



Evaluation of the Effect of Interventions on the Improvement of the Risk Management Process in Intensive Care Unit of Ziaee Hospital – Ardakan: Failure Mode Effects Analysis

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ABSTRACT

Background: Failure Mode Effects Analysis (FMEA) is an analytical method for risk assessment that seeks to identify and rank as far as possible the potential risks within the scope of risk assessment, as well as the causes and effects associated with it. Considering the classification of the Intensive Care Unit (ICU) as one of the high-risk wards, this ward of Ziaee Hospital- Ardakan is studied to identify, prioritize and evaluate errors, and present and implement proposed measures to reduce or eliminate possible errors.

Methods: This is a quasi-experimental study of interventional type. The present study is a quantitative, qualitative combination of inductive and applied method and evaluates and analyzes the states and effects of the error using FMEA method in the form of a before-after study. Studies of this research were carried out during the period of January 26 to December, 2016 on the processes of the intensive care unit of Ziaee Hospital in Ardakan. The information collection is based on FMEA standard worksheet and formation of FMEA team.

Results: Re-evaluate the risk priority number (RPN) after performing corrective measures showed that the priority score of all common errors was decreased in the ward. The results of this study indicated that out of 26 identified clinical errors, 10 first error modes were selected for further study. Selected error modes accounted for the highest error rate. This was related to the non-usage of routine disinfectants in hand washing with a score of 504, and the lowest score was related to the failure of the nurse to identify alarm type with a score of 240.

Conclusion: We can reduce as much as possible the severity of injuries by re-measuring the priority score and making effective control and corrective measures by identifying the errors and methods of reducing these errors in the intended ward or in any other ward in the organization.

Keywords: FMEA, Risk Assessment, Intensive Care Unit

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Introduction

Avoiding errors and the feeling of the need for security throughout history have been considered as intrinsic and essential element of human nature. Nowadays, all professions have turned to risk management in order to protect against the various hazards that surround them and also to preserve their nature in competitive conditions of the present era (1). Although there are different definitions of risk, the risk in general is theoretically the probability of deviating from reaching the desired target at a specific time and the risk of causing a potential deviation. The healthcare area is one of the most important areas in which risk management issues are of particular importance. Health risk management was initially considered as a means of controlling complaints, but gradually paying attention to the underlying clinical problems led risk management strategies to reduce the prevalence of injuries and improve the quality of treatment. The risk management enables the organization to anticipate events that are likely to produce adverse and harmful results in the future, as well as predict the severity and the procedure to control them (2). The purpose of risk management in the healthcare sector is to reduce the likelihood of adverse events occurring in patients and includes identifying undesirable events, analyzing the cause, estimating the likelihood of occurrence, and taking appropriate action to prevent these events. The fact is that the errors in the medical professions have been less studied compared to other occupations in our world and in our country. Various surveys around the world indicate that human error in these occupations has resulted in huge costs. Given the sensitivity and importance of the medical group's occupations, the incidence of a seemingly simple error can lead to the death of one or even some person (s). The nurse is often responsible for these errors; he is the last person in the patient care chain, while the cause of the pressure of the underlying factors remains unresolved. Different statistics on the incidence of medical errors have been published in various hospitals. According to estimates, in every ten people admitted to hospitals, one person experiences an unpleasant event, about half of

which can be prevented. In addition, about one-third of these events are harmful to the patient, which can be varied in several ways from raising the length of stay to death (3). The Failure Mode Effects Analysis (FMEA) is a systematic, structured, bottom-up and group-based approach that is used to define, identify, prevent, eliminate or control modes, causes and effects of potential errors in a service system, and manages the implementation and documentation of these activities before the final service reaches the customer. The most important achievement of this method is to identify vulnerable elements and critical areas of the system (4) which requires the prediction of errors and how to avoid them. This prediction is carried out by experts who have sufficient knowledge and experience about the design process or the service. That is why choosing the team and planning the FMEA and its full implementation is important (5).

FMEA consists of five main stages:

- 1- Selecting the process or care to be studied.
- 2- Working team formation
- 3- Collection and organization of information about processes or activities
- 4- Analysis of risks and proposed actions
- 5- Following proposed actions and reassessing risks

Since intensive care unit (ICU) are classified as high-risk wards in the hospital due to the critical conditions in all patients and the sensitivity of the patient assessment process (6) as the source of many risk management issues (7), this ward is used to identify and analyze errors and its strengths and improvements. Recent epidemiological studies have estimated that more than 1.3 million people suffer from unwanted injuries annually that occurred in intensive care units in the United States. Considering the importance of caring for critically-ill patients in the intensive care units and the high mortality rate of patients admitted to these wards, it is necessary to study the risk factors and causes of mortality in ICU patients. Therefore, this research was conducted with the aim of identifying, evaluating and providing appropriate measures for controlling, reducing and eliminating possible risks

of activities performed in ICU in Ziaee Hospital of Ardakan, Yazd.

Materials and Methods

The present study is a quasi-experimental study of interventional and applied type that was performed in the form of before-after study. This study was evaluated and analyzed in the form of a qualitative-quantitative method with the modes and effects of the errors using the FMEA methodology in the form of a before-after study. The present study was conducted from January 26 to December, 2016 on the processes of the intensive care unit of Ziaee Hospital in Ardakan. The first phase was conducted in the form of literature review through the study of library resources, magazines and articles and Internet searches in a systematic review using the English keywords of FMEA, Risk, Risk Management, ICU, etc. at the databases of Springer, BMJ journals Science direct, Pubmed, Emerald, and Persian keywords such as risk, risk management, ICU risks, and intensive care at Iranmedex, Irandoc, SID, Magiran, Civilica sites. This phase was performed only to obtain more information on FMEA, justification and education of others. In the second phase, following the completion of necessary investigations, the FMEA team (one head nurse, one hospital matron, one experienced nurse in the field of accreditation and improving the quality of work in the ICU and one nurse with a history of working in the patient safety field) was formed. Following the necessary training in this field, brain storm technique was used during a session with the members. Key activities were achieved in 5 sessions for 10 h. In the third phase, the scoring was carried out using RPN in order to finalize the error mode for the desired study. The RPN number for each of the error modes was obtained from the multiplication of the three factors of severity, probability of discovery and probability of occurrence, and calculated as follows:

$RPN = \text{severity} \times \text{probability of occurrence} \times \text{probability of discovery}$ (score ranged from 1 to 10 for every 3 items).

Severity Index: The severity of the immediate and direct impact of the error on the treatment process is identified in several aspects such as satisfaction, cost, injury, etc.

Probability of occurrence: The probability of occurrence indicates the frequency of occurrence of a cause or mechanism of potential risk. It identifies the occurrence of the event in the processes in question.

Probability of discovery of a risk: The probability of discovery is an assessment of the degree of the ability to identify a cause / mechanism of occurrence of a risk. In other words, the probability of discovery refers to the ability to detect the risk before it occurs (8). After analyzing the obtained information and calculating the RPN, the error modes that received the highest score were determined for review and continued implementation of the FMEA technique. In fact, the team should work on the error modes where their priority score is higher than the rest ($RPN \geq 100$ errors with 95% confidence level were selected as high priority errors). After identifying the potential error modes, in the fourth phase, the team members were asked to list potential errors or possible errors of any of the activities identified in "failure do", "incomplete doing", "doing with delay", and "doing wrong" frameworks. These errors are considered objectively with respect to the study setting and errors that cannot be practically eliminated. In the fifth phase, the causes of the occurrence of each of the errors were identified so that the team, by using tools such as brain storming and cause and effect chart (fish bone), could identify the causes that could have led to any of the error states by modeling ECM (Eindhoven Classification Model). This model places the root causes of errors into two main categories of latent errors (including technical and organizational errors) and obvious errors (including human errors and other errors). In the sixth phase, the FMEA team, using the brain storm approach, proposed measures that reduced the priority factor in the potential risk profile that includes three domains: reducing the probability



of occurrence of the error, reducing the severity of the effect and increasing the probability of identifying the error before occurrence. Finally, interventions were selected, which were feasible in accordance with the intended prioritization. In the seventh phase, preventive and corrective measures were then taken to reduce identified errors. The focus of the researcher and the ward's manager was to reduce the errors based on the principle of education, which was materialized through the holding of three training classes theoretically in the conference room of Ziaee Hospital, Ardakan and in the ICU ward. In the training classes, domestic and foreign professors were used in coordination with supervisors and education discussions were mainly focused on the identification of physiology and respiratory anatomy in order to reduce the possibility of high risk, including suction and use of the endotracheal tube. Then, in the last step, in the form of an after-study, we measured the effect of using the FMEA model on improving the risk management process in the intensive care unit in Ziaee hospital in Ardakan by re-measuring the RPN after a 10 month time interval for risky processes And the effectiveness of the measures and strategies used in these wards were assessed.

In addition, the declaration of Helsinki was considered for ethical issues.

Results

In total, information on the FMEA was collected by reviewing 18 related articles (6 foreign articles and 12 domestic articles). The aim of the literature review was to obtain higher level of familiarity regarding the FMEA method, the procedure with which the method was used and carried out in various studies, the errors detected in different processes in various studies, etc. The members of

the FMEA team include; head nurse, hospital matron, experienced nurse in the field of accreditation and improving the quality of work in the ICU and a nurse with a history of working in the patient safety field. Twenty seven potential error modes were selected by the members of the group for risk assessment using group agreement technique. These numbers of error modes were selected based on three factors of effect severity, identification capability and probability of occurrence. The results of this study showed that out of 26 identified clinical errors, 10 first error modes were selected for further study. Selected error states accounted for the highest error rate. This was related to the lack of use of routine disinfectants in hand washing with a score of 630, and the lowest score was related to a nurse's failure to identify alert type with a score of 240.

The team members proposed measures to control and eliminate any identified clinical errors that include measures related to enhancement of nursing skills, more precise shifting, measures to purchase equipment and consumables of higher quality required by the department etc. The proposed control measures are presented in Table 2.

In the final stage and after the implementation of the proposed measures in the previous stage, RPN was re-calculated for each of the 10 error states in order to re-measure the priority score for each of the error modes during the ten-month period (from January 26 to December 2016). In other words, the effect of using the FMEA model on improving the risk management process was assessed in the intensive care unit in Ziaee Hospital of Ardakan in the form of a before-after study and the effectiveness of the measures and strategies used in this ward was identified.

**Table 1.** Identification and assessment of potential risks and RPN measurements

Selected processes	Identification capability	Probability of occurrence	Effect severity	RPN
Incorrect Diagnosis of need for suction	5	7	2	70
Registration with Narcotic Delay for the Patient	3	2	4	24
Wrong medication (dose-time)	2	5	3	30
Lack of taking into account the patient's recovery condition	3	5	2	30
Early transfer of patient to ICU without taking into account his transfer condition	4	2	5	40
ICU nurse's failure to fully evaluate the patient	4	3	2	24
Mismatch between the device setting and setting designed based on the doctor's instructions	3	4	6	72
Early discharge	5	2	4	40
Failure to respond to alarm of the equipment attached to the patient due to lack of hearing the alarm sound	3	5	4	60
Wrong gavaging	9	7	6	378
Detachment (EVD) External head shunt	3	5	6	90
Aspiration of the patient during suction	5	9	7	315
Chest tube blockage	3	5	5	75
Tracheal bleeding during suction	6	8	7	336
Deep vein thrombosis (DVT)	3	4	5	60
Absence of ventilator alarms	4	2	6	48
Lower head of the bed during gavaging	5	8	9	360
Creation of bedsore	7	6	8	348
Patient falling on the ground from the bed	8	5	7	280
Lack of use of routine disinfectants in hand washing	7	10	9	630
Nurse's failure to identify the type of alarms	5	6	8	240
Failure to do the right hand washing procedure	2	6	6	72
The tracheal tube blockage	7	8	8	448
Removal of tracheal tube cuff	2	9	5	90
Wrong intubation	9	8	7	504



Table 2. Possible causes and appropriate interventions for the examined processes

Process	Possible causes	Intervention
Wrong intubation	Insufficient intubation skills of anesthesia personnel-Difficult intubation due to laryngeal position- Blood clotting - Pulmonary discharge of the patient during intubation - Performing a suction technique to remove pulmonary discharge that damage the tracheal tube.	Increasing the skills of anesthesia personnel by contacting a specialist to educate staff who have made the errors- Using skilled nurses in the intubation process (Shifting the presence of the personnel in a way that one well-trained staff attends in each shift)
Tracheal tube blockage	Stimulation of the pharynx and reflexes that cause vomiting.	Blood clotting - Pulmonary discharge of the patient during intubation - Performing a suction technique to remove pulmonary discharge that damage the tracheal tube
Aspiration of the patient during suction	Low staff experience during suction- Use of inadequate catheter during suction	Training staff on how to take into account the patient's condition (for example, patient suction after eating), Use of anesthetic drugs for vomiting stimulation reflexes
Tracheal bleeding during suction	Low staff skills in performing suctioning (performing suctioning technique in an un standardized way) - and their inaccuracy - the inappropriate size of the suction catheter	Training and justifying personnel in this case - Using a suitable catheter - Replacing current catheter with more suitable catheter like niltone - Reducing the frequency of suctioning - Providing personnel with the suction manual
Patient falling on the ground from the bed	Weakness - Reduced level of consciousness - Disturbed balance - Restlessness - Physical disability	Reporting patient fall from the bed - Fall assessments - Defining and implementing policies and procedures for preventing patient fall- Increase hospitalized safety - Assessing hazardous situations and creating safe situations - Training the fall reduction program to Personnel - Monitoring and recording all fall cases- Non-standard railings-
Creation of a bed sore	Improper nutrition - Non-control of urine and feces - Highly moist or dry skin - Blood flow disorder - Weak sense of touch- Elderly	Changing body posture -Use of low pressure equipment - Use of wavy mattresses- Movement - Instantly wash and dry the skin after each bladder discharge - High protein and vitamin D diet - Reduce caffeinated fluids - No smoking and alcohol - Using the recommended amount of fluids
Wrong gavaging	Insufficient education - Insufficient accuracy - Shortage of personnel and time	Teaching the correct way of making the gavaging- Supervising the gavaging process - Providing educational pamphlets to the staff
Lower head of the bed during gavaging	Insufficient training - Insufficient accuracy - Insufficient attention	Teaching the correct principles of training to the personnel - Supervising the proper gavaging process by the head nurse - Raising the patient's head to thirty degrees
Lack of use of routine disinfectants in hand washing Nurse's failure to identify the type of alarms	Lack of adequate training, personnel unfamiliarity with the infection control cases and overworked nurses Lack of sufficient training - Personnel unfamiliarity with the device	Providing sufficient training to personnel - Staff supervision - Holding training classes and personnel justification Providing sufficient training to personnel - Providing personnel with manual on how to use devices- Holding training classes

**Table 3.** Comparison of priority score before and after intervention

Process	Before Corrective Action	After Corrective Action
Tracheal tube blockage	448	388
Wrong intubation	504	414
Lack of use of routine disinfectants in hand washing	630	325
Lower head of the bed during gavaging	360	285
Wrong gavaging	378	286
Bedsore	348	293
Tracheal bleeding during suction	336	145
Patient falling on the ground from the bed	280	262
Nurse's failure to identify the type of alarms	240	195
Aspiration of the patient during suction	315	325

Discussion

The very important issue about risks is that risks that are always considered to be invisible or small are very threatening, because no control and preventive measures are taken against them and finally they lead to incidents one day in the future (4). Critical status of the intensive care unit because of certain circumstances of patients, the use of special equipment and the need for personnel with expertise in this ward have doubled the importance of adopting preventive approaches to prevent risks and to ensure patient safety and quality processes. This study was designed to identify errors, their root causes and provide suggestions to correct errors in the intensive care unit of Ziaee hospital in Ardakan. The method of analyzing potential modes of error and its effects is used to evaluate the implications and processes in healthcare services. ICU nursing care errors were identified using the FMEA technique. The potential effects, along with the causes and proposed measures were later determined by the team members, and one person was appointed to perform the recommended measures (training supervisor). The reason for using this preventive approach technique and the basis of the workgroup was to predict the potential modes of the error and its effects before the occurrence, in order to increase satisfaction and reduce the complaints of patients and their companions. Clinical errors accounted for the eighth causes of common death in the United States to the extent

that they cause roughly 100,000 deaths each year, thereby causing harm to many patients and increasing costs of treatment in many other countries (9). Over the period from 1995 to 2000, 1720 patients died unexpectedly in American hospitals, and 9584 died due to maltreatment of certified nurses. Furthermore, a high level of these errors will impose huge costs a great deal, with more than 20 million dollars being spent annually by American hospitals on medical errors (10). A significant portion of medical errors relates to the errors made by the nursing staff during the provision of care services, as such, these errors lead to deaths and injuries to thousands of people, as well as increasing annual treatment costs (11). According to previous reports, ICU nurses are more likely to be summoned as the accused and informed to the courts compared to other wards. Nurses are widely involved in the care of patients (12). On the other hand, it was reported in a research conducted at the University of Pennsylvania that 30% of the nurses under study made at least one error during the 28-day study (13). Overnight work, long shifts and their unpredictable activities increase the likelihood of fatigue. This situation reduces the physical function and physical capacity of nurses and increases the likelihood of work-related errors (14). In a research, Yarmohammadian et al.(15), stated that techniques such as FMEA that are applicable using a preventive approach based on teamwork, increase the accuracy of the staff and



their attention to the potential professional weaknesses and strengthen their determination to eliminate them. This research was aimed to implement a risk assessment process in the clinical departments, thus decisions on proposed measures were made in such a way that they enjoy feasibility feature. One of the differences observed between this study and other studies was its interventional nature, while other studies mainly aimed to identify errors and evaluate them and, then, measure the risk priority number and eventually provide preventive recommendations. In this study, the researcher attempts to calculate RPN after interventions. Therefore, during a session with team members, control recommendations and measures were introduced to reduce the errors identified in the ward by the team members. The highest score was related to nurses' incomplete hand disinfection. Hand hygiene is the first challenge of controlling hospital infections, thus identifying and reducing these errors can be critical for all hospitals. Nobahar et al. (16), performed a study in the field of hand hygiene titled "Comparative Evaluation of Bacterial Contamination in surgical, medical and neonatal intensive care units in Educational hospitals in Semnan Province". In this study, 161 cases were sampled and cultured for 18 months. The results revealed that the bacterial contamination was 77.3, 44 and 20.6% in the internal, surgical and neonatal ICU, respectively. Given that the contamination rate in the internal and surgery ICU was more than that of the neonatal ICU, the researchers concluded that an important component in reducing the contamination rate in the neonatal ICU is to establish a more active care system by the hospital infections control committee. The increased contamination rate in the present study was attributed to lack of adequate training, lack of familiarity of personnel with infection control cases and nurses' overwork. The results of this study were consistent with the results of a study carried out by Arab et al. (17), in one of Tehran non-governmental hospitals. Holding training

sessions and enhancing the sense of responsibility of ICU staff as one of the suggested solutions and its implementation increased their awareness and accuracy and eventually reduced the number of errors. In this regard, the encouragement and punishment technique was employed through timely payment coordinated by the person in charge of the financial department. We use guidelines, standards and management of specific moments and circumstances in the nursing profession. But even with these principles, it is difficult to decide what led to the error or what the component of the error is. Also, errors are hardly known due to their complexity. Comprehensive conceptualization of errors includes more complex factors, such as agent, environment, performance theories, diagnostic theories, and explanatory theories of human error. In his research, Asefzadeh et al. (18), identified ten types of error modes in the ICU ward, with the highest RPN score related to the absence of a DVT ventilation alarming device, lower bed heads when gavage feeding and creation of bedsores. On the contrary, the results of Apkon's et al. (19), study showed that the intravenous injection process can be redefined and patient safety and nursing staff working efficiency can be improved by analyzing the errors of the continuous drug injection process in the neonatal ICU. Nasiri et al. (20), stated in his research that the calculation power of nurses in relation to drugs with a unit other than milligram or micrograms is weak or moderate and they make great errors while calculating these drugs. It was suggested to provide in-service training for all ICU nurses in the field of medication computation and to pay more attention to this issue in nursing education. In the present study, the training classes were presented as proposed measures for potential error modes. For this purpose, training classes on the accreditation field, which were directed by domestic and foreign trainers, were held so as to familiarize nursing staff with various types of errors and reduce their occurrence rate.



Conclusion

According to the results of this study, continuous training courses in risk management and risk assessment, improvement of the correct planning of work shifts, the use of motivational methods for nurses, the use of experienced and interested personnel, training for personnel to quickly identify the tracheal tube blockage, increasing staff skills in using the tracheal tube replacement technique, changing tracheal tube replacement frequency from weekly basis to once in 3 days, examination of the tracheal tube blockage by an ICU specialist and head nurse from once within two to three days to a daily basis, training personnel, improving the skills of anesthesia personnel by contacting a specialist, the use of skilled nurses for the intubating purposes (shifting presence of the personnel in a way that one well-trained staff attends in each shift), staff training to take into account the patient's condition (for example, patient suction after eating), the use of anesthetic drugs, raising the staff's accuracy and enhancing their sense of responsibility by using encouragement and punishment technique, training the service force (to carry out patient health care), providing personnel with the suction manual and placing emphasis on patient mobility on the bed were among important measures that significantly helped in reducing and controlling clinical errors. One is not expected to be synchronized with the technology of the day by having academic information of several years ago and even decades ago. Providing the right conditions for ICU nurses to participate in such courses is one of the other requirements confirmed by the findings of this study. Providing conditions means that a positive safety culture is created in an organization. In a positive safety culture, all members of the team from management team to staff are committed to maintaining and upgrading safety. In conclusion, it should be mentioned that the medical profession is always associated with errors, but the medical community is obliged to minimize the incidence of errors and also, inaccuracy accounts for

incidence of significant portion of human errors and mistakes. Nursing is one of the professions in which errors and inaccuracy cause irreparable damage to the lives of individuals, the economy of the family and the country. Today, errors occur in healthcare system more than ever. Although there is a need for supportive and abundant efforts to reduce the incidence of healthcare service errors in order to provide patients with safer care of higher quality, it must be accepted that the error is a consequence of the general and unavoidable human condition. According to Harvard Medical Studies, more than 70% of the harmful events for the patient occurred due to the negligence of all health and care workers, of which more than 90% were preventable. Several factors are the cause of nursing errors. A system must be formed to examine the components and effective organizational elements and thereby identifying the grounds for work-related errors and trying to fix them as much as possible and eventually decreasing the error rate and providing the conditions for error-free work and improved patient security and safety. On the other hand, in this approach, it is emphasized that humans make errors which are expected and we do not blame the individual, and more often seek to identify the causes of the error. It is also emphasized that every error and defect gives us the opportunity to improve our performance by improving our knowledge of obstacles to provide safe care to patients. Overworked nurses with regular job shifts and relying on less trained nurses, as well as overstressed work environment and a shortage of qualified nurses and health professionals endanger patient's health by increasing the likelihood of nursing work errors. The best solution is to improve the knowledge of nursing staff and to employ more experienced nurses as managers or leaders in each ward.

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Conflict of interests

There are no conflict of interests to be declared

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Authors' Contributions

Eftekhari A and Mirzaei S designed research. Eftekhari A and Azimpour S conducted research. Eftekhari A, Mirzaei S and Azimpour S analyzed data. Taher A wrote the paper. Taher A had primary responsibility for final content. All authors read and approved the final manuscript.

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