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ORIGINAL RESEARCH **INTENSIVE CARE**

Risk assessment of biological hazards to the nurses using 'Failure Modes and Effects Analysis' (FMEA) in the intensive care unit

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ABSTRACT

Background: Nursing staff in the intensive care unit (ICU) is exposed to multiple biologic hazards. We aimed to identify biological hazards threatening the health of nurses in the ICU using the technique of Failure Modes and Effects Analysis (FMEA) tool.

Methodology: A cross-sectional study by Focus Discussion Group (FDG) was performed in the ICU. Participants were familiar with the processes in ICU. The sampling method was purposeful and discrete and the researcher selected FDG group members. The study instrument was standard worksheet. Data analysis was performed by FMEA technique and based on Risk Priority Number (RPN).

Results: 53 possible errors were identified in 14 common activities in the ICU. Error cases with unacceptable risk were identified, including "lack of hand hygiene" (RPN 177.75), "needle stick injuries" (RPN 167.62), "lack of personal protective equipment" (RPN 133.92) and "absence of N95 or FFP2 mask during CPR of COVID-19 patients" (RPN 111.60).

Conclusion: The causes and effects of the errors were identified, and corrective measures were presented in three areas: reducing the frequency and severity and increasing the error detection capability. It was suggested that retraining courses for nurses be held to prevent errors and ensure the health of nurses.

Abbreviations: FMEA **-** Failure Modes and Effects Analysis; FDG - Focus Discussion Group; ICU - intensive care unit; RPN - Risk Priority Number

Key words: Biological Hazards; FMEA; Intensive Care Unit; Risk Assessment

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1. INTRODUCTION

Intensive Care Units (ICUs) are one of the most high-risk places in a hospital, regardless of the services they provide to the patients. Numerous factors, such as the critical condition of patients and low level of facilities available in an invasive care create a high-risk environment. One of the hazards is the biological hazard, which includes contact with contaminated blood and secretions, needle sticks, and splashes of blood and body fluids in the eye.[1]

Biological hazards lead to infectious diseases, in addition to the high costs to the health system and staff.[2] These costs range from $6.1 million in France to $118-591 million in the United States.[3] It also leads to stress, disruption of social relationships, absenteeism, reduced job satisfaction, compromised safety and low motivation in nurses, and ultimately leads to reduced quality of nursing services.[4] In the ICU, the possibility of contact with blood and secretions is much higher due to procedures such as suction, endotracheal intubation, dressings and drains containing secretions. There are several factors that contribute to the occurrence of biological hazards that must be predicted, identified and evaluated. Risk assessment in the ICU is an important factor in improving the quality of care.[5]

Among the many methods of risk assessment, 'Failure Modes and Effects Analysis' (FMEA) is a very efficient tool. FMEA was first begun in the 1940s by the U.S. military, later on used by NASA in the 1960s, then in industry and finally in the healthcare systems. The FMEA is considered to be a systematic procedure for the analysis of a system to recognize the potential failure modes, and their causes and effects on system performance. The analysis is carried out at the primary stage of a system, so that elimination or mitigation of the failure mode is the most cost-effective. A significant index in the FMEA is Risk Priority Number (RPN), which is the result of occurrence (O), severity (S) and detection (D) ratings as presented in the equation: RPN = O × S × D; where 'O' is the "occurrence of failure" indicator of the probability that the failure mode will happen as a result of a particular cause; 'S' is the "severity", an estimate of the seriousness of the effect of the possible failure mode on the process when it has happened; and 'D' the probability that a possible failure will be 'discovered'. Risk factor with a high RPN will require to be urgently considered. On the whole, these three components are guessed by experts in accordance with a scale based on usually consented evaluation criteria. As the RPN is a scale of the risk of failures, it is able to use to rank failures and to prioritize proceedings. Proceedings are ranked according to the priority given to the failure by the RPN.[6–8]

Since the health of nurses in the ICU is important for provision of continuous quality services, and the preventive approach of risk identification solves the existing problems, so this paper aims to use FMEA to recognize potential failure modes of the biological hazards and assess their effects for mitigating risks threatening the health of nurses in the ICU.

2. METHODOLOGY

This was a cross-sectional study by Focus Discussion Group (FDG) performed in the ICU. Participants were familiar with the ICU routines and processes. The study population included ICU' nurses. The sampling method was purposeful. The researcher selected FDG group members, including the head nurse, ICU nurses, as well as an FMEA technique specialist. The study instrument was a standardized worksheet. Data analysis was performed by FMEA technique and based on Risk Priority Number (RPN). The steps of the FMEA were as follows:

1. Determining FMEA team members

In this study, team members were first identified, which included ICU nurses, hospital officials and people familiar with the FMEA technique.9

2. Identification of common ICU processes

Common nursing processes that might pose a potential biological risk to the nurses were listed and finalized during correction and approval sessions.9 These procedures included 14 cases of "suction of patient's mouth and trachea", "endotracheal intubation", "endotracheal tube removal", "incentive spirometry", "respiratory physiotherapy", "chest tube care", "chest tube insertion", "blood sampling", "cardiopulmonary resuscitation (CPR)", "intramuscular / intravenous injections", "peripheral venous cannulation", "arterial catheter care", "dressing change", "glucometry", and "drain care". Then the standard methods of personal protection during the procedure by the nurses in each activity were briefly mentioned.10

3. Analysis of failure modes and effects analysis

The potential error cases of the processes were 53 cases, each of which along with its effects and causes was recorded in the final worksheet with the consensus of the team members. For each error condition, three indices of severity (S), probability of occurrence (O) and detectability (D) were determined and finally the RPN of that case was obtained by multiplying three indices and among all the error cases, the cases with RPN ≥ 100 was recognized as unacceptable and high risk errors.9 Measurements of effect intensity index (S), probability of occurrence (O), and error detection capability (D) were usually expressed on a scale of 1 to 10. The result was a number between 1 and 10009 (Table 1).

4. Determining risk priority number (RPN)

Errors with RPN ≥ 100 were identified as high risk and unacceptable errors in selected processes.[9]

5. Corrective suggestions

Decisions were made to reduce, eliminate, transfer and accept the risk. Suggestions were made based on the root causes of the unacceptable error, which were identified using focused group discussion techniques and the root

Table 1: Index probability of occurrence (O), severity (S), and detect ability (D)

Probability of occurrence (O)	Severity (S)	Ability to detect (D)	Points
More than once during 8 h	System failure and death	< 10%	10
Once a day	Severe damage to the system and the individual	20%−10%	9
Once in 3 days	Too much damage to the system and the person	30%−20%	8
Once a week	High damage to the system and the individual	40%−30%	7
Once a month	Moderate damage to system and individual	50%−40%	6
Once in 3 months	Low damage to system and individual	60%−50%	5
Once in 8 months	Very little damage to the system and the individual	70%−60%	4
Once in 2 y	Minor damage to the system and the individual	80%−70%	3
Once in 6 y	Very minor damage to the system and the individual	90%−80%	2
Once in more than 6 y	No damage to the system and the individual	> 90%	1

Table 2: Demographic characteristics of FMEA team members

Variables		N = 10
Gender	Male	2 (20)
	Female	8 (80)
Education	B.Sc.	7 (70)
	M.Sc.	2 (20)
	PhD	1 (10)
Age (Mean ± SD)		41.87 ± 9.25
Married		7 (70)
Occupation	Nursing Services Manager	1 (10)
	Disaster / emergency health specialist	2 (20)
	Infection Control Supervisor	2 (20)
	Occupational health expert	1 (10)
	Head of ICU	1 (10)
	ICU Nurse	3 (30)
Work experience	0−10 y	2 (20)
	11−20 y	6 (60)
	21−30 y	2 (20)
Work experience in ICU	0−10 y	3 (30)
	11−20 y	4 (40)
	21−30 y	3 (30)

Data presented as n (%) unless specified.

analysis method. These suggestions were to reduce the severity of the effect and the rate of occurrence, and increase the error detection capability.

3. RESULTS

The results showed that the majority of FMEA team members were female (80%), a nursing job (30%), married (70%), having a bachelor's degree (70%), 11-20 y of work experience (60%), 11-20 y' work experience in intensive care (40%) and the age average 41.87 ± 9.25 y (Table 2). Based on the researcher's observations and the experiences of ICU nurses, 14 processes were selected and 53 potential error cases were identified. Among these errors, 4 were identified as unacceptable and high-risk errors, including: "lack of hand hygiene" (RPN 177.75), "needle stick injuries" (RPN 167.62), "lack of personal protective equipment" (RPN 133.92) and "absence of N95 or FFP2 mask during CPR of COVID-19 patients" (RPN 111.60) (Table 3).

Table 3: Unacceptable error cases

Error mode	D	O	S	RPN
Lack of hand hygiene	2.1	9.2	9.2	177.75
Needlestick Injuries	1.8	9.6	9.7	167.62
No use of PPE	1.5	9.6	9.3	133.92
N95 or FFP2 mask absence in CPR of COVID-19 patients	1.2	9.3	10	111.60

The causes and the effects of each error were identified and recorded in the FMEA worksheet. Finally, with the consensus of team members, for 4 unacceptable error modes, suggestions were made to reduce the severity of the error, reduce the occurrence of the error, and increase the error detection capability (Table 4).

4. DISCUSSION

The highest risk priority was related to the error status of "Lack of hand hygiene". The causes of this error included, insufficient knowledge of the nurses,

Table 4: Determining the causes, effects and suggestions related to unacceptable error cases

Error mode	Causes	Effects	Suggestions
-Lack of hand hygiene	-Insufficient knowledge of the nurse -Insufficient time to wash hands -Poor quality and unpleasant odor of hand washing liquid -Using gloves instead of disinfecting the hands	-Blood-borne diseases -Skin sensitization -Cost increase -Mortality and morbidity	**Occurrence reduction strategy:** -Hand hygiene training -Creating educational content for hand hygiene -Encourage nurses to wash their hands properly -Prepare a suitable soap -Measure the level of hand washing liquid at the end of each shift **Strategy to increase detection capability:** -Monitoring the washing of nurses' hands -Prepare a hand wash checklist -Microbial culture of hands
-Needlestick Injuries	-Decreased risk perception -Lack of training of new nurses -Lack of safety box -Habit of recapping the syringe	-Blood-borne diseases	**Occurrence reduction strategy:** - Needle recapping training -Prepare safety box **Error reduction strategy:** -Continuous training nurses - Evaluation of vaccination and antibody
-Lack of PPE	-Shortage of PPE -Decreased risk perception	-Blood-borne diseases especially Covid19 -Sickness of nurses and their families -Absence from hospital due to illness	**Occurrence reduction strategy:** - PPE use training -Require nurses to use PPE -Justifying managers to provide PPE
-N95 or FFP2 mask absence in CPR of COVID-19 patients	-Shortage of N95 or FFP2 mask -Ignore the difference between simple mask and N95 or FFP2 mask	-Possibility of transmission of COVID- 19	**Occurrence reduction strategy:** -Justify for preparing N95 or FFP2 masks

insufficient time to wash hands, poor quality/unpleasant odor of hand washing liquid, and using gloves instead of disinfecting the hands. Hand hygiene is the first challenge related to controlling nosocomial infections, and so many studies have been done to document its importance. The studies showed that despite the cheapness and convenience of hand washing, it was practiced less than expected, so identifying the causes and preventing the error was essential.[11–14] The results of Terzi study showed that hand washing was performed in 924 situations, most of which were after contact with the patient, but in general, the results showed that hand

washing was not sufficient and satisfactory. It was recommended that related barriers be addressed in the ICU. Also, regular programs should be developed to review and improve hand hygiene.[15]

The second unacceptable error was "Needlestick Injuries". The causes of this error included, decreased risk perception, lack of training of new nurses, lack of safety box, and habit of recapping the syringes. The results of the study by Jahangiri showed that the most common activity leading to needle sticks in nurses is syringe resealing.[16] Other studies have found factors such as gender, work shift, number of night shifts, and work experience on the prevalence of needle stick among nurses, but none of them denied the role of syringe recapping in needle stick rate.[2,17,18]

The third unacceptable error was "Lack of use of PPE ". The causes of this error included, shortage of PPE and decreased risk perception. Nurses do not use PPE for reasons such as lack of knowledge and/or lack of need to use PPE or due to a lack of such equipment in the hospital.[19] The results of Ndejjo study showed that the

incidence of biological hazards in nurses was associated with not using PPE and a high percentage of nurses who experienced biological hazards did not use PPE completely.[20] The use of PPE in the COVID-19 pandemic was significant. The pandemic has increased nurses' perception of the importance of using PPE.[19]

The last unacceptable error was “N95 or FFP2 mask absence in CPR of COVID-19 patients". The causes of this error included, shortage of N95 or FFP2 masks in the ICU, and lack of knowledge the difference between a simple mask and N95 or FFP2 mask. CPR, due to aerosol formation, is one of the of most dangerous processes for transmitting COVID-19 to nurses. Complete PPE is essential for CPR of COVID-19 patients.[21] The results of the Shwe study, which aimed to examine the attitude and behavior of health workers in the use of PPE, showed that 23% of the participants had experienced blood spray on the face. Health workers considered the use of PPE more important now than before the COVID-19 epidemic. These results indicate that the COVID-19 epidemic has a significant impact on employee perception.[19] The results of Wong study aimed at evaluating the adequacy of N95 mask in CPR of COVID-19 patients showed that the use of N95 is highly recommendable.[22] The results of the Boškoski study aimed at "examining PPE deficiency and comparing the effectiveness of different types of masks and practical methods for reusing masks in the COVID-19 epidemic" showed that the N95 mask should be used in high-risk situations such as aerosol production.[23]

5. LIMITATIONS

There are several limitations to using the FMEA method, such as it is time consuming; however, the most important limitation of this method may be the lack of skill by the managers in the risk assessment. Lack of team skills in group discussion is another limitation of this study.

6. CONCLUSION

Biological hazards are one of the major health risks to the ICU nurses. Risk assessment is thus essential to ensure the health of nurses. Many biological hazards in the ICU are preventable. In this study, four unacceptable errors were identified, including ‘Lack of hand hygiene’, ‘Needlestick Injuries’, ‘Lack of use of PPE’ and ‘Lack of use of N95 or FFP2 masks during CPR of COVID-19 patients’. Finally, corrective measures were presented in three areas: reducing the frequency of errors, the severity of errors and increasing the error detection capability. It is suggested that retraining courses be held for nurses to prevent errors.

7. Ethics approval and consent

This study was approved by Hamadan University of Medical Sciences with the number 9805223862 and ethics code IR.UMSHA.REC.1398.405. Written consent was obtained from the study participants. This study has permission to publish.

8. Availability of data

The data is available on request.

9. Competing interests

There is no conflict of interest between the authors.

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12. Authors' contributions

LH, AK, and HA made substantial contributions to the conception and design of the study. Sampling was carried out under the supervision of AK and HA. Data analysis was performed by LH, AK, and HA were involved in the writing-up of the manuscript. All read and approved the final manuscript.

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