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Original Article

Risk Assessment of Operating Room Occupational Hazards Using Failure Modes and Effects Analysis (FMEA)

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Abstract

Background: The operating room is one of the most risky parts of the hospital. All employed personnel are exposed to occupational hazards. This study aimed to assess and control the risk of occupational hazards in urology surgeries using the technique of analysis of error states and its effects in the operating room.

Methods: In this cross-sectional study, data were collected through observation of common operating room processes, background checks and documents, and focus group discussion. Data analysis was in accordance with the failure modes and effects *analysis* (FMEA) method based on risk priority number (RPN).

Results: Considering 16 common operating room processes, there were 23 potential error modes of which 5 of them were identified as unacceptable and high risk. These five items included "working with sharp tools with RPN8/311", "working under high pressure and risky conditions with RPN 292", "hand washing with RPN 254.6", "intubation/extubation/suction of secretions with RPN 213.2", and "working with radiation equipment with RPN 206.9".

Conclusion: In case of unacceptable errors, corrective actions were presented in three areas of decreasing occurrence and severity and increasing the ability to detect errors. It is suggested that retraining courses be held to prevent errors, ensure the health of operating room personnel, and increase the quality of services.

Keywords: Risk assessment, Potential risks, FMEA, Occupational hazards, Operating room

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Introduction

One of the most important and dangerous parts of the hospital is the operating room (1,2) which has numerous occupational hazards threatening health and safety (3). Patients and all operating room personnel, including surgeons, anesthesiologists, nurses, and others, are exposed to these risks (3-5). Occupational hazards refer to workplace-related factors that have the potential for injury or illness and are classified into five categories of physical, biological, chemical, ergonomic, and psychosocial hazards. Exposure to any of these hazards can cause occupational diseases and occupational accidents (6).

Physical hazards include noise pollution, sensory overload, sensory deprivation, inadequate ventilation, inadequate light and lighting, radiation hazards, and falling (7). Biological hazards are contact with blood and other fluids, needle stick, infectious disease, and blood and body fluids in the eye (8). Chemical hazards include skin allergy following contact with drugs, detergents, and disinfectants, breathing disinfectant vapors, and disinfectant spray in the eyes. Chemicals in the operating room encompass anesthetic gases, hazardous drugs, disinfectants, solvents, and latex gloves (9,10). Exposure to these substances has many respiratory and skin problems, the most common of which are chronic bronchitis and severe skin sensitivity (11).

Ergonomic hazards are another occupational hazard in the operating room (12). Lack of observance of ergonomics causes musculoskeletal disorders. The most common ergonomic disorders were low back pain (30%-76%), neck (30%-48%), shoulder (43%-53%), and arms, wrist, and knee injuries (13). The main cause of these disorders is the relocation of patients to change position, static posture, monotonous and boring tasks, and time pressure (13). All

the mentioned risks impose exorbitant costs on the system (14). Occupational injuries, in addition to the mentioned costs, reduce job satisfaction, security, and motivation, ultimately leading to a decrease in the quality provided to patients (15).

Since the occupational hazards of accidents are not completely random and there are many factors involved in their occurrence, it is possible to predict these events and identify the effective factors in their occurrence and eliminate them as much as possible. There are several ways to prevent these problems (16). Risk assessment as a scientific indicator with quantitative and qualitative methods is able to investigate the potential adverse health and safety effects in at-risk personnel (17). Risk management by reducing costs increases productivity in healthcare settings (18-20). There are several risk assessment methods, including job safety analysis, error tree risk assessment, and root cause analysis (21). The failure modes and effects *analysis* (FMEA) method is one of the prospective methods. In this method, to prevent the occurrence of errors and failure events, the risks in the system are predicted and prevented by making necessary changes (22). With the advent of the systematic approach to medical errors and risks and prospective study of errors, this method entered the field of healthcare. In 2001, the Joint Commission on the Accreditation of Health Organizations announced the regular implementation of FMEA in special wards as the need of all hospitals. The FMEA generally has five stages, including process study, error analysis, planning, implementation, and monitoring performed by the team (22).

Considering the importance of the health of the staff working in the operating room and their role in the quality of services provided to patients, along with limited studies conducted in the field of risk assessment in the operating room, the researchers aimed at managing occupational hazards risk in urology practices using the technique of analysis of error states and its effects in Shahid Beheshti hospital in Hamedan.

Materials and Methods

The present cross-sectional study was conducted in the operating room using direct observation, reviewing the existing records and documents, holding meetings with team members by focused group discussion, and using a standard FMEA-based technical data collection worksheet. The study population consisted of personnel familiar with operating room processes, and purposeful sampling was used in this method. The team members included researchers, urologists, operating room technicians, and anesthesiologists, as well as expert professors familiar with the FMEA technique. Data analysis was performed according to the FMEA method based on risk priority number (RPN). The steps of the analysis of potential error states and its effects were as follows:

1. Determination of FMEA team members: In this study, first, the team members were identified.
2. Identification of common operating room processes: Common operating room processes that pose a risk to personnel were listed and modified and finalized during the meetings (14). These processes include hand washes such as "working with chemicals", "working with lasers", "working with electrical devices", "working with radiation equipment", "transfusion of blood and blood products", "working with infected tissues", and "working with sharp tools". The other processes were "working with hot materials and equipment", "working in high-pressure and risky conditions", "working with cylinders containing gases", "patient transfer on the bed", "cardiopulmonary resuscitation", and "intubation/extubation/suction of secretions, peripheral vessel insertion, and nasal gastric tube insertion.
3. Failure mode and effects analysis: The potential scenarios of process errors were 23 cases, each of which was recorded in the final worksheet with the consensus of the team members' comments. For each error state, three indices of severity (S), probability of occurrence (O), and detectability (D) were determined, and finally, the RPN of that case was obtained through the multiplication of three indices together. Of all error cases, those with RPN ≥ 200 were identified as unacceptable and high-risk errors. The determination of the effect intensity index (S), probability of occurrence (O), and error detection capability (D) was expressed in terms of a rank scale of 1 to 10. The result was between 1 and 1000 (Table 1).
4. Determination of risk priority number: RPN ≥ 200 errors were identified as high-risk and unacceptable errors in selected processes.
5. Corrective suggestions: Decisions were made to alleviate, eliminate, transfer, and accept risks and suggestions based on the root causes of unacceptable error states that were identified using focused group discussion techniques and the root analysis method. These suggestions were based on the obtained scores of each of the S, O, and D indices in the form of reducing the intensity of the effect, reducing the occurrence rate, and increasing the ability to detect errors (14).

Results

The results demonstrated that most of the studied subjects were males, with an average age of 35.21 ± 5.84, married, and experts with an average of 18.82 ± 6.70 work experience. In addition, the most physical hazards were related to cuts, biological hazards related to hepatitis B, chemical hazards related to anesthesia gases, and ergonomic hazards related to heavy surgery. The highest risks were chemical, biological, physical, and ergonomic hazards respectively (Table 2).

The RPN for all processes was calculated based on the scores of three indexes S, O, and D (Table 3).

According to the FMEA team, scores above 200 were

Table 1. Three Scoring Indicators for Error States

Probability of Occurrence (O)	Intensity (S)	Discoverability (d)	Score
More than once in 8 hours	System failure and death	<10%	10
Once a day	Damage to the system and the person is severe	10-20%	9
Once in 3 days	Damage to the system and the person is extremely serious	20-30%	8
Once a week	Damage to the system and the person is serious	30-40%	7
Once a month	Damage to the system and the person is moderate	50-40%	6
Once in 3 months	Damage to the system and the person is low	50-60%	5
Once in 8 months	Damage to the system and the person is extremely little	60-70%	4
Once in 2 years	Damage to the system and the person is minor	70-80%	3
Once in 6 years	Damage to the system and the person is extremely minor	80-90%	2
Once in more than 6 years	No systemic or personal damage is expected	>90%	1

Table 2. Frequency Distribution of Demographic Variables in Operating Room Personnel Participating in the Study

Variables	Groups	n=18
Gender (n, %)	Male	12 (67.66)
	Female	6 (33.34)
Age (Mean±SD)	35.21±5.84	
Marital status (n, %)	Single	7 (38.89)
	Married	11 (61.11)
Education (n, %)	Expertise	4 (22.22)
	Expert	14 (77.78)
Work experience (Mean±SD)	18.82±6.70	
Physical hazards (n, %)	Incision	10 (56.55)
	Noise pollution	3 (16.67)
	Radiation	4 (22.22)
	Ambient temperature changes	1 (5.55)
Biological hazards (n, %)	Hepatitis B	13 (72.22)
	Hepatitis C	4 (22.22)
	TB	1 (5.56)
Chemical hazards (n, %)	Anesthesia gases	10 (55.56)
	Toxic vapors	8 (44.44)
Ergonomic hazards (n, %)	Heavy surgery	8 (44.45)
	Fatigue	4 (22.22)
	Working with high-risk patients	6 (33.33)
Arrange the importance of risks (n, %)	Chemical hazards	9 (50.00)
	Biological hazards	4 (22.22)
	Physical hazards	3 (16.67)
	Ergonomic hazards	2 (11.11)

Note. SD: Standard deviation.

selected as high-risk and unacceptable errors. They included "working with sharp tools", "working in high-pressure and high-risk conditions", "hand washing", "intubation/extubation/suction of secretions", and "working with radiation equipment". Suggestions were made for these modifications (Table 4).

Discussion

The present study was conducted with the general objective of "assessment and control of occupational hazards risk in urology practices using the technique of analyzing the error states and its effects in the operating room". The results of the study demonstrated that in 16 common operating room processes, there were 23 potential error modes, 5 of which were identified as unacceptable and high-risk errors. These 5 items included "Working with sharp equipment with RPN 311.8", "Working in high-pressure and precarious conditions with RPN 292", "Hand washing with RPN 254.6", "Intubation/Extubation/suction of secretions with RPN 213.2", and "Working with radiation equipment with RPN 206.9". It should be noted that these 5 error modes had RPN ≥ 200.

The first error was "Working with sharp and winning devices with RPN 8/311". In this study, working with winning devices was the highest RPN. Several studies have focused on cutting and needle sticking devices, and several complications have arisen from this problem. Aghabeigi et al aimed to determine the frequency and causes of injuries caused by sharp instruments contaminated with the patient's blood in the operating room staff of Ahvaz state hospitals. The results showed that 92 (23.9%) cases had never experienced needle sticking, but 293 (76.10%) of them had experienced needle stick 1 to more than 5 times. From the employees' point of view, effective factors in needle sticking are rushing (61.5%), co-worker carelessness (39.0%), and department overcrowding (35.6%). The most common devices that cause needle sticks are suture needles (51.4%), needle syringes (37.4%), and Bistro blades (30.6%), respectively (23). Gabr et al investigated factors associated with needle stick injuries among health workers in Menofia in Egypt. According to the results, the occurrence of needle sticks significantly increased in cases with work experience of less than 5 years, female gender, and those working in the surgical ward, having more than 2 shifts a night per month, and not receiving training and needle-restraining. More precisely, 61.5% of the staff had needle sticks more than three times in the last three months following syringe recapping (24), which is in line with the results of the present study.

Jahangiri et al investigated needle stick injuries and related safety measures among nurses (25). The results

Table 3. Determining the Risk Priority Number for Processes With Error States

Process/Task	Potential Error Mode	Risk Priority Number
Working with sharp and winning equipment	Lack of caution when working with sharp and cutting gear	311.8
Working in high-pressure and risky conditions	Unprepared for stressful and precarious conditions	292
Washing hands	Use of non-standard washing materials	254.6
Intubation/extubation/suction of secretions	Lack of proper personal protective equipment Throwing the patient's secretions into the eyes and mucus or breathing contaminated droplets Lack of adequate ventilation in the operating room	213.2
Working with beaming equipment	Lack of caution when working with radiation equipment Reused equipment Lack of radiation shields	206.9
Nasal-gastric tube insertion	Spray the patient's discharge into the eye and mucosa technician during nasal-gastric tube insertion	195.9
Patient transfer on the operating table	Failure to properly transport the patient to the bed	194.2
Cardiopulmonary resuscitation	Spray the patient's discharge into the eyes and mucus of the technician during cardiac massage	189.9
Working with chemicals (disinfecting the environment and operating room equipment)	Lack of ventilation Ventilation failure	187.7
Working with electrical appliances	Lack of caution in the use of electrical devices Utilization of faulty electrical devices	144.5
Working with gas cylinders	Lack of caution in using cylinders containing gases	130.7
Working with infected tissues	Lack of caution when working with infected tissues	120.4
Blood transfusions and blood products	Lack of caution during transfusion	92.5
Working with laser	No use of face shields	72.9
Working with hot materials and equipment	Lack of caution in using hot materials and equipment	64.5

Table 4. High-risk and Unacceptable Error States With Suggestions for Corrective Action

Process/Task	Potential Error Mode	Risk Priority Number	Offers
Working with sharp and winning equipment	Lack of caution when working with sharp and cutting gear	311.8	Reduction of occurrence strategy: - Teaching how to recap in a single hand - Safety box next to the operating table Discovery enhancement strategy: - Easier reporting process needle stick Error reduction strategy: - Continuous training of the first steps during the needle stick - Evaluation of the vaccination of personnel and regular antibody titer check
Work in high-pressure and risky conditions	Unprepared for stressful and precarious conditions	292	Reduction of occurrence strategy: - Holding mental health training classes - Providing enough manpower in the operating room -Using relaxation methods Discovery enhancement strategy: - Paying attention to the symptoms of burnout Error reduction strategy: - Continuous mental health education
Washing hands	Use of non-standard washing agents	254.6	Reduction of Occurrence Strategy: - Proper hand washing training, especially for new arrivals - Preparation of high-quality disinfectants
Intubation/extubation/suction of secretions	- Lack of proper personal protective equipment - Throwing the patient's discharge into the eyes and mucus or breathing contaminated droplets - Lack of adequate ventilation in the operating room	2/213 213.2	Reduction of occurrence strategy: - Holding regular training classes - Requiring personnel to use personal protective equipment - Providing optimum ventilation in the operating room
Working with beaming equipment	- Lack of caution when working with radiation equipment - Reused equipment - Lack of radiation shields	206.9	Reduction of occurrence strategy: - Repairing defective equipment - Providing radiation protection equipment

of this study are completely consistent with the findings of the present study. In other studies, several factors such as gender, shift work, number of night shifts, work history, and the like are known to affect the prevalence of needle stick among nurses (16,26-28). The second error was "Working in high-pressure situations with RPN 292". According to multiple studies, operating room personnel suffer extensive stress due to work pressure. In this regard, Calgary et al sought to determine the stress level of the operating room staff of hospitals affiliated with Gorgan University of Medical Sciences and its association with some related factors. The results represented that most (54.4%) research units had poor stress, and of all the stressors in the operating room environment, the most stressor was unpleasant smells (76%), while the least stressors were inappropriate communication and collaboration of the working team (29.7%). Moreover, personnel equipment (42.6%) was considered a medium stressor (29). Rahmani et al compared the level of job satisfaction and job stress and the relationship between these two components in the nurses and the staff of the operating room and anesthesia. The results revealed that nurses had the highest job satisfaction and anesthesia, while operating room staff had less job satisfaction. Likewise, the highest and lowest levels of job stress were related to anesthesia workers and nurses, respectively, and the difference in both components was significant between the three groups. Further studies in this field showed that there was a negative and significant correlation between job satisfaction and job stress (30).

The third error was "Hand washing with RPN 6/254". Pourpak et al conducted a cross-sectional study to determine the frequency of allergy to latex gloves and its effective factors in operating room staff of Tehran University of Medical Sciences hospitals in 2001-2002. The findings demonstrated that 178 (34.8%) had a history of latex glove allergy, 59 of whom volunteered for the tests. Of these, 13 (22%) cases had type I allergies to latex, 3 (5.1%) had type IV allergies, and 9 (15.3%) had both. There was no significant association between latex allergy and age, gender, occupation, season, family and personal history of allergy, and type of gloves. There was a significant relationship between using kitchen gloves and type I allergy to latex and between allergy to other plastic coatings and type IV allergy to latex. It was concluded that the prevalence of latex allergy is extremely higher than in the other studies; therefore, identifying the causes of high latex allergy in this population needs further investigation (31).

The fourth error was related to "Intubation/extubation/suction of secretions with RPN 2/213". Nurses often do not use PPE due to various reasons such as lack of knowledge and lack of personal protective equipment or lack of these equipment in the hospital and ultimately suffer biological hazards in the hospital (32,33). There are different studies in this area. Ndejjo et al investigated occupational hazards among health workers and found that its incidence among nurses was strongly associated with multiple factors such as non-use of PPE, and a high percentage of nurses who experienced biological hazards did not use full PPE (34). The findings of this study are completely in line with the results of this study. Likewise, Nabil et al addressed the occupational hazards of nursing students at an Egyptian University and evaluated 458 nursing students. The results showed that nursing students were mostly exposed to ergonomic (88.8%) and psychological hazards (88.4%), while the lowest rate was related to biological hazards. More than half of the students were fully aware of the use of personal protective equipment and their safety (35). The results of this study contradict the findings of the present study on the non-use of personal protective equipment because, in this study, most personnel did not use personal protective equipment (PPE) because of a lack of personal protective equipment or lack of knowledge about the necessity of using PPE and were exposed to biological hazards.

The fifth error was related to "working with radiation equipment". Similar to the present study, Moosavi's study showed that the majority of personnel complain about the lack of facilities against X-rays (86%) and the lack of standard air conditioning systems (90%) (36), while Movahedi's study aimed at determining the radiation dose of orthopedic surgeons during fluoroscopy indicated that the radiation dose was not more than the determined threshold (37). The co-occurrence of sampling with coronavirus disease 19 caused a prolonged study time. The implementation of this method depends on the motivation of the leaders and team members, as well as the skill of the team in group discussion. In this regard, the researcher attempted to overcome this limitation and selected the team members very carefully and from experienced personnel.

Conclusion

By the FMEA method, 5 cases of unacceptable error were identified, along with identifying probable causes and effects of the error, and finally, corrective actions were presented as suggestions in two areas of decreasing frequency and severity, and increasing the ability to detect errors. To prevent the occurrence of errors, it is suggested to provide the health of operating room personnel, increase the quality of services, and reduce the costs of the treatment system, and retraining courses should be held for operating room personnel.

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Author's Contribution

Conceptualization: Arezou Karampourian, Behzad Imani.
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Competing Interests

There is no conflict of interests between the authors.

Ethical Approval

This study was approved by Hamadan University of Medical Sciences. Written consent was obtained from study participants (Code of Ethics: UMSHA.REC.1398.858).

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