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Assessing Common Medical Errors in a Children's Hospital NICU Using Failure Mode and Effects Analysis (FMEA)

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Abstract

Background: Neonatal intensive care units are prone to a variety of errors due to their special conditions. Failure mode and effects analysis (FMEA) is a method for risk assessment and management, which assesses the safety of patient care processes through its system approach.
Objectives: The present study aimed to identify and assess common medical errors at Amirkola Children's hospital NICU in 2016.
Methods: This was a cross-sectional study conducted from September 2015 to February 2016 in the NICU of Amirkola Children's Hospital in the city of Babol to identify and assess the medical errors and their effects qualitatively and quantitatively using FMEA through direct observations of the NICU processes, brainstorming, and focus group discussions (FGD). The FMEA standard worksheet was used for data collection. The collected data were analyzed using Excel 2010.
Results: In this study, 4 key processes were selected through studying the care methods and brainstorming including drug administration, infection control, medical equipment use, and laboratory tests; 27 activities and 50 potential failure modes, as well as their impacts were detected and recorded in the final worksheet of FMEA. According to the calculated PRNs, 27 potential failure modes with PRN > 65 were determined as high-risk failures. The highest and lowest PRNs were, respectively, related to improper and incomplete washing and disinfecting the hands (PRN = 127) and illegibility of the lab requests for laboratory tests (PRN = 32).
Conclusions: Based on the findings of this study, 57 potential failure modes in 4 key processes of the studied NICU were determined, among which 27 potential errors and failures with high risks were recognized. Therefore, it can be suggested that the senior managers and administrators should create multidisciplinary teams for patient safety at the organizational and unit levels.

Keywords: Neonatal Intensive Care Unit (NICU), Failure Mode and Effects Analysis (FMEA), Risk Probability Number (RPN), Risk Assessment

1. Background

The rapid progress in understanding neonatal pathophysiology, as well as an increase in the capacities for adapting this knowledge have raised the need for suitable areas of caring for neonates with serious conditions. Intensive care for sick and premature neonates requires special knowledge and skills. The slogan of public health in 2020 has 2 major goals and 10 health indicators. These indicators are methods for assessing the progress of the public health in the following decade and a turning point in providing coordination in the widespread efforts for national health (1-2). Patient safety is a national priority. The reports of the US Institute of Medicine shows that an average of the 98 000 preventable errors occur in the US hospitals annually, which in addition to the risk of death for patients, will cost about 29 million dollars each year. Therefore, identifying and decreasing harmful sources is vital for delivering safe intensive care. Harm reduction is possible only when the health care processes are reliable and patient safety is created (3).

The neonatal intensive care units (NICUs) have a complex system, which is prone to a variety of unexpected and threatening errors and risks for the neonates and caregivers should make critical decisions in a limited time. The neonates admitted in this unit need special care, which is provided to them by different specialists. Any of these complex layers of the system provides the basis for incurring additional errors and mistakes. Determining these factors

can prevent medical errors (3). There is a limited interrelationship between neonates and service providers. As a result, the sensitivity of work processes for a patient is considered as the source of many risk management issues in this unit (4).

Failure mode and effects analysis (FMEA) is a risk management and assessment tool. Furthermore, the use of FMEA in the health system establishes a systematic thinking for providing services safely (5), and its preventive and futuristic approach provides opportunities for determining and resolving the potential problems before affecting the system, services and customers (6). Because the early childhood's comprehensive health and development, which includes physical, social, feelings, communication, and cognitive status have an important effect on the neonates' future health, determining and predicting the available risks in the neonatal intensive care play a major role in maintaining and promoting their overall health and development (7).

On the other hand, medication errors are considered to be an indicator for patient safety (8) and are among the important problems of the hospitals, and neonates are highly susceptible to their harmful impacts because of their weak physiologic buffering system, limited communication skills, and use of the neonates' weight in calculating medication dosages (9). Clearly, these errors can lead to an increase in mortality rates, hospital stay, and costs. Therefore, controlling errors are highly important because they are costly for patients and hazardous to safety (8). According to the statistics, such errors are the most common types of medical errors in Iran. Medication errors, which occur by physicians and nurses at the time of drug administration in many cases, have caused severe problems for patients. Based on the results of a study, most medication errors in hospitals are made by nurses administering medications to the patients. However, a systematic approach to record, identify, and manage the medical and medication errors in Iran has not been undertaken (10).

There are several tools to identify and assess medial errors such as safety audit, tree analysis methods, hierarchical analysis, and FMEA (11). Risk management assessment at hospitals is important to decrease medical errors and improve patient safety. the clinical staff, particularly physicians and nurses should be familiar with risk management methods (11).

Also, assessing the the risks in the ICUs were highly important and required teamwork (12). Tofighi et al. (2009) in their study used FMEA method to identify and assess medical errors and found 4 high risk errors including delayed arrival of the patients at the triage room (risk priority number: RPN = 252), very short initial visit to prioritize patients and incorrect recording of patient blood oxygen (RPN = 245), and delays in performing patients' ECG (RPN = 160), respectively (13).

Kunac and Reith (2005), detected and ranked potential errors in medication therapy processes of the NICU using FMEA. The researchers found 72 errors with 193 causes, among which "the lack of knowledge about the drug safety" and "when and how to prescribe the drugs" received the highest ranks, respectively (14).

2. Objectives

This study aimed at identifying and assessing the common medical errors in the Amirkola Children's Hospital NICU in 2016.

3. Methods

This was a cross-sectional study conducted from September 2015 to February 2016 in the NICU of Amirkola Children's hospital in the city of Babol aimed to assess the medical errors and their effects qualitatively and quantitatively using FMEA and through direct observations of the NICU processes, brainstorming, and focus group discussions (FGD).

The FMEA Steps

The steps of FMEA were as follows:

1. Creating a team
2. Identifying the process steps or components of the system
3. Listing the potential failure modes of each process steps or components of the system
4. Determining the potential effects of each determined failure modes
5. Determining the causes of each failure and error
6. Listing the current controls to recognize each failure and error
7. Priority calculation (the importance of each failure and error)
8. Taking and implementing corrective and preventive measures (15, 16)

1. Creating a Team in the Present Study:

A team was created in the neonatal intensive care unit (17).

Using purposive sampling method, the researcher selected the team members based on their individual experience and the level of involvement in the respective processes (Table 1).

2. Identifying the Process Steps or Components of the System:

In this step, the flowcharts of drug administration, infection control, medical equipment use, and laboratory

Table 1. The FFMEA Team Members

Degree	Position
Neonatologist	The head of studied NICU
Pediatrician	The fellow of neonatology
MSc in NICU	The NICU nurse
BSc in Nursing	The NICU head nurse
BSc in Nursing	The infection control supervisor
BSc in Laboratory	The laboratory supervisor
MSc in Health Services Management	The head of quality improvement unit
BSc in Medical Equipment	The expert in medical equipment

tests were approved through conducting individual and group interviews and holding team sessions. The final flowcharts were designed using Visio software, and the related activities of each of the 4 selected processes were listed in the final worksheet of FMEA.

3 & 4. Listing the Potential Failure Modes of Each Process Steps or Components of the System and the Potential Effects of Each Determined Failure Modes:

In this step, the team members determined the potential failure modes of each process steps or components of the system using brain storming, and recorded them in the related form.

5. Determining the Causes of Each Failure and Error:

In this step, the team members determined the causes leading to the failure modes using brainstorming, and cause and effect diagrams.

6. Priority Calculation (The importance of each failure and error):

In this step, occurrence (O), severity (S), detection (D), and risk probability number (RPN) were determined using the existing tables and unanimous votes of the team members. Then, RPNs were calculated and ranked according to $RPN = O \times S \times D$ using team members' opinions and considering NICU condition (Tables 2, 3, and 4)

Table 2. Ranking the Severity (S) Indicator

Point	Wound and Injuries Descriptions
5	Death or losing one of the body's main functions
4	Continuous decreases in one of the body functions
3	Temporary harm or injury, which increases the neonate's stay in hospital or requires more care
2	Temporary harm or injury, which requires care and treatment
1	No harm or injury to the neonate, only monitoring is required

Table 3. The Failure Occurrence (O) Indicator

Point	Type	Amount of Occurrence	
10	Unavoidable	More than once in 8 hours	More than 3 errors per 100 cases
9	Frequent	Once a day	One error in every 100 cases
8	Very high	Once in every three days	3 errors in every 1000 cases
7	High	Once a week	One error in every 1000 cases
6	Moderate to high	Once a month	3 errors in every 10,000 cases
5	Moderate	Once in 3 months	One error in every 10,000 cases
4	Moderate to Low	Once in 8 months	3 errors in every 100,000 cases
3	Low	Once in 2 years	One error in every 100,000 cases
2	Very Low	Once in 6 years	3 errors in every 1,000,000 cases
1	Rare	Once over 6 years	Less than one error per 1 million cases

Table 4. The Failure Detection (D) Indicator

Point	Type	Probability, %	Detection
10	Completely unknown	< 10	Undetectable
9	Highly unlikely	10 - 20	Highly unlikely to be detected
8	Unlikely	20 - 30	Unlikely to be detected
7	Very low	30 - 40	Very low probability to be detected
6	Low	40 - 50	Low probability to be detected
5	Average	50 - 60	50% probability to be detected
4	Average to high	60 - 70	Generally detectable
3	High	70 - 80	High probability to be detected
2	Very high	80 - 90	Very high probability to be detected
1	Highly known	> 90	Certainly detectable

7. Taking and Implementing Preventive and Corrective Measures:

In this step, the FMEA team offered suggestions for reducing the PRNs through brainstorming. These suggestions included the reduction of the probability of error occurrence, decrease in the error severity, and increase in the probability of error detection (D). Excel 2010 was used to calculate the PRNs.

4. Results

In the first step and after consulting with the NICU experts, 4 key processes were selected through studying the care processes and brainstorming including drug administration, infection control, medical equipment use, and laboratory tests. In the second and third steps, 27 activities of these processes and 50 potential failure modes, as well as their effects were detected and recorded in the final worksheet of FMEA. In the fourth step, the PRNs were calculated and given the range of $1 < RPN < 130$, and the ranking scale of 1 to 10 for 3 indicators mentioned above, 27 potential failure modes with $PRN > 65$ were determined as the high risk failures, and were listed in the final worksheet. In the fifth step, their causes were determined using the team members' opinion and recorded in the root causes column of FMEA worksheet. Finally, suggestions for reducing the probability of error occurrence, decreasing the error severity, and increasing the probability of error detection were offered according to the scores of D, O, and S indicators. As demonstrated in process of drug administration, mistakes in the drug calculation (PRN = 115) and failures in the medicine card (PRN = 55) had the highest and lowest PRNs, respectively. The root causes were the lack of enough information. In the process of medical equipment use, the highest and lowest PRNs were, respectively, related to defects in the quality of using medical equipment (PRN = 104) and malfunctions of the equipment and machines due to not supplying spare parts (PRN = 45). The root causes were the lack of users' awareness. In the process of performing laboratory tests, delays in confirming and sending laboratory tests results (PRN = 77) and illegibility of the lab requests for laboratory tests (PRN = 32) were the highest and lowest PRNs, respectively. The root causes were the lack of lab secretary attention and lab technician attention, and the related suggestions offered were the increase in the detectability and the decrease in the probability of occurrence and severity of impact. In the process of infection control, the highest and lowest PRNs were, respectively, related to improper and incomplete washing and disinfecting hands (PRN = 127) and hospital reports on nosocomial infections (PRN = 34). The root causes were the lack of sufficient training for service provider, the low number of nurses to number of patients, the lack of adequate facilities for washing hands, and the use of gloves instead of washing hands.

5. Discussion

According to the nature and importance of neonatal intensive care units (NICUs) and their patients' special condition, these units need highly skilled staff and special equipment. In addition, using preventative measures to avoid errors and risks and enhance the neonates' safety is of great importance.

In the present study, some failures and their causes related to 4 processes of drug administration, infection control, medical equipment use, and laboratory tests were recognized. In the drug administration process, the highest PRNs were, respectively, related to mistakes in the drug calculation (PRN = 115), the wrong quantity (PRN = 95), and the wrong drug (PRN = 92), which was similar to Kunac and Reith's study results (2005) (14). Also, in their study, the lowest PRNs were related to defects in the equipment and verifications of medication therapy outcomes. The main root cause of failure in this process was the employees' lack of awareness of the medication safety, and to prevent such errors, the hospital managers and administrators should use a briefing and training package for the new staff. It can be stated that the use of unskilled physicians and nurses and poor training are some important factors leading to the medical errors and their occurrence (14).

The results of Vafaee Najar et al. study (2016) (15) revealed that 68% and 45% of the 48 determined potential failure modes were, respectively, related to drug prescription and drug administration, and the RPNs were between 20 and 40, which were classified as moderate risk modes. Khani-Jazani et al. (2015) (16) identified 48 failure modes for 14 subprocesses of drug administration process, most of which were related to drug supply, prescription, preparation, distribution, and safety follow-up and monitoring, respectively.

In the current study and in the process of infection control, the highest RPNs were, respectively, related to improper and incomplete washing and disinfecting hands (RPN = 127), non-compliance with the hand washing principles in 5 situations (PRN = 126), and non-compliance with the sterilization principles in catheterization, chest tube, intubation, and bladder catheterization (PRN = 104). The results of Nazari et al.' study (2011) (18) revealed that although the studied nurses had worn gloves in 94.3% of the situations, they had disinfected their hands only in 16.98% of the situations, most of which were after contacting with patients, and there was a significant association among the kind of gloves used by nurses, infection risks, and the method of hand washing. Furthermore, Attar Jannesar Nobari et al. (2015) (19) found 378 potential failure modes from 15 selected processes and 180 activities, and the highest PRNs were related to the suctioning process and improper and incomplete washing and disinfection of the hands by nurses.

In the present study and in the process of performing the laboratory tests, the highest PRNs were related to delays in sending the sample test results (RPN = 77), delays

in recording test results in HIS (PRN = 70), and delays in sending test results (RPN = 67). Their root causes were organizational and human factors. Shams et al. (2012) (20) concluded that from 425 inpatients and outpatients' complaints, 375 complaints were related to the delays in sending test results, 50 to the nonconformity of laboratory test results with the patients' characteristics, and 106 to the lake of recording test results in HIS; and finally, they suggested, continuous monitoring and improvement of the process of sending test results, and physicians- nurses cooperation with the laboratory staff.

In the current study and in the process of medical equipment use, the highest PRN was related to defects in the quality of using medical equipment (PRN = 104) and all potential failure modes received PRN > 65.

Asefzadeh (2011) in his study identified 48 potential failure modes using FMEA and found that the highest PRN in the respiratory care process was related to the inactive alarm system of the ventilator (PRN = 288); negligence and malpractice, the lack of providing proper training to the employees, and employees' fatigue caused were the cause (21). In their study, Arenas Villafranca et al. (2014) (22) found 82 potential failure modes. The processes with the highest PRNs were transcription of the medication orders, formulation of the neonatal parenteral nutrition, and preparation of materials for the formulation. Then, they developed a checklist to achieve greater control on the error detection process and demonstrated that the use of this checklist reduced the PRNs and improved the detectability of errors.

Furthermore, the results demonstrated that despite the low detectability of errors, the PRNs were high, indicated that the physicians and nurses working in the studied NICU were familiar with the available potential errors and failure modes and could determine their causes quickly.

Some methods such as FMEA, which are a preventive approach and are based on teamwork, can lead to the increase in the employees' attention to the professional potential weaknesses and attempts to overcome them. The results of the present study indicate that taking timely decisions and performing appropriate procedures in the organizational levels are some solutions for reducing potential errors.

In their study, Tofighi et al. (2009) have stated that one of the advantages of FMEA is that it does not consider the employees as guilty and tries to create a safe environment for employees through detecting the root causes of errors, especially human errors and errors caused by the working processes (13).

Dominici and Brams (2006) in their study concluded that to improve the effects of HFMEA on the quality of patient care, it is essential to form a team of different specialists, especially managers and administrators to identify and classify potential risks (23).

Finally, it should be noted that despite the FMEA's strengths including its futuristic and system approach to the errors, it has some limitations, one of which is that its implementation is very time-consuming, and another important limitation is that its implementation depends on the senior managers and team members' motivation, as well as their skills in group discussions.

Weber (2006) in his study emphasized that FMEA provides a preventive mechanism to improve the processes to prevent deviations (24).

In FMEA, the RPN is an indicator for determining the clinical errors. In this regard, Sankar and Prabhu (2001) have stated that the potential failure modes with high RPNs are high priorities (25).

In spite of FMEA limitations, it seems that the use of futuristic and system approach of FMEA to the errors in the complex and sensitive units, including NICUs, is efficient and effective for early detection and elimination or reduction of errors and failure modes and for improving the neonates' quality and safety.

According to the results, 57 potential failure modes in 4 key processes of the studied NICU were determined, among which 27 potential errors and failures with high risks were recognized, with the highest PRN relating to improper and incomplete washing and disinfecting hands (PRN = 127). Our findings show the great ability of FMEA to identify, evaluate, and analyze the errors in the sensitive and complex units such as NICUs. Therefore, it can be suggested that the senior managers who are key persons in the hospitals should create multidisciplinary teams for patient safety at organizational levels.

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Footnotes

Authors' Contribution: Khalil Alimohammadzadeh and Mohammadkarim Bahadori developed the study concepts

and design. Tahereh Jahangir collected the data. Mohammadkarim Bahadori and Taherh Jahangir analyzed and interpreted the data. Tahereh Jahangir and Mohammadkarim Bahadori wrote the manuscript. Ramin Ravangard revised and edited the manuscript. All authors read and approved the final manuscript.

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