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# Challenges and prerequisites of risk management program in the operating rooms of Iranian hospitals: A qualitative study

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## Abstract:

**BACKGROUND:** The World Health Organization (WHO) considers a safe operating room as one of the necessities of hospitals that support patients. Achieving safety in surgical operations in all countries of the world is the basic goal of healthcare centers and organizations; hence, the present study investigated the challenges and prerequisites for the implementation of an active risk management program in the operating rooms of Iranian hospitals.

**MATERIALS AND METHODS:** This qualitative-phenomenological study was conducted in 2022. Data were collected using semi-structured interviews, targeted sampling, and the participation of 20 experts (health policy and management experts and academic officials and faculty members of universities) and executive staff (nurses and operating room technicians, doctors and surgical specialists, and officials of surgical departments) and were analyzed using the framework analysis method.

**RESULTS:** In the resulting qualitative study, the challenges and prerequisites for active risk management in the operating room from the point of view of experts and executive staff were divided into three sub-themes. These three themes include managerial challenges and prerequisites, organizational resources (financial resources, human resources, equipment, and facilities), and cultural issues.

**CONCLUSION:** Considering managerial prerequisites, organizational resources (financial, human, equipment, and facilities), cultural issues, and removing challenges, an active risk management program in the operating room can be implemented correctly. With the correct implementation of this program, injuries in the operating room for personnel and patients will be greatly reduced, and the satisfaction of beneficiaries and the productivity of the hospital will be greatly increased.

## Keywords:

Operating rooms, risk, risks management

## Introduction

Crisis is one of the most important problems and the most frequent events that hospitals worldwide face and are challenged by.<sup>[1]</sup> Because most accidents and disasters are unpreventable, it is necessary to increase the level of preparedness of the healthcare system, especially

hospitals, to reduce the number of deaths and injuries caused by them.<sup>[2]</sup> Hospitals must have a pre-prepared operational plan to deal effectively with critical situations. The absence of such a program will increase disorder and confusion in affairs.<sup>[3]</sup> The existence of a suitable clinical risk management system is necessary for the health systems of countries. It is

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necessary to take a more holistic view of the occurrence of the risk, understand the structure that governs it, and learn from the way systematic risks appear.<sup>[4]</sup> The risk management components include safety, employee health, patient safety, employee safety, infection control, incident plans, quality assurance, incident reporting, and environmental safety. Safety is an important mission for hospitals and should be considered by hospital managers. Safety programs are no less important than employees, facilities, equipment, budgets, and other management duties.<sup>[5]</sup> The operating room is one of the most important treatment environments in the healthcare system, with special complications. This complexity is related to patient issues and the use of complex medical equipment and technology. The operating room is considered the driving force of the hospital, which is the center of the concentration of valuable scientific and technological funds for the treatment units of each center. The operating room is threatened by a variety of activities and specializations as well as various types of accidents and crises, such as electric shocks, explosions caused by medical gases, and fires.<sup>[6]</sup> In this regard, the need for effective management to coordinate with fast and increasing changes is necessary to ensure the safety of this medical department for the employees working in it, as well as for the patients. Concerning accidents and disasters, and in general, any crisis inside or outside the hospital, increasing the safety level of patients and staff working in the operating room is the main goal. Providing the required security and efficiency in times of crisis is of particular importance because of limited resources, medical equipment, suitable spaces, and economic issues in this regard.<sup>[7]</sup> The World Health Organization considers a safe operating room to be one of the necessities of patient-supporting hospitals. Achieving safety in surgical operations in all countries is the main goal of healthcare centres and organizations; therefore, the operating room is an integral part of healthcare facilities worldwide.<sup>[8]</sup> Detailed planning in the field of quality assurance and possible risk management will help to identify risk areas in the surgical department and eliminate or reduce these potential risks. Because the operating room is especially concerned with people's health and society monitors its actions with special sensitivity, managing it and managers' awareness of the principles of safety and security in the operating room is of particular importance. The purpose of managing potential risks in the operating room is to prevent patients from being harmed and prevent and limit financial losses.<sup>[9]</sup> Electrocutation, fire, contact of employees with contaminated blood products, and inhalation of toxic gases are among the major physical injuries in operating rooms. Therefore, employees and patients are never completely safe, but the risks can be minimized. If employees are careless in using devices such as lasers, radiography equipment, and

chemical sterilizers, it can lead to long-term damage. The operating room and surgery department of each hospital are known as the most dangerous parts of the hospital based on the educational, environmental, and technological needs of the organization.<sup>[8]</sup> According to evidence from developed countries, nearly 50% of all unwanted events in hospitals occur in operating rooms, and more than half of them are preventable.<sup>[10]</sup> The lack of effective management and other deficiencies related to technical, human, and organizational factors lead to the occurrence of errors and adverse events. For example, there is a lack of proper communication and training, as well as inadequate standard procedures. These cases have led to the occurrence of issues such as mistakes in the place of surgery, the method of surgery, and the management of anesthesia, which are very significant in the operating rooms, as well as endangering the lives of patients, imposing a lot of costs on the healthcare system. Therefore, some factors affecting the occurrence of medical errors in the operating room can be prevented. To increase the quality of care, errors and adverse events in the operating room should be reduced.<sup>[11]</sup> Considering the positive results of active risk management in hospital operating rooms in order to reduce risks and increase the satisfaction of patients and employees, it is necessary to analyze the challenges and prerequisites of implementing active risk management in hospitals, especially in operating rooms where most of the complaints related to risks is assigned to itself. Also, according to cross-sectional studies scattered across the country, thus far, the summary of the results of the studies that examine the challenges and prerequisites and the implementation of the active risk management program in the operating room has not been completed. Therefore, this study investigated the challenges and prerequisites for the implementation of an active risk management program in the operating rooms of Iranian hospitals.

## Materials and Method

### Study design and setting

This study was conducted using qualitative and phenomenological methods in 2022.

### Study participants and sampling

Interview sessions were conducted to identify the barriers and prerequisites for active risk management in the operating room from two perspectives. The first point of view is that of hospital staff (nurses and operating room technicians, doctors and surgical specialists, and officials of surgical departments), and the second point of view is that of experts in this field (health policy and management experts and academic officials and faculty members of universities). The sampling of the study was purposeful and heterogeneous (participants

with the highest diversity) and continued until the data reached saturation. This method seeks to collect data from those who have a lot of information and sufficient experience in the field under investigation and who also have a sufficient desire to participate in the study. The criteria for entering people for the study were at least five years of work experience in the healthcare system and willingness to participate in the study. An interview guide was developed to conduct the interviews, and the interviews were conducted based on it. Approximately, 20 interviews were conducted, with an average duration of  $40 \pm 15$  min. After obtaining consent from study participants, their comments were recorded and implemented. Content analysis was performed to analyze the data.

### Data collection tool and technique

The content of the interviews was typed and reviewed several times to extract the primary codes concerning various aspects of the data obtained; first main codes related to the challenges of hospitals were identified in the text of interviews by two researchers, similar codes with close meanings were grouped into sub-categories, and, finally, in the main categories. The primary and secondary contents were reviewed several times and, if necessary, combined, modified, and separated to create a logical thematic map of the relationships between creating primary and secondary contents; then, the main and sub-themes were named and defined, and in case of disagreement between the researchers, the opinions of the third researcher were used, ultimately, the primary and secondary themes were named and described. As to the purpose of the research, the main themes and sub-themes identified through codes and relevant quotes from the interviewees were prepared as a report in the form of a purposeful story. To check the validity of the transcripts, they were given to four participants, and their opinions were applied after review by the research team. In addition, the primary codes, sub-topics, and main topics were examined by two researchers, and targeted sampling and rich descriptions of the data were used to improve data transferability.

### Ethical consideration

Ethical issues included obtaining permission from the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1401.369), obtaining a permission letter from the Honorable Research Vice President of the Faculty of Management and Medical Information, and providing information at the beginning of the study to inform the participants about the process of conducting the study. Written informed consent was obtained from the collection of information, the freedom of experts to cooperate in the study, respect the decisions of the participants, and not publish the details of the participants in the research.

## Results

Challenges and prerequisites for active risk management in the operating room were categorized into six sub-themes and 48 final codes according to Tables 1 and 2. Challenges to active risk management include issues that cause failure to properly implement an active risk management program in the operating room (OR). These challenges are divided into three parts: management, organizational resources (financial, human, equipment, and facilities) and cultural issues [Table 1].

In the managerial dimension, the existence of faulty processes, lack of coordination, planning, policymaking, and a specific trustee have been identified as the most important challenges. One of the participants in the study regarding managerial challenges states as follows:

*“Until risk management is included in the main policies of the hospital, it will not be able to be fully implemented.”*

In the organizational dimension, lack of budget and high costs for implementing active risk management, high workload of personnel and long shift time, low safety of equipment, and old physical structure are considered organizational dimensions. In this regard, one of the participants in the study states that:

*“fatigue caused by long surgeries is one of the important Challenges that make employees unable to properly implement the correct risk management process”*

regarding the cultural dimension as well. Marginalizing issues related to safety have been mentioned as one of the most important challenges. Regarding cultural barriers, the participants also stated the following:

*“In hospitals, if the managers and senior officials do not believe in risk management and do not have the commitment to implement it, it will not be possible to implement risk management.”*

Unlike barriers, prerequisites are necessary for proper implementation of an active risk management program in the operating room. The prerequisites are also divided into three parts: management, organizational resources (financial, human, equipment, and facilities) and cultural issues [Table 2]. In the managerial dimension, the existence of a specific plan and policy, coordination, control, and commitment were mentioned among the most important managerial prerequisites, so a participant stated:

*“The existence of commitment among managers and employees is one of the essential components for the implementation of risk management before the design and implementation process.”*

**Table 1: Main barriers to an active risk management program in the operating room**

Component	Main theme/definition	Sub-themes	Examples
Challenges to proactive risk management	Management barriers	<ul style="list-style-type: none"> <li>Defective processes, lack of team working spirit,</li> <li>Lack of coordination, unfavorable planning,</li> <li>Lack of a specific trustee,</li> <li>Weak policy,</li> <li>Mere supervision,</li> <li>Failure to include active risk management among the main policies.</li> </ul>	<p>P1: "One of the most important issues that causes risk management to not be implemented correctly is the lack of cooperation between personnel to implement operating room safety." P4: "Until risk management is included in the main policies of the hospital, it will not be able to be fully implemented."</p>
	Barriers related to organizational resources	<ul style="list-style-type: none"> <li>Financial resources: lack of funds, high cost of risk management,</li> <li>Human resources: high workload of personnel, long shift time, high volume of surgeries, unmotivating payment system, lack of providing adequate amenities, low quality of training, the low skill level of employees, the low experience of personnel,</li> <li>Equipment and facilities: low safety equipment, old physical structure, lack of personal protective equipment, lack of provision of active risk management facilities</li> </ul>	<p>P18: "Risk management will not be effective if the personnel is not informed about the reports made about the risks and the analysis and root finding done continuously to prevent the repetition of that mistake." P20: "Fatigue caused by long surgeries is an important obstacle that prevents employees from properly implementing the risk management process." P11: " If there is a malfunction or problem in the field of medical equipment, for example, they are not by the standard, they are not calibrated and they do not give alarms in time, it can threaten the lives of patients and employees and prevent the proper implementation of risk management." P7: "If the hospitals do not have enough financial power to meet the needs of risk management, risk management plans will certainly not be implemented."</p>
	Barriers related to cultural issues	<ul style="list-style-type: none"> <li>The inattention of officials toward safety,</li> <li>Lack of attention to active risk management issues by doctors and a certain class of employees,</li> <li>Putting safety issues on the sidelines.</li> </ul>	<p>P3: "If managers and senior officials, in hospitals, do not believe in risk management and do not have the commitment to implement it, it will not be possible to implement risk management"</p>

**Table 2: Basic prerequisites of an active risk management program in the operating room**

Component	Main theme/definition	Sub-themes	Examples
Prerequisites for proactive risk management	Management prerequisites	<p>Determining safety manager, existence of improvement plan, presentation of clear policies, coordination of affairs, correct control, formation of safety assessment team, distribution of responsibilities, existence of appropriate evaluation system, support of senior managers, commitment of managers, encouragement of effective people in active risk management, encouragement, and people to report errors</p>	<p>P13: " Forming a skilled safety team and continuously monitoring all risk management processes is one of the most important steps in risk management." P7: "The existence of commitment among managers and employees is one of the most important components for implementing the risk management process. Managers and employees, if they have a commitment, make more efforts to properly implement risk management."</p>
	Prerequisites related to organizational resources	<p>Human resources: personnel training, periodic review of risk samples and reports, training needs assessment, root analysis of risks, and use of results</p> <p>Equipment and facilities: provision of facilities, provision of sufficient manpower, provision of facilities and equipment</p> <p>Financial issues: adequate and sustainable financing</p>	<p>P8: Training is one of the important prerequisites of risk management. In such a way that we can first convince people that these things are very important, then we can train nurses and staff to recognize the risks and perform the necessary interventions.</p> <p>P4: " If there are enough facilities and enough power, and the processes are done most appropriately, we can say that we can implement active risk management." P10: " The implementation of active risk management can be done well if the senior managers take steps to provide financial resources as soon as possible."</p>
	Safety culture	<p>Creating belief in employees, creating a culture, not hiding errors and accidents, and instilling a sense of individual responsibility</p>	<p>P6: "Compliance with safety is another important principle in culture building. For example, people who make error reports or identify errors should be honored in writing or verbally."</p>

From an organizational perspective, personnel training, provision of facilities, adequate and stable financing, etc., are among the important elements, so one of the participants stated:

*“If the high-level authorities take measures to provide financial resources, the implementation of active risk management can May it happen well.”*

Finally, in the cultural dimension, culture building and not hiding errors and accidents are among the basic principles; as one of the participants stated in this regard, compliance with safety is another important principle in culture building. For example, people who report or identify errors should be honored in writing or verbally.

## Discussion

In the resulting qualitative study, challenges and prerequisites for active risk management in the operating room were divided into six sub-themes from the perspectives of experts and executive staff. These challenges and prerequisites include managerial and organizational dimensions (financial, human, equipment, and facilities) and cultural issues.

The high correlation between management and safety culture clearly shows the vital role of management in an effective and dynamic safety culture in an organization.<sup>[12]</sup> In previous studies, the dimension of management commitment had the strongest positive correlation with safety culture and is considered one of the important dimensions of safety culture.<sup>[13]</sup> The participants in the managerial dimension emphasized the existence of faulty processes and the lack of coordination, planning, policymaking, and specific trustee as the most important managerial challenges, the existence of a specific plan and policy, coordination, control, team formation and distribution of responsibilities, and the existence of an evaluation system, the support and commitment of senior managers, encouragement of people, and appointment of a safety supervisor were mentioned as the main prerequisites for active risk management in the operating room. These cases are emphasized in most quality models as well as in the clinical governance programs of the countries.<sup>[14]</sup>

Examining the risk management models implemented in different organizations shows that only through a comprehensive and accurate plan, the risks in the healthcare space are managed. To control and reduce all clinical risks in the healthcare space, it is necessary to manage them coherently, which will make the organizational structure appropriate through organization and coordination. To control and reduce all clinical risks in health and treatment systems, it is necessary to create a coherent management that makes the organizational structure appropriate

through organization and coordination, and on the other hand, managed programs to prevent injury and ensuring the safety of the patient care process, which is developed in order to avoid accidental injuries caused by medical care and as a result of medical errors, and also define a specific and structured process for follow-up and compensation of potential victims, and finally, that all these actions and activities should be supported and implemented through a specific financial program. Define the possible visions finally that all these measures are supported and implemented through a detailed financial plan.<sup>[15]</sup> Therefore, if an efficient management system exists, it is possible to minimize the effects of errors by creating a logical management structure, explaining responsibilities, and creating transparent reporting networks. The highest efficiency of medical services can be achieved by using facilities and minimum human resources.<sup>[16]</sup>

In the organizational dimension, financial resources, human resources, equipment, and facilities are emphasized. Lack of budget and high costs for implementing active risk management, the high workload of personnel and long shift time, lack of incentives for payments and amenities, low quality of training and skill level of employees, the low experience of personnel, low safety of equipment, physical structure, lack of personal protective equipment, and lack of facilities for active risk management are considered organizational dimensions. According to Smits et al.'s<sup>[17]</sup> study, organizational factors are among the most important principles in risk management and play a very important role in the occurrence of errors. The lack of necessary infrastructure for the components of the active risk management operational plan, the high workload of employees, and the reduction in their participation in the implementation of the active risk management plan are among the most important challenges related to the lack of resources. Also, the non-standard physical space of hospitals and the lack of financial resources to fill the gaps are among the other challenges related to the correct implementation of active risk management.<sup>[18]</sup> The issue of training and skills for employees, which is mentioned in the Wilson and Taylor model, under the title of “continuous training and development of employees,” plays a vital role in the implementation of risk management processes.<sup>[19]</sup> The strategy of this training must contain educational need assessment, educational planning, find the best educational approaches, the best educational content, and the best educational tools with notice to educational involved organizations.<sup>[20]</sup> Neglecting the needs of personnel will weaken the quality of care and failure to properly solve problems that threaten the health of patients and personnel. Structural problems, lack of facilities, improper organization of human resources, and incorrect allocation of resources are among the most important reasons for the lack of access to healthcare centers to the desired level of crisis management.<sup>[21]</sup>

Safety culture is one of the main factors determining the safety level of an organization. Safety culture means accepting safety and paying attention to it as the priority and usual value in the organization or as the values, opinions, perceptions, and common tendencies of healthcare service employees toward safety, which is manifested in their behavior.<sup>[22]</sup> In cases such as not hiding errors and accidents because of the fear of punishing and revealing them, reducing the blame of people and Encourage the person reporting the error, the existence of a reporting system for all types of errors, using the data of the reporting system to improve processes, training employees in the field of patient safety, the existence of teamwork, and transparent communication. The units and departments and their cooperation with each other for the benefit of the patient and the attention of the organization's leadership to safety are the prominent characteristics of such a culture.<sup>[23]</sup> Hospital safety rules by creating belief in employees, creating a culture, and evoking a sense of individual responsibility in personnel and safety principles can be institutionalized in the hospital. Cultural beliefs may have positive or negative effects in creating the perception of disasters impact. Therefore, the identification and development of positive beliefs and the neutralization and suppression of negative beliefs require analysis, planning, and implementing strategies.<sup>[24]</sup>

Many studies have focused on clinical risk management in different countries, all of which have examined clinical risk management in hospitals and the general standard variables of risk management. However, to our knowledge, no study has accurately identified the components of the risk management system including challenges and prerequisites in the operating room. Therefore, according to the increasing importance of patient safety and the role of risk management in reducing medical errors and treatment costs, the strength of this study checks the challenges and prerequisites of active risk management in the operation room of hospitals in the country from the point of view of experts and executive staff. One of the weak points of the study is not dealing with the correct implementation of risk management in the operating room. Further studies can identify and present the correct implementation of risk management in the operating room by continuing the path and using the results of this study.

### Limitation and recommendation

Like most qualitative studies, the findings of this study were obtained by relying on the views and experiences of the people and the environmental conditions of the research, and the results can be generalized in similar conditions and environments. It is recommended that for future researches, the challenges and prerequisites should be investigated through statistical studies and

tools such as structural interpretive modeling should be used to determine how these challenges and prerequisites affect the implementation of risk management. Another limitation of this study is the lack of similar studies that have evaluated the challenges and prerequisites of risk management in the operating room, which limits the possibility of comparing the findings with similar studies.

## Conclusion

In this qualitative study, the challenges and prerequisites for active risk management were identified as basic factors in the management of clinical risks in the operating room. According to the obtained results, considering that it is very important to observe the safety and responsibility for the safety of clients, patients, and employees, the above issue should be considered very serious for hospital officials and the necessary arrangements and prerequisites, both in terms of management and organizational and cultural terms, and other cases to be adopted. By considering these prerequisites and removing challenges, an active risk management program can be implemented correctly in the operating room. With the correct implementation of this program, injuries to the operating room for personnel and patients will be greatly reduced, and the satisfaction of beneficiaries and the productivity of the hospital will be greatly increased. It is suggested that hospital authorities conduct a needs assessment regarding the problems and challenges of implementing active risk management and removing challenges, as well as hold safety training courses related to the operating room at different levels for employees, follow up seriously, and create monitoring and control levels. Fully implementing an active risk management program leads to an improvement in service quality in the operating room.

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### Conflicts of interest

There are no conflicts of interest.

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