Sakarya Üniversitesi Fen Bilimleri Dergisi
Sakarya University Journal of Science

e-ISSN : 2147-835X
Publisher : Sakarya University

Vol. 29, No. 2, 226-239, 2025
DOI: https://doi.org/10.16984/saufenbilder.1585752

Research Article

A New Risk Assessment Methodology Based on Control Limits

Müfide Narlı[1*], Şeyda Taşkınırmak[2], Cansu Dağsuyu[2], Ali Kokangül[1]

[1] Cukurova University, Faculty of Engineering, Department of Industrial Engineering, Adana, Türkiye, mnarli@cu.edu.tr, kokangul@cu.edu.tr, ror.org/05wxkj555
[2] Alparslan Türkeş Science and Technology University, Faculty of Engineering, Department of Industrial Engineering, Adana, Türkiye, scelikcan@atu.edu.tr, cdagsuyu@atu.edu.tr
[*]Corresponding Author

ARTICLE INFO

Keywords:
Operating room
Risk analysis
FMEA
Control limits

Article History:
Received: 15.11.2024
Revised: 03.02.2025
Accepted: 12.03.2025
Online Available: 18.04.2025

ABSTRACT

Operating rooms where surgical procedures are conducted involve hazards under various groups and potentially many health problems may arise from these hazards. The degree of the importance of the hazard in each risk group varies according to the groups and it is important to reflect this situation in the risk analyses. In the present study, the dangers may occur in the main groups, namely physical, chemical, and psychological hazard groups in the operating rooms, and the potential health problems that may result from these hazards were evaluated with Failure Mode Effect Analysis (FMEA) method for the first time. By taking the distribution of the FMEA values about the health problems due to hazards that may occur in each main group into consideration, a new approach is suggested in this study. With the new scale that is created based on the average and standard deviation of FMEA values, the comparative importance of the hazards within their groups was revealed. Thus, considering the comparative evaluations, the degrees of importance for health problems in terms of physical, chemical, psychological, and biological categorization were put forth. The COVID-19 outbreak caused a pandemic in the world was also considered in the biological risk class in the study. At the end of the study, the most critical health problems in the operating rooms were detected to be from the risk group resulting from chemical conditions.

1. Introduction

The healthcare industry is one of the fields where employees are faced with a high degree of physical and psychological tension due to the broadness and complexity of its activity area [1-3]. Because the patients, illnesses, and the rate at which the illnesses spread are ever-increasing, healthcare services and safety have been gradually gaining importance. The mistakes that may occur in the healthcare industry can easily jeopardize both the employee's and the patient's health. The risks that occur can cause serious results as well as small damages for those who are exposed to them. While providing healthcare services, these risks may cause injury to the patients, prolonged hospital stay, disability, and even death. These increase the risk of exposure to the health care problem for healthcare workers and lead to many problems for them such as injury.

Because the hazard factors creating risks in health services cause serious results, it is important to manage healthcare mistakes proactively [4]. According to the report entitled "To Err Is Human" prepared by the Institute of Medicine in 1999, 44000 – 98000 people lose their lives in the USA due to preventable medical mistakes every year. In the report, it is also stated that the deaths resulting from medical mistakes are greater in number than those caused by traffic accidents, lung cancer, and AIDS [5]. Surgical interventions constitute 52% of all patients presenting to the hospital [6]. This ratio displays the importance of operating rooms, where

Cite as: M. Narli, Ş. Taşkınırmak, C. Dağsuyu, A. Kokangül (2025). A New Risk Assessment Methodology Based on Control Limits, *Sakarya University Journal of Science*, 29(2), 226-239. https://doi.org/10.16984/saufenbilder.1585752

surgical interventions are conducted, in hospitals. Hence, it is important to determine the risks that may occur in healthcare institutions especially in operating rooms beforehand and to analyse them.

The risks that may occur in every unit in health institutions and their effect degrees are different from each other. Because the operating rooms where surgical procedures are carried out are used by many units, the risks that may occur in them may have an impact on the whole health institution. Prolonged working times depending on the time needed for the procedures make the operating room a critical unit.

In recent years, technological evolution has played an important role also in the development of surgery. This brings about important changes in the working conditions of the operating room. An increased number of complex devices leads to an increase in the interactions between people and technology [7]. Surgical operations are a key health service constituting 40% of the expenditures of the hospital [8]. In addition to this, hospital and operating room directors should determine preventive precautions for hazards that may create danger in the operating room to decrease the probability of risks that occur depending on the infrastructure-materials, experience, education and the services given and to eliminate them.

The hazards that may occur in the operating room are evaluated under three main headings in general, namely physical, chemical, and psychological hazards. The hazards that may occur in the operating rooms where the hazards are more effective on hospital workers cause temporary and permanent health problems for employees. Furthermore, it is stated that the gradual increase in the high cognitive and physical workloads of the workers may even affect the career life of the workers [2]. Thus, the hazards should be analysed by taking the health problems caused by them and their levels of importance into consideration. These analyses would also be effective in determining the precautions to be taken.
The studies in the literature have investigated the risks that may occur in the operating room, the results of these risks, and health care problem. Pan et al. (2018), have studied the risk factors of the infections associated with the operating room after coronary artery bypass grafting [9]. They detected that factor such as the operation durations exceeding four hours, guests in the operating room, and the successive use posed a high risk. When Sheikhzadeh et. (2009) examined the ergonomic risk factors of the nurses and technicians in the surgical environment, they stated that the workers perceived the operating room as a demanding, stressful, and complex work environment and that they had tiring physical work activities resulting in problems of musculoskeletal system [1].

Some studies demonstrate that the conditions of the operating room cause long-term occupational healthcare problems for the workers. In the study conducted by El Ata et al. (2016), back pain was detected as the most prevalent problem amoung the nurses in the operating room with a ratio of 76.1% among the workers as a result of having to stand up for extended periods and repeated motions and this problem is followed by the problems of the knees, shoulders, and ankles as the most affected organs [10]. In the study carried out by Yu et al. (2016), working for 6 or more years, more than one-night shifts, working for 40 or more hours during the week, weak health status, and feeling of fatigue were found to be associated with musculoskeletal system injuries due to work [2]. It has been stated that nurses working night shifts were more inclined to exhaustion, emotional inconsistency, and emotional depletion and their feeling of personal achievement was lower. Some studies that evaluate the operating rooms ergonomically [3, 11].

Vos s et al. (2017) argued that the surgeons tried to optimize the working conditions which were not ergonomic and that they had to take a break frequently [11]. By examining the working conditions of the operating room in terms of ergonomic risk factors, and grouping them as physical, cognitive, and corporate ergonomic risk factors, Vural and Sutsunbuloğlu (2016), makes recommendations for the specified risks [3]. Matern and Koneczny (2007) state that general working positions were found to be uncomfortable or painful by 84% of the surgeons, that sunlight is insufficient in the operating room environment, and that the air created a sense of dryness [7].

By examining the operating rooms in terms of air conditions, lighting, temperature, and oxygen status, the risks that may be caused by these factors were studied [12-15]. Ho et al. (2009) recommend a layout for supply grills for removal of the contaminating materials by simulating air conditions in the operating room [12]. In the study in which they evaluated the physical conditions of the operating rooms, Daskalakis et al. (2009), detected the temperature, moisture, ventilation, and light conditions to be more satisfactory while finding the air quality of the operating room insufficient [13]. Rinder (2008), stated that operating rooms had fire risks due to factors such as laser and oxygen use [14]. Culp et al. (2013), evaluated the ignition properties of the materials depending on the changing oxygen concentrations in the operating rooms [15]. They observed that the ignition time increased as the oxygen concentration decreased.

As seen in the literature the operating room consist of many risks and it is crucial to calculate their importance level them by using risk assessment techniques such as FMEA, Fine Kinney, AHP, etc. In the health sector, the use of FMEA is increasing due to the advantages it presents especially in the analysis and evaluation of the caused by people and medical devices [16]. Mosallanezhad (2018) handled the five basic processes, namely patient admission to the operating room transferring the patient, cleaning of the operating room, request for equipment repair in the operating room, and request for medical and pharmaceutical products in the operating room of a hospital, and analysed the risks that may occur by Fuzzy FMEA method [17]. Corrective precautions were recommended for the risks with RPN values over 4.

Khasha et al. (2013) used the Fuzzy FMEA method to determine the importance of investigating the factors that cause surgical cancellations [8]. As a result of this method, insufficient intensive care beds, high-risk intervention, high blood pressure, and diabetes patients were analysed as the most important factors causing surgical cancellations. Liu et al. (2014) proposed a 2-part hybrid-weighted method that considered the subjective and objective weights of risk factors and developed the classical FMEA method [18]. The proposed method was used in the blood transfusion study. Health risk analysis studies were examined which is different than the FMEA method [19-22].

Trucco and Cavallin (2006) proposed the "Clinical Risk and Error Analysis" method, which also takes into account the quantitative evaluation of critical organizational factors affecting patient safety [19]. The study was tested in drug applications in the vascular surgery department. Guo (2015) developed a risk management program based on Australian risk management standards in a hospital operating room in China [20]. The effects of risks were examined with the X-type matrix diagram for the 10 risk groups that were identified. Kasatpibal et al. (2016) examined the risk factors that cause blood-borne pathogenic diseases in operating room nurses using logistic regression analysis [21]. Pinhole and sharp blade injuries were found to be at high risk. Amghar et al. (2017) proposed a fuzzy Bayes network to identify and analyse operating room risks [22]. It has been demonstrated that factors such as the patient's age, physical condition, anaesthesia type, and wrong drug use have different effects on the patient's risk of death.

In the studies in the literature, the hazards that may come up in the operating rooms and their groups are studied. However, no risk analysis study comparing the importance levels of the hazards quantitatively was encountered in the literature review. In the present study, the risk groups that may occur in the operating room and the hazards that may come up in these groups were described and a risk analysis was done. The FMEA method recommended by the World Health Organization was preferred while conducting the risk analysis. The Joint Commission (JC), formerly called the Joint Commission on Accreditation of Health Care Organization (JCAHO), now requires all acute care hospitals to perform FMEA regularly [23]. The Technical Committee of the International Organization for Standardization (ISO) also suggests FMEA as a method for reducing high medical risks (ISO/TS 22367). In classical

FMEA studies, the risk score is determined according to the FMEA scale values but the change between the hazard groups and the hazards is not taken into consideration.

On the other hand, the risk score with the same value that may occur at different hazard dimensions (physical, chemical, psychological etc.) is expected to have different impacts. This situation was taken into consideration in the present study, and by considering the average and distribution values in the FMEA parameter values of the health problems that may occur in the main hazard sources in each hazard dimension, a new methodology was proposed. Thus, in the comparison of the scores of the health problems that may result from probable risks, the change in the hazard dimension would also be considered. In the proposed method, the total risk score, which was determined according to the average and distribution values of each hazard, was obtained and the hazard analysis was done precisely and comparatively. The rest of the study is organized as such: methodology is in Section 2; case study is in Section 3 and conclusion is in section 4.

2. General Methods

The method proposed in this study is based on the principle of considering the distributions in the groups by grouping the hazards. Risk analysis constitutes the first step of this method. Of the risk analysis methods, FMEA, which is commonly used in healthcare, was preferred. The FMEA method consists of Probability (P), severity (S) and detectability (D) parameters. The scale values for these parameters are given in

Table 1,2 and 3 respectively. This scale was determined by the Institute of Healthcare Improvement for Healthcare. The risk score according to the FMEA method is obtained by the multiplication of these three parameters as seen in Equation 1. The hazards that occur in real systems may be caused by different hazard sources and these hazards are categorized according to their sources. In the classical approach, when the hazards in different hazard sources have the same RPN value, this causes these hazards to be interpreted with equal importance. However, assessment of the hazards in the hazard source they belong to and their interpretation accordingly would be more effective in determining the importance levels of the hazards.

$$RPN = PxSxD \quad (1)$$

The approach developed as being based on the consideration of hazards consists of the following steps.

1. Description of the hazard sources
2. Determining the sub-hazards depending on the hazard sources or the health problems that may occur about to the hazard sources
3. Calculation of RPN values for each health problem based on hazards with Equation (1) by taking the scales in Table 1-3 into consideration.
4. Determining the control limits of P, S and D parameters (average (μ), standard deviation (σ), 2σ and 3σ values) based on of each hazard source(n)
5. Creating the scale table given in Table 4 according to the average and standard deviation values of each hazard

The FMEA scale consists of integer numbers. Thus, the limit values found in the scale table created according to the new approach are rounded to the nearest integer number. The limit values change according to the FMEA evaluation conducted. Although the lower limit's being smaller than 1 is not taken into consideration, the upper limit can be a maximum of 10.

Table 1. FMEA probability (P) scale [24]

Criteria/ risk	Rating	Description (Detection of failure)
None	1	Remote: failure is unlikely, one occurrence in greater than five years
Very Low	2	One occurrence every three to five years
Low	3	Low: relatively few failures, one occurrence every one to three years
Moderate	4	One occurrence per year
	5	One occurrence every six months to one year
	6	Moderate: occasional failures, one occurrence every three months
High	7	One occurrence every month
Very High	8	High: repeated failures, one occurrence per week
Extremely High	9	One occurrence every three to four days
Dangerously High	10	Failure is almost inevitable. More than one occurrence per day

Table 2. FMEA severity (S) scale [24]

Criteria/ risk	Rating	Description (Detection of failure)
None	1	No noticeable effects
Very Minor	2	Slight inconvenience at delivery; minor rework. Failure detected and corrected at delivery.
Minor	3	Slight inconvenience at next function; minor rework. Failure detected and corrected at next step of the process.
Very Low	4	Inconvenience at subsequent function; minor rework. Failure detected and corrected at subsequent step of the process.
Low	5	Inconvenience for patient and provider with failure being detected.
Moderate	6	Failure causes disruption of patient activities of daily living leading to dissatisfaction
High	7	Failure seriously affects patient's health leading to high patient dissatisfaction.
Very High	8	Failure causes patient's health to be seriously affected and patient has to return for major correction.
Extremely High	9	Failure involves regulatory noncompliance and could cause long term disability.
Dangerously high	10	Failure could cause terminal injury or death of the patient

Table 3. FMEA detection (d) scale [24]

Criteria/ risk	Rating	Description (Detection of failure)
Almost certain	1	Current controls almost certain to detect the failure mode. Reliable detection controls are known with similar processes. Process automatically prevents further processing.
Very High	2	Current controls almost certain to detect the failure mode. Process automatically detects failure mode.
High	3	Current controls almost certain to detect the failure mode. Process automatically detects failure mode.
Moderately High	4	Controls have a good chance of detecting failure mode. Error detection at service delivery.
Moderate	5	Controls may detect the existence of a failure mode. Error likely to be detected after service delivery.
Low	6	Controls may detect the failure.
Very Low	7	Controls have a low chance of detecting the existence of failure.
Remote	8	Controls have a poor chance of detecting the existence of failure mode.
Very Remote	9	Controls probably will not detect the existence of failure mode. Control achieved with indirect or random checks only.
Absolute Uncertainty	10	Controls will not or cannot detect the existence of a failure. No known controls available to detect failure mode.

If σ value is less than 1; for P, S, and D value in $(\mu, \mu + \sigma)$ interval not to have a value less than the value in $(\mu - \sigma,\ \mu)$ interval, $1/\sigma$ value is considered as σ and this situation is reflected in Table 4. Also, since the upper limit value will not be greater than 10if the μ+3σ

value is greater than 10 for the P, S, and D values, this value is accepted as 10 and this situation is reflected in Table 4.

P, S, and D values for the hazard (i) in each hazard source (n) are determined according to the scale values found in Table 4 for P, S, and, D and the proposed RPN ($\boldsymbol{RPN_n}$) value is calculated with Equation (2).

$$\boldsymbol{RPN_{ni} = P_n * S_n * D_n} \quad \text{i=1,2,..m} \tag{2}$$

By taking the sum of $\boldsymbol{RPN_n}$ values about a sub-hazard of each hazard group, the importance levels of the sub-hazards are determined.

$$\boldsymbol{Total\ RPN_n} = \sum_{i=1}^{m} \boldsymbol{RPN_{ni}} \tag{3}$$

Table 4. Proposed scale method

Class	Limit Values		Scale value (P_n, S_n, D_n)
	Lower limit	Upper limit	
1	$\mu + 2\sigma$	if $(\mu + 3\sigma) \geq 10.10$ otherwise $\mu + 3\sigma$	3σ
2	$\mu + \sigma$	$\mu + 2\sigma$	2σ
3	μ	$\mu + \sigma$	σ
4	$\mu - \sigma$	μ	$if\ \ \sigma \geq 1.1/\,\sigma$ $otherwise\quad \sigma$
5	$\mu - 2\sigma$	$\mu - \sigma$	$1/\,2\sigma$
6	$if\ \ (\mu - 3\sigma) \leq 1.\,1/\,\sigma$ $otherwise\quad \sigma$	$\mu - 2\sigma$	$1/\,3\sigma$

3. Case Study

The study was conducted out in a private hospital with a high bed capacity and operating room with different characteristics. The hazards that occur in the operating room were examined under 4 main headings, which are physical, chemical, psychological, and biological hazards. A description of the hazards that may occur under each main heading and the assessment of the health problems resulting from these hazards were carried out with the classical risk analysis approach and with the approach proposed in this study. The hazards were determined by literature review and by taking the operating room team. The risks taken from the literature are given in the tables together with their sources. Determining the hazards and their assessment were conducted in collaboration with the operating room team of a large-scale hospital.

i. Risk Analysis for Physical Conditions

The physical hazards that might take place in the operating room were gathered under three main headings noise, insufficient ventilation, and lighting by the literature and expert opinion. The health problems that may occur due to physical conditions such as hearing loss, cardiovascular disorder problems, etc. are given in Table 5. Risk analysis was done based on FMEA with Equation (1) according to the health problems caused by physical hazards and the results are given in Table 5. This risk analysis determined that the most important health problem for the noise hazard was "headache", the most important health problem caused by insufficient ventilation was "heat injury" and the most critical health problem occurring as a result of lighting hazard was "eye disorders". The "hearing loss" and "cardiovascular disorder" with 25 RPN values calculated by Equation (1) as a result of FMEA have the respective 3rd and 2nd importance levels in the hazard group they belong to. This situation necessitates the investigation of distributions in the hazard group when determining the RPN values. Thus, for each hazard group, value description was done according to distribution of P, S, and D values of FMEA parameters. P, S, and D values for each hazard group are given in Table 5.

The average and standard deviation values for these values were rounded to the nearest integer number and scale values for P, S, and D parameters according to Table 4 are given in Table 6, 7, and 8. It can be seen in Table 5 that although the rankings of the health problems in the hazard group do not change according to the classical RPN and the proposed RPNn, differences occur in the comparisons between hazards. Although "hearing loss" in the noise hazard group and "cardiovascular disorder" under the insufficient ventilation group possess equal importance in the classical assessment (RPN=25), the order of importance could be determined with the proposed method and it is seen in Table 5 that the "cardiovascular disorder" has a higher level of importance. Moreover, some hazards have a higher ranking in importance according to the proposed method despite having a lower RPN value. The "psychological disorder" in the noise hazard group has a higher RPN value than the "eye disorder" under lighting. But "eye disorder" has a higher importance level with the RPNn value where distribution in the hazard groups is taken into consideration. Thus, the level of importance for each health problem based on each hazard is determined and a more precise and correct assessment is done. With Equation (3), the RPNn values of the health problems in each hazard group were added mathematically and the importance levels of the health problems were determined and given in Table 5. According to this evaluation, as seen in Table 5 the order of the health problems due to physical hazards in the operating room according to importance can be sequenced as “headache”, “heat injury”, “psychological disorder” and “cardiovascular disorder”. However, the order of importance does not change for the health problems when the sum of the classical RPN values is taken into consideration. It is seen that the importance level of other health problems is examined. It can be seen in Table 5 that total prioritization can be made between health problems (hearing loss and cardiovascular disorder) with equal total RPN value in the classical evaluation with the proposed method.

Table 5. Risk assessment for physical conditions

No (i)	Health Problems	Noise					Insufficient air conditioning					Lighting					Total RPN	Total RPN_n	Rankig RPN_n
		P	S	D	RPN	RPN_{ni}	P	S	D	RPN	RPN_{ni}	P	S	D	RPN	RPN_{ni}			
1	Hearing loss	1	5	5	25	0.079 [25]											25	0.079	10
2	Cardiovasculer disorder						1	5	5	25	0.715						25	0.715	4
3	Psychological disorder	3	3	8	72	0.341 [25]	1	3	5	15	0.442						87	0.782	3
4	Heat injury						3	4	4	48	1.294						48	1.294	2
5	Heat loss						2	4	3	24	0.566 [26]						24	0.566	5
6	Faint						1	5	1	5	0.156						5	0.156	9
7	Tearing											5	3	2	30	0.331	30	0.331	7
8	Eye disorder											2	5	4	40	0.378 [27]	40	0.378	6
9	Headache	7	4	4	112	1.468	1	3	4	12	0.442 [13]	3	4	2	24	0.283	148	2.193	1
10	Fluid loss						3	3	2	18	0.175						18	0.175	8

Table 6. Noise hazard P, S and D description

	P			S			D		
	Lower Value	Upper Value	Value	Lower Value	Upper Value	Value	Lower Value	Upper Value	Value
$\mu + 2\sigma, \mu + 3\sigma$				6	7	3.00			
$\mu + \sigma, \mu + 2\sigma$	7	10	6.11	5	6	2.00	8	10	4.16
$\mu, \mu + \sigma$	4	7	3.06	4	5	1.00	6	8	2.08
$\mu - \sigma, \mu$	1	4	0.33	3	4	1.00	3	6	0.48
$\mu - 2\sigma, \mu - \sigma$	0	1	0.16	2	3	0.50	1	3	0.24
$\mu - 3\sigma, \mu - 2\sigma$				1	2	0.33			

i. Risk Analysis for Chemical Conditions

The hazards that may occur due to chemical conditions in the operating room were classified under four main headings “disinfectants and sterilizers, “Cleaning Chemicals”, “laser” and “waste gases” given in Table 9 as a result of expert opinion and literature review. According to the classical FMEA assessment, the most important health problem for the “disinfectants and sterilizers” “allergic reaction”. ‘Toxic effects such as nausea and dizziness’ and the “destroying the skin's protective properties” are the problems with equal and highest importance for the heading cleaning chemicals; "destroying the skin's protective properties" is again the health problem with the highest importance for the laser hazard group, and "toxic effects such as nausea and dizziness" is the most important health problem for waste gases hazard group.

Table 7. Insufficient ventilation hazard P, S and D description

	P			S			D		
	Lower Value	Upper Value	Value	Lower Value	Upper Value	Value	Lower Value	Upper Value	Value
$\mu+2\sigma,\mu+3\sigma$	4	5	2.85	6	7	2.70	6	8	4.54
$\mu+\sigma,\mu+2\sigma$	3	4	1.90	5	6	1.80	5	6	3.02
$\mu,\mu+\sigma$	2	3	0.95	4	5	0.90	3	5	1.51
$\mu-\sigma,\mu$	1	2	0.95	3	4	0.90	2	3	0.66
$\mu-2\sigma,\mu-\sigma$	0	1	0.53	1	3	0.56	1	2	0.33
$\mu-3\sigma,\mu-2\sigma$				0	1				

Table 8. Lighting hazard P, S and D description

	P			*S*			*D*		
	Lower Value	*Upper Value*	*Value*	*Lower Value*	*Upper Value*	*Value*	*Lower Value*	*Upper Value*	*Value*
$\mu+2\sigma,\mu+3\sigma$	6	8	4.58	6	7	3	5	6	3.46
$\mu+\sigma,\mu+2\sigma$	5	6	3.06	5	6	2	4	5	2.31
$\mu,\mu+\sigma$	3	5	1.53	4	5	1	3	4	1.15
$\mu-\sigma,\mu$	2	3	0.65	3	4	1	2	3	0.87
$\mu-2\sigma,\mu-\sigma$	1	2	0.33	2	3	0.5	1	2	0.43
$\mu-3\sigma,\mu-2\sigma$				1	2	0.33			

With the consideration of distribution in the hazard group in Equation (2) based on Table 4 formulations proposed in the study;

- It could be determined that among the health problems "toxic effects such as nausea and dizziness" and "destroying the skin's protective properties" that are in the cleaning chemicals hazard group and have equal RPN values, the 'destroying the skin's protective properties was more critical; and that 'allergic reactions' was more critical when compared with the health problem 'headache'.

- In the laser hazard group, 'headache' and "eye disorders" have equal points and importance according to classical RPN assessment but with RPN_n, "eye disorders" were detected to be more critical in this group.

- Although "eczema" and "fatigue" health problems caused by disinfectants and sterilizers and "waste gases" hazards respectively have the same importance in terms of classical RPN value, it was determined that "fatigue" problem due to "waste gases" had more critical importance when compared with the proposed method. When the total value of classical RPN values resulting from chemical conditions are taken into consideration, it is seen in Table 9 that the most important health problem is "toxic effects such as nausea and dizziness". According to the total risk score values calculated by equation (3), the order of health problems according to importance are "destroying the skin's protective properties", 'toxic effects such as nausea and dizziness' and "allergic reaction". Working in a closed environment for long hours and especially the use of many disinfectants sterilizers and components in the operating room make the operating room critical due to exposure to chemical effects.

ii. Risk Analysis for Psychological Conditions

Another main hazard group encountered in the operating rooms is psychological hazards due to intensive and stressful working conditions. Psychological hazards were divided into three basic hazard groups, namely 'working conditions', 'night shift' and 'fear of contamination". The sub-hazards that may be caused by these hazards and the risk evaluation of these hazards are given in Table 10. By taking the distribution of the “over fatigue” hazard group within itself into consideration, it is seen that (RPN_{ni}) “over fatigue” creates a greater risk in the “night shift” than the “working conditions” that has the same RPN value with the classical analysis. While “unwillingness to work” on the night shift has a lower importance point than all the hazards caused by working conditions according to the classical RPN value, it was detected to have a higher importance than the hazards caused by the working conditions because of the RPNni assessment. In the general evaluation, the most important hazards according to the Total RPN value are ranked as follows: 'anxiety disorder,' non-adaptation to the working environment, and depression. However, the order of importance of the probable hazards, based on the RPN values calculated with Equation (3), is: 'anxiety disorder,' depression, and 'unwillingness to work,' as shown in Table 10."

Table 9. Risk assessment for chemical conditions

No	Health Problems	Disinfectants and sterilizers					Cleaning chemicals					Laser					Waste gases					Total RPN	Total Risk Score RPN_n	Rank RPN_n
		P	S	D	RPN	RPN_{ni}	P	S	D	RPN	RPN_{ni}	P	S	D	RPN	RPN_{ni}	P	S	D	RPN	RPN_{ni}			
1	Allergic Reaction	9	7	2	126	2.216	2	3	4	24	0.501											150	2.717	3
2	Toxic Effects Such as Nausea and Dizziness	8	7	2	112	2.216	3	5	3	45	0.706						2	5	3	30	0.765	187	3.686	2
3	Fatigue											1	2	4	8	0.174	3	2	4	24	0.330	32	0.504	7
4	Headache	8	5	2	80	0.484	4	3	2	24	0.252	1	3	5	15	0.354	1	3	2	6	0,.63	125	1.253	5
5	Destroying the Skin's Protective Properties	3	8	2	48	0.111 [28]	3	5	3	45	2.520 [28]	4	6	3	72	2.855						165	5.486	1
6	Egzama	6	4	1	24	0.024 [28]	4	4	2	32	0,50 [28]											56	0.528	6
7	Eye Disorders	1	7	7	49	1.044						1	5	3	15	0.638						64	1.681	4

Table 10. Risk assessment for psychological conditions

No	Health Problems	Working Conditions					Night Shift					Fear of Contamination					Total RPN	Total Risk Score to Ensure Accuracy	Ranking
		P	S	D	RPN	RPN_{ni}	P	S	D	RPN	RPN_{ni}	P	S	D	RPN	RPN_{ni}		RPN_n	RPN_n
1	Non-adaptation to the Working Environment	7	3	3	63	0.365 [1]	2	2	4	16	0.137 [2]	6	6	4	144	0.514		1.016	5
2	Unwillingness to Work	6	6	4	144	2.191	6	3	2	36	0.626 [2]	7	5	1	35	0.243	223	3.060	3
3	Over Fatique	6	5	2	60	1.095	5	4	3	60	1.826 [2]						215	2.921	4
4	Depression	8	6	2	96	2.191						6	7	3	126	1.027	120	3.218	2
5	Anxiety Disorder	6	5	4	120	2.191	3	6	6	108	6.390	6	6	3	108	0.514 [29]	222	9.095	1

Table 11. Risk assessment for biological conditions

No	Health Problems	Exchange of Potentially Contaminated items		Working at Close Distance		Damage of Protective Equipment, Gloves, Mask etc.		Training and Practice of Health Personnel on the Subject	
		P S D RPN	RPN_{ni}	P S D RPN	RPN_{ni}	P S D RPN	RPN_{ni}	P S D RPN	RPN_{ni}
1	Hepatit B	3 2 3 18	0.306 [30]			2 1 8 16	0.212	1 2 7 14	0.133
2	HIV	1 8 1 8	1.500 [30]			1 7 8 56	3.394	1 8 7 56	1.673
3	HCV	1 8 2 16	2.750 [30]			1 7 8 56	3.394	1 7 7 49	1.673
4	Tbc			1 5 2 10	0.157 [31]				
5	HDV-delta Hepatit	1 8 3 24	2.750			1 7 8 56	3.394	1 7 7 49	1.673
6	Covid-19			3 8 5 120	6.364 [32]	3 8 5 120	1.886 [32]	4 8 9 288	12.048 [33]

Table 12. Ranked evaluation of biological agents based on total risk score under unidentified infection conditions

No	Health Problems	Unidentified Infection					Total RPN	Total Risk Score RPN	Ranking RPNn
		P	S	D	RPN	RPN_n			
1	Hepatit B	2	1	8	16	0.156	64	0.806	6
2	HIV	2	7	8	112	2.049	232	8.616	4
3	HCV	2	7	8	112	2.049	233	9.866	3
4	Tbc	3	7	7	147	1.502	157	1.660	5
5	HDV-delta Hepatit	2	7	9	126	2.185	255	10.003	2
6	Covid-19	5	8	10	400	12.821	928	33.118	1

Hepatitis virus-related diseases, tuberculosis, and Covid-19 which affect the whole world are the main biological risks encountered in operating rooms. Since the hepatitis virus and COVID-19 tests are usually performed before surgery, probability values are usually low. However, since the confidence intervals of the tests are changeable, waiting for the test results in situations that require emergency surgery such as brain haemorrhage can lead to untested situations, as the patient dies. Biological risk increases in the operating room due to "Contamination during the insertion and removal of the injector, etc'' during insertion and removal of a piercing cutting tool like an injector.
There is an evaluation for five groups and two of them are "Contamination during the the insertion and removal of the injector, etc ". Apart from this, the hazard of 'contamination of infected particles from the ventilation system' is also one of the biological risk factors in the operating room. However, this hazard was determined but the evaluation of it could not be done. Generally, negative compressed air is used in the operating rooms, and the ventilation system uses clean air; these are the only risk factors for COVID-19.

Probability, severity, and detectability values for COVID-19 were determined as 3.8.7, respectively with expert opinion. According to this evaluation, the RPN value poses the most significant risk with 168 but it was not considered in the evaluation since no other hazard was identified.

As a result of the evaluation based on biological risks, COVID-19 disease is the riskiest disease due to "unidentified infection". According to the total evaluation, Covid-19 disease is followed by HDV, HCV, and HIV. The ranking obtained with the approach suggested in the study is provided in Table 11 and Table 12.

The results obtained according to the total RPNn for each hazard group are given in Figure 1. The hazard numbers within each hazard group are given on the bars. The most critical health problem in the operating room according to Figure 1 occurs due to biological conditions with the “Covid-19”. This health problem is followed by the hazards with numbers 5 and 3 that occur also due to biological conditions. This situation shows that the most critical risk source consists of biological conditions. In Figure 1, it is seen that the most critical hazard group after the hazards and health problems due to biological conditions result from psychological conditions. The fact that teams consisting of many workers from different levels work in the operating room for long working hours also makes psychological conditions important and its importance status is seen in Figure 1.

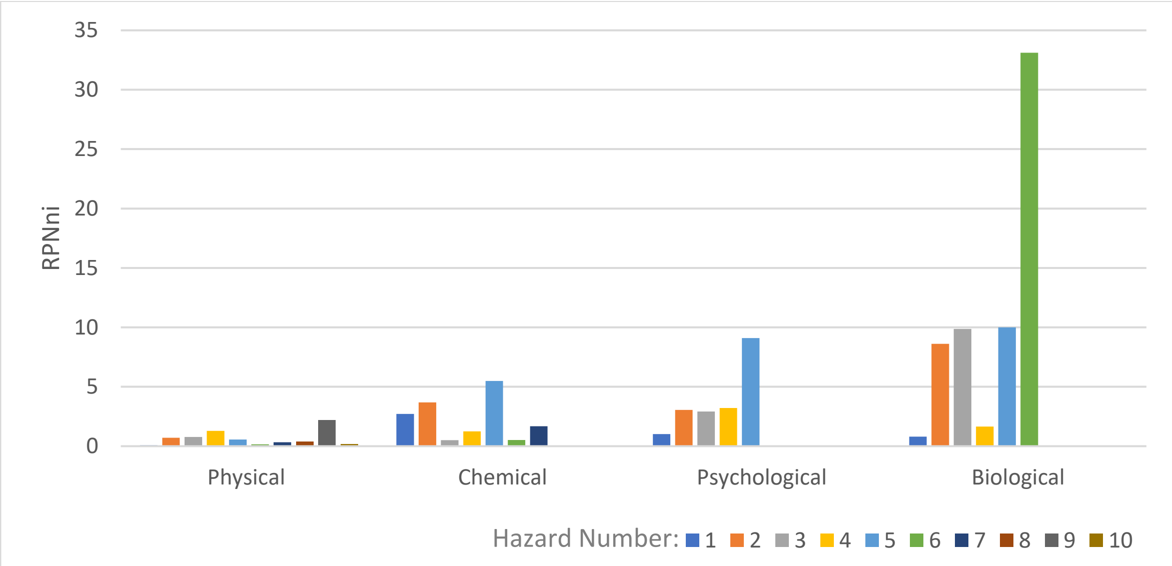

Figure 1. General evaluation

4. Conclusion

Risk analyses find an application area in every sector with legal regulations and with the increase in social conscience. There are many methods used in risk analyses and scaling is done according to the scales determined in these methods. However, when risk analyses are investigated on practices, it is seen that the place and distribution of the hazard in its source is an important factor. Risk analyses that take the distribution of each health problem in the hazard source contribute to determining the importance levels of the health problems more precisely and correctly. The steps that were followed in the method that was developed in this study and the sub-hazard (health care problems) caused by these hazards by the FMEA method, scale definition of the P, S, and D points in this evaluation according to the average and standard deviation values in the related hazard source and obtaining the RPNn values by doing the risk analysis according to this new scale and calculation of the total RPNn value. The risk analysis done depending on the scale according to the distribution of P, S, and D values in the hazard source constitutes the original aspect of the study.

Healthcare services are work areas in which activities related to every section of society are carried out and which contain many risks to work and about the health of workers. With its many departments, factors such as the generally long working hours in the operating rooms where all surgical procedures are performed and the simultaneous work of many people in the operations bring about many probable hazards and may cause health problems.

This situation necessitates risk analyses to be done in the operating rooms. Thus, the approach proposed in this study was carried out by taking the operating room department of a big hospital into consideration. The hazards that could occur in an operating room were analysed in four classes: Physical, chemical, psychological, and biological hazards.

The descriptions of hazards and potential risk and/or sub-hazards that can occur due to hazards in each group were made, and risk assessment was done with the proposed method. As a result of this evaluation, the most important hazards were determined as "headache", 'Loss of protective feature of the skin', "anxiety disorder" and "Covid-19" in the physical, psychological, and biological conditions respectively. The approach proposed in the study can be used in the production sector or different departments of the hospitals in future studies.

Article Information Form

Acknowledgments
We would like to thank Prof. Dr. Yasemin Güneş from the Department of Anesthesiology at Çukurova University and Dr. Mesut Koca, pediatric surgeon at a private hospital, for their valuable support and contributions to this study

Funding
Authors have not received any financial support for the research, authorship, or publication of this study.

Authors Contribution
Authors contributed equally to the study.

The Declaration of Conflict of Interest/ Common Interest
No conflict of interest or common interest has been declared by authors.

The Declaration of Ethics Committee Approval
This study does not require ethics committee permission or any special permission.

The Declaration of Research and Publication Ethics
Authors of the paper declare that they comply with the scientific, ethical, and quotation rules of SAUJS in all processes of the paper and that they do not make any falsification of the data collected. In addition, they declare that Sakarya University Journal of Science and its editorial board have no responsibility for any ethical violations that may be encountered and that this study has not been evaluated in any academic publication environment other than Sakarya University Journal of Science.

References

[1] A. Sheikhzadeh, C. Gore, J.D. Zuckerman, M. Nordin, "Perioperating nurses and technicians perceptions of ergonomic risk factors in the surgical environment," Applied ergonomics, 40(5), 833-839, 2009.

[2] D. Yu, B. Lowndes, C. Thiels, J. Bingener, A. Abdelrahman, R. Lyons, S. Hallbeck, "Quantifying intraoperative workloads across the surgical team roles: Room for better balance?," World journal of surgery, 40(7), 1565-1574, 2016.

[3] F. Vural, E. Sutsunbuloglu. "Ergonomics: an important factor in the operating room," Journal of perioperative practice, 26(7-8), 174-178, 2016.

[4] N. Rafter, A. Hickey, S. Condell, R. Conroy, P. O'Connor, D. Vaughan, D. Williams, "Adverse events in healthcare: learning from mistakes," *QJM*, 108(4), 273–277. 2014.

[5] L.T. Kohn, J. M. Corrigan, M. S. Donaldson. To Err Is Human: Building a Safer Health System, National Academies Press, 2000.

[6] D. Gupta, "Surgical Suites' Operations Management," Production and Operations Management, 16(6), 689–700, 2009.

[7] U. Matern, S. Koneczny, "Safety, hazards and ergonomics in the operating room," Surgical endoscopy, 21(11), 1965-1969, 2007.

[8] R. Khasha, M. M. Sepehri, T. Khatibi, T, "A fuzzy FMEA approach to prioritizing

surgical cancellation factors," International Journal of Hospital Research, 2(1), 17-24, 2013.

[9] L. Pan, S. Tan, L. Cao, X. Feng, "Risk factor analysis and management strategies of operating room-related infections after coronary artery bypass grafting," Journal of thoracic disease, 10(8), 4949, 2018.

[10] G. Abo El Ata, S. El Desouky, M. Manawil, E. Khalifa, "Assessment of work-related musculoskeletal symptoms in operation room nurses," Curr Sci Int, 5(2), 215-22, 2016.

[11] R. K. Voss, Y. J. Chiang, K. D. Cromwell, D.L. Urbauer, J. E. Lee, J. N. Cormier, C.C. H. Stucky, C. C. H. "Do no harm, except to ourselves? A survey of symptoms and injuries in oncologic surgeons and pilot study of an intraoperative ergonomic intervention," Journal of the American College of Surgeons, 224(1), 16-25, 2017.

[12] S. H. Ho, L. Rosario, M. M. Rahman, "Three-dimensional analysis for hospital operating room thermal comfort and contaminant removal," Applied Thermal Engineering, 29(10), 2080-2092, 2009.

[13] E. G. Dascalaki, A. G. Gaglia, C. A. Balaras, A. Lagoudi, "Indoor environmental quality in Hellenic hospital operating rooms," Energy and Buildings, 41(5), 551-560, 2009.

[14] C. S. Rinder, "Fire safety in the operating room," Current Opinion in Anesthesiology, 21(6), 790-795, 2008.

[15] W. C. Culp, B.A. Kimbrough, S. Luna, "Flammability of surgical drapes and materials in varying concentrations of oxygen," Anesthesiology: The Journal of the American Society of Anesthesiologists, 119(4), 770-776, 2013.

[16] J. W. Senders, "FMEA and RCA: the mantras; of modern risk management," *BMJ* Quality & Safety, 13(4), 249-250, 2004.

[17] B. Mosallanezhad, "Using fuzzy FMEA to increase patient safety in fundamental processes of operating room," Journal of Industrial and Systems Engineering, 11(3), 146-166, 2018.

[18] H. C. Liu, J. X. You, X. Y. You, "Evaluating the risk of healthcare failure modes using interval 2-tuple hybrid weighted distance measure," Computers & Industrial Engineering, 78, 249-258, 2014.

[19] P. Trucco, M. Cavallin, "A quantitative approach to clinical risk assessment: The CREA method," Safety science, 44(6), 491-513, 2006.

[20] L. Guo, "Implementation of a risk management plan in a hospital operating room", International Journal of Nursing Sciences, 2(4), 348-354, 2015.

[21] N. Kasatpibal, J. D. Whitney, S. Katechanok, S. Ngamsakulrat, B. Malairungsakul, P. Sirikulsathean, T. Muangnart, "Prevalence and risk factors of needlestick injuries, sharps injuries, and blood and body fluid exposures among operating room nurses in Thailand," American journal of infection control, 44(1), 85-90, 2016.

[22] M. Amghar, B. Zoulloutı, N. Sbıtı, "Risk analysis of operating room using the fuzzy bayesian network model," International Journal of Engineering, 30(1), 66-74, 2017.

[23] Institute for Healthcare Improvement (Access date: April 1, 2025). Patient safety essentials toolkit: Failure Modes and Effects Analysis (FMEA) tool [Online]. Available: https://www.ihi.org/sites/default/files/SafetyToolkit_FailureModesandEffectsAnalysis.pdf

[24] D. H. Stamatis, "Failure mode and effect analysis: FMEA from theory to execution. Quality Press," 2003.

[25] Alemdağ, M. Ameliyathanede Çalışan Sağlık Personelinin Sağlığı Geliştirici

Yaşam Biçimi Davranışları ve İlişkili Faktörlerin Belirlenmesi (Doctoral dissertation, Ankara Yıldırım Beyazıt Üniversitesi Sağlık Bilimleri Enstitüsü), 2019.

[26] R. Van Gaever, V. A Jacobs, M. Diltoer, L. Peeters, S. Vanlanduit, "Thermal comfort of the surgical staff in the operating room," Building and Environment, 81, 37-41, 2014.

[27] M Lembo, V. Cannatà, A. Militello, M. Ritrovato, S. Zaffina, P. Derrico, M Borra, "Artificial lighting and blue light in the operating room: What risks for the surgeon," La Medicina del lavoro, 106(5), 342-350, 2015.

[28] S. Q. Wilburn, G. Eijkemans, "Preventing needlestick injuries among healthcare workers: A WHO–ICN Collaboration," International Journal of Occupational and Environmental Health, 10: 451–456, 2004.

[29] M. S. Spoorthy, S. K. Pratapa, S. Mahant, "Mental health problems faced by healthcare workers due to the COVID-19 pandemic–A review," Asian Journal of Psychiatry, 51, 102119, 2020.

[30] S. Reddy, R. Manuel, E. Sheridan, G. Sadler, S. Patel, P. Riley, P, "Brucellosis in the UK: A Risk to Laboratory Workers? Recommendations For Prevention and Management of Laboratory Exposure," J. Clin Pathol, 63, 90-92, 2010.

[31] S. Hoşoğlu, A. Ç. Tanrıkulu, C. Dağlı, Ş. Akalın Ş "Bir Üniversite Hastanesinin Çalışanlarında Tüberküloz Riski," Toraks Dergisi, 5(3): 196-200, 2004.

[32] A. S. Karaca, M. M. Özmen, A. D. Uçar, A. Ç. Yastı, S. Demirer, "COVID-19'lu hastalarda genel cerrahi ameliyathane uygulamaları," Turk J Surg, 36(1), 6-10, 2020.

[33] R. Pan, L. Zhang, J. Pan, "The Anxiety Status of Chinese Medical Workers During the Epidemic of COVID19: A Meta-Analysis", Psychiatry investigation, 17(5), 475–480, 2020.