Kesieme et al. nurses' knowledge of the care of chest drain is poor and they require education in this area [29].

The incidence of this clinical error in the study department indicates inadequate patient care provision for drainage. This can be due to poor training or high workload and fatigue. Staff training is among the suggested strategies that can effectively reduce the incidence of such clinical errors.

In the present study, the most important reasons that influenced all clinical errors were lack of knowledge, high workload, and fatigue. Khalili et al. reported the causes of failure as the lack of knowledge, attention, motivation, and time [27]. Salavati et al. and Kaboodmehri et al. stated that considering the emergency nurses' working conditions, including the workload level and the number of treated patients, could be effective in preventing clinical errors [30, 31]. One of the suggested solutions to reduce clinical errors is to educate staff and raise their awareness about treatment principles and their proper implementation.

Identifying unacceptable clinical errors, investigating the causes and effects of these errors, as well as controlling and suggesting measures indicate the high efficiency of the HFMEA method. These factors also highlight the preventability of these errors by increasing the knowledge and awareness of staff through holding training courses. In this study, the leading causes of human error in clinical care processes were the high workload and fatigue of nurses. This has made access to nurses whose clinical care processes were studied extremely difficult; this is a significant limitation of our study.

It is recommended that the HFMEA method be applied to all critical wards in public and private hospitals. Moreover, it is suggested to use the results to reduce human errors which can save resources, reduce costs, reduce complaints, and increase patient safety.

Based on the results obtained through RCA, one of the causes of error was poor training. It is recommended that continuing education courses be planned and implemented. Training on the necessity of writing orders in the medical record and Kardex, minimizing verbal in-

structions in the department, emphasizing the presence of a physician in the patient's bedside, obtaining written instructions, and receiving the written instructions and supervisions by matron are other necessary suggestions to control the occurrence of human errors.

Other measures include the periodic expert control of device, nurse control of the device at the beginning of each work shift, providing sufficient workforce, reducing workloads, periodically controlling the expiry date of drugs, and the disposal of out dated drugs, assigning a person in charge of the medication at each shift, controlling the vein line at the beginning of each shift, and following the intravenous line replacement protocol in each department.

## Ethical Considerations

### Compliance with ethical guidelines

This research was approved by Ethics Committee of Guilan University of Medical Sciences (Code: IR.GUMSREC1394.289).

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### Authors contributions

Conceptualization, supervision: Abdolhosein Emami Sigaroudi, Majid Pourshaikhian; Support for the design of the study and data collection: Mahmood Heidari; Data collection, assembly, possession of raw data, drafting the final report: Leila Moradi.

### Conflict of interest

The authors declared no conflicts of interest.

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