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Original Article

Identification of priorities for medication safety in the neonatal intensive care unit via failure mode and effect analysis

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ABSTRACT

***Background*:** Prevention of medication errors in neonatal intensive care units (NICUs) is of paramount importance due to age-specific and physiological conditions of neonates. This study aimed to evaluate the risk of medication prescription and administration via failure mode and effects analysis (FMEA), which was carried out at the Research and Medical Teaching Center of Imam Reza Hospital in Mashhad, Iran.

***Methods*:** In this study, we adopted qualitative (action research) and quantitative (descriptive cross-sectional research) methods. The FMEA of the prescribed and administered medications in the NICU was performed using the nine-step FMEA by the National Center for Patient Safety. A diagram was plotted to determine the potential failure modes and effects of an error by the brainstorming team and to evaluate factors leading to errors. It was suggested to determine improvement strategies via interviews with team members and consider the requirements of the study units. Quantitative analysis of descriptive statistics (total points) was used to assess the content and qualitative data and reach expert consensus.

***Results*:** In this study, two processes, including prescription and use of drugs in the pediatric intensive care unit, were used. In this regard, seven activities, 29 sub-processes 29, and 68 failure modes were identified by FMEA technique, five of which were identified as high-risk modes using prioritization matrix. Moreover, a risk priority number (RPN) of 100 was considered critical for the possible errors in drug prescription by physicians and was proposed as a method to reduce or eliminate failure modes.

Conclusion: FMEA is an effective proactive risk-assessment tool, used to help multidisciplinary teams to understand the healthcare process and identify the possible errors. In addition, it helps prioritize remedial interventions for patients and enhance the safety of drug prescription in neonates.

Keywords: Failure mode and effect analysis, Medication errors, Neonatal intensive care unit

Introduction

Medical error is a common adverse effect of care in hospitals, accompanied with major potential risks for patients. Evaluation of medical errors can be used as an indicator of patient safety. According to the literature, almost one-third of medical complications have been due to medication errors (1).

Since patients use medications as prescribed by their physicians, the complex process of drug intake requires awareness, decision-making, and proper functioning of hospital staff (2, 3). There is a high rate of possible errors in each step of drug prescription and administration, which naturally has diverse effects on different age groups with respect to patient characteristics, type of drug, and route of drug intake (4, 5).

Administration of a drug dose to a patient requires 80 to 200 individual medical steps. These processes can be divided into five stages in the hospital, including prescription, transcription, preparation, distribution, and administration of drugs. While errors may occur in each of these processes, most of the errors are observed in the prescription stage (53%). Moreover, 17% of the errors can be identified in the later stages of preparation and transcription (6).

The specific physiological conditions of neonates have made them more vulnerable to the

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negative impacts of medication errors, compared to adult patients (7). However, the highest rate of errors was observed in prescription and administration stages in infants, respectively (11% and17%, respectively)(5).

Intensive care units (ICUs) are characterized by the urgent need for multiple interventions for high-risk patients in a complex environment (8). The frequency of drug prescription in these units is twice as high as patients outside the ICUs, and more drugs are administered through injection, based on the patient's weight (9, 10). Therefore, training and education are essential in reducing medication errors in NICUs.

According to previous studies, no accurate statistics are available on medication errors in Iran; however, this scarcity of evidence does not necessarily lead to medication errors. Medical records of plaintiffs sometimes implies high frequency (11, 12). Although coercive policies and recommendations are available to reduce the problems associated with medical errors, undoubtedly, errors by medical staff and organizations in the process of prescription and administration of analgesics are the most important of all (13).

Failure mode and effect analysis method (FMEA) is a systematic and prospective method, used to identify and understand the contributing factors involved in the failure of a process, system, or method (14). In addition, this method can be used as an active tool to improve patient safety and hospital efficiency (15-20). The crowning of the method determines the vulnerable and critical elements of a system (21).

Given the importance of medication errors in drug prescription and administration and lack of available studies on this phenomenon, we aimed to identify and analyze the potential errors in drug prescription and administration in the NICU of Imam Reza Teaching Hospital (the largest hospital in east of Iran) in Mashhad, Iran, using the systematic FMEA approach. Moreover, in this study, we suggested risk management methods to increase the safety and quality of services and improved patient trust.

Methods

This descriptive cross-sectional study was conducted to evaluate the process of drug prescription and administration during late September 2014-March 2015 in the NICU of Imam Reza Teaching Hospital of Mashhad, Iran. In this study, modes and effects of prescription errors were identified and analyzed using FMEA.

Imam Reza Hospital is a leading general hospital with 1,212 available beds. In addition to patient treatment in this hospital, educational programs are carried out for physicians and students of different medical majors. Moreover, this hospital has been the setting of choice for various studies. As the largest general teaching and patient referral center in the east of Iran, Imam Reza Hospital consists of Edalatian Emergency Center, polyclinics, and inpatient wards.

After reaching consensus at the end of each stage, collected data were entered into FMEA worksheet. In general, this study was conducted in nine steps, as proposed by the Center for Patient Safety (20) based on the FMEA method. Different stages of this method are as follows:

Step 1

Process selection*:* A process was chosen through the investigation of patient safety sheets and warnings issued by the Committee on Natural Disaster Reduction. Data were obtained from the hospital office for quality improvement. In addition, the viewpoints of risk management experts in this regard were recorded through interviews.

Step 2

Team formation: Six people were selected as team members, including two nurses (recommended by a head nurse), one physician, one FMEA expert (group leader), a group consultant in charge of risk management, and one person in charge of hospital quality improvement. The only inclusion criterion of this group was a minimum of two years of clinical experience in the ICU.

Step 3

Drafting process: Drug prescription and administration processes were drafted through observation and individual interviews. Accuracy of the overall plot in processes and sub-processes was verified and confirmed in a group discussion by the team members. Afterwards, the results were illustrated using the Visio software as a process flowchart.

Steps 4 and 5

Listing of error modes and potential effects of error: In this step, modes of error were identified according to medication prescription and administration processes using triangulation process (i.e., comprising a group discussion meeting, a brainstorming session, and analysis of documents and records). Furthermore, the effects of each error mode on the patient and treatment

process were assessed in the brainstorming sessions, and recorded in the FMEA worksheet after reaching the consensus of the group members. For a more detailed notion of the targeted design of interventions, the FMEA team categorized errors based on previous studies conducted on the classification of medication errors. The seven classes of categorized errors were as follows: 1) drug prescription; 2) transcription; 3) preparation; 4) distribution; 5) administration; 6) monitoring and 7) drug transcription records.

Step 6

Sources of error calculation: Factors affecting modes of error were identified using Fishbone's cause and effect diagram and the brainstorming method. Moreover, these factors were categorized based on (10) the classification of medication errors.

Step 7

Ongoing control of medication errors: In this step, measures were taken to reduce or eliminate medication errors for each mode via brainstorming sessions and using the recorded data in the FMEA worksheet**.**

Step 8

RPN assessment: According to the results of brainstorming sessions and Table 1, each failure mode was assigned a numeric score (range: 1-5) to quantify the following: a) severity of the damage caused by the failure mode; b) likelihood of the failure and c) detectability of the failure. RPN was deduced from these measures, which was in line with the classification suggested by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The obtained RPNs were classified through the prioritization of each error mode (Table 1), as follows: low-risk zone (green) (score range: 5-19), moderate-risk zone (yellow) (score range: 20-39), high-risk zone (orange) (score range: 40-59), very high-risk zone (red) (score range: 60-125).

Step 9

Recommendations for preventive and reformative measures: With regard to RPN, risk zones, and table of error mode priorities, measures needed for each mode of errors included monitoring in the green zone, reforms in the yellow zone, re-planning in the orange zone, and urgent actions in the red zone.

First, we determined error control strategies at this stage. The proposed strategies, such as preventive and reformative measures for each of the error mode factors, were presented based on the highest RPNs obtained for each medication error class.

All team members received full-time training on the FMEA methodology three days a week, which was supervised by a risk-assessment consultant for the proper execution of the process.

Results

In this study, the third step (drafting of the process flowchart), which followed drug prescription and administration in NICUs (as the processes of risk-assessment) and formation of the FMEA team, resulted in the identification of seven activities and 29 sub-processes in all the drug prescription and administration processes.

Table 1. Rating scales used to assign values to the occurrence (O), severity(S), and detection (D) Scores in the failure mode and effect analysis of the drug administration process

Occurrence(O)		Severity(S)		Detection(D)	
Score	Failure mode probability	Score	Description of injury	Score	Likelihood of detection
1	Remote :failure unlikely to occur(happening 1 in 10000 episodes observed)	1	NO injury or patient monitoring alone	1	Very high:detected 9/10 times
2	Low:relatively rare failure (happening in 1 in 1000 episodes observed)	2	Temporary injury needing additional intervention or treatment	2	High: detected 7/10 times
3	Moderate:occasional failure (happening in 200 episodes observed)	3	Temporary injury with longer hospital stay or increased level of care	3	Medium: detected 5/10 times
4	High:recurrent failure (happening in1 in 100 episodes observed)	4	Permanent effects on body functions	4	Low: detected 2/10 times
5	Very high:common failure(happening in 1 in 20 episodes observed)	5	Death or permanent loss major body functions	5	Remote: detected 0/10 times

Table 2. Analysis of failure modes with RPN≤40

Failure modes	Severity	Likelihood	Detection	RPN	Class
Errors in prescription method	5	4	3	60	Prescription
Incomplete comment in physician order	5	4	2	40	Prescription
Allergic reaction of the patient to the prescribed drug	5	2	4	40	Prescription
Prescription of drugs based on another patient's physician order	5	4	2	40	Prescription
Errors in use of drugs with similar packages	5	4	2	40	Preparation

Table 3. Strategies to prevent medication errors in failure modes with RPN≤40

Failure modes	Strategies
Errors in prescription method	Pharmacists' participation on physician rounds, approval of all prescription medications by pharmacists
Incomplete comment in physician order	Computerized physician order entry; Disapproval of the incomplete comment in prescription by pharmacists and organizations
Allergic reaction of the patient to the prescribed drug	Identification of all allergic reactions of a patient before admission or transfer to ward; Recording of adverse reactions to drugs in patient's medical history; Medical record management
Prescription of drugs based on another patient's physician order	Use of electronic bracelets; Disregarding bed numbers for patient identification; Change of drug regimen by the nurse's offer during administration and examination of prescription sheets
Errors in use of drugs with similar packages	Separation of similar drugs; Returning all unused drugs to storage; Labeling drugs by brand and generic name; Reduction of medical supplies

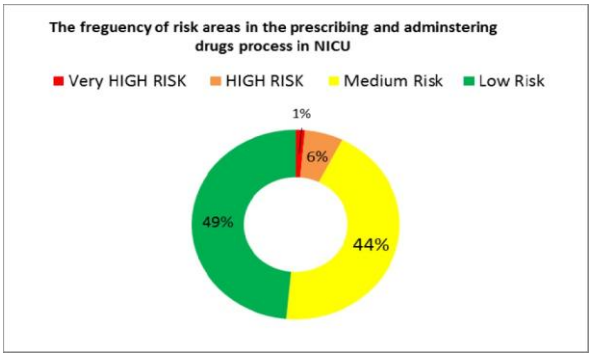

Figure 1: at 6 weeks and 3, 6, 9, and 18 months. (17).

In the next stage, we identified 68 error modes through brainstorming sessions. These modes were divided into seven classes of errors, including drug prescription, transcription, preparation, distribution, administration, monitoring, and drug transcription records.

We performed the FMEA in the fifth, sixth, seventh, and eighth steps of all the failure modes for continuous monitoring and RPN calculation.

According to the results of the present study, 48 failure modes were identified. However, no high-risk errors were observed in the prescription process of five failure modes (10.42%), as well as in 20 failure modes of the administration process (40≤RPN). On the other hand, 68% of failure modes in the prescription process and45% of failure modes identified in the administration process were classified as moderate-risk modes (20≤RPN≤40).

In this regard, the highest rate of RPN-related (RPN=60) errors were identified in the drug prescription process by physicians. Among these high-risk errors, 80% were observed in the drug prescription class, while20% were identified in the preparation class. Frequency error modes in terms of the need for preventive measures to reduce the errors in the process indicated that 53.48% of errors needed supervision, 12.44% required planning modification, 89.5% needed activity upgrade, and 47.1% required immediate action.

Evaluation of the error factors in the provision of risk-reduction strategies based on RPN indicated that the majority of these factors were caused by the negligence of medical staff (physicians, nurses, and pharmacists). Moreover, other error factors during patient care in the ICU were mainly associated with the performance of the healthcare organization and mechanism of errors caused by the combination of treatment-related activities.

In this regard, we conducted interviews with the team members to reduce or remove prescription errors in the PICU of Imam Reza Hospital in Mashhad, Iran, addressing the following issues:

1) Education of nurses and medical staff regarding risk factors
2) Medication reload (elimination of out-of-date drugs from medication lists)
3) Implementation of medical training courses
4) Request for a computer-based clinical decision system

5) Participation of pharmacists in medical rounds
6) Inadequate recruitment of healthcare staff
7) Standardized prescription and administration protocols
8) Use of skilled nursing staff in the ICU
9) Provision of a comfortable work environment
10) Provision of support and hospital information systems to upgrade hospital equipment

Discussion

In the present study, a mixed qualitative and quantitative method was used to evaluate the safety of drug prescription and administration in the PICU of Imam Reza Hospital (the largest hospital in the east of the country) in Mashhad, Iran using the FMEA technique.

In a study by Weingart, it was demonstrated that the FMEA technique has a high efficacy in the identification, evaluation, and prioritization of preventable cases of medication errors in terms of prescription and administration. Furthermore, the researchers proposed modifications for the FMEA technique in order to reduce the risk factors of medication error (22).

Techniques such as FMEA (a prospective and preventive approach) are based on teamwork and personnel participation to identify error modes, which raises the awareness of healthcare personnel regarding the weaknesses and risks of their profession. As a result, healthcare personnel are sufficiently motivated to eliminate medication errors (23).

In the present study, errors in medication prescription comprised of 17.6% of all the error modes, which involved three RPNs, including prescription errors (RPN=60), neglected allergic reactions to drugs, and medication prescription based on the physician order of another patient (RPN=40 for both). These results were in line with a study by Zeleka & Krahenbuhl (24, 25).

According to the results of the current study, errors in drug transcription comprised of 25% of all the error modes. Similarly, previous studies have shown that most of the errors in drug transcription are due to the difference between the prescribed and administered dose of medication (26-28).

The results of the present study demonstrated that errors in drug preparation accounted for 14.5% of all the error modes. In this regard, errors in the use of drugs with similar packages (RPN=75) were identified as high-risk error modes, which was in accordance with the results obtained by Laggo and Zeraatchi (29, 30).

Errors of distribution class comprised of 17.8% of all the modes of error. In particular, verification of the expiration date and dosage of purchased drugs with RPN=30 were considered as the highest RPNs identified in the medium-risk zone. This result was in congruence with the results obtained by Ava Mansoori et al. (31).

In the current study, errors of administration class accounted for 14.7% of all the modes of error. According to the findings of Aronson, high error rates were observed in the administration class (53%), which were mostly due to the negligence of system examination by nurses in relevant units (32).

Finally, errors associated with the monitoring class comprised of 5.9% of the error modes, while errors in record transcription accounted for 4.5% of all the modes of error. However, these errors were not observed in the high-risk zone (33).

Study limitations

In the present study, differences in the mode and frequency of medication errors and criteria of each of the three RPNs were based on the environment of the hospital. Therefore, the findings of this study could not be generalized to other hospitals or even similar wards. Moreover, similar to other qualitative approaches, we were not able to elaborate on the reduction of adverse events after the intervention.

On the other hand, team formation and FMEA implementation are time-consuming and costly processes. Given the pivotal role of team members in the development of patient safety, the success rate of FMEA implementation relies on the dedication and participation of these individuals. Therefore, more acceptable outcomes could be achieved by the active participation of first-line clinical personnel in decision-making about patient safety.

Conclusion

According to the results of this study, 68 potential modes of error in drug prescription and administration were identified using the FMEA method. These error modes were categorized into high-risk, moderate-risk, and low-risk zones, and their corrective intervention zone was recognized. Moreover, causes of errors were identified and corrective measures were determined in this regard.

It was concluded that use of the FMEA technique has beneficial effects on the healthcare system, which could enhance high-risk processes and eliminate concerns regarding a certain medical process or service.

In the current study, high potentials of FMEA were observed in the identification, evaluation, prioritization, and analysis of errors in drug prescription and administration processes in the NICU. However, it should be noted that emphasis on high RPNs in the application of FMEA in healthcare centers should not result in the negligence of error modes with low RPNs, which might be highly severe or less likely to be discovered by personnel and decision-makers. In this regard, Kruer believes that modification and identification in covert conditions lead to human errors; however, these errors could be avoided prior to occurrence. Consequently, this method of error identification could contribute to prospective risk management (9).

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