

Article

Enhancing Patient Safety: A Systematic Approach to Risk Management in Intensive Care Units within Hellenic Health Care Units

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Abstract: The paper emphasizes the critical importance of effective operations, procedures, and work plans, including a comprehensive Risk and Threat Management Plan, for the long-term viability of modern business entities, particularly within the healthcare industry in Greece. It underscores the necessity for business management, especially in the context of hospital administration and medical staff, to maintain a high level of alertness and vigilance in the complex, dynamic, and ever-evolving healthcare environment. This vigilance is essential in light of new investments, equipment purchases, competitive challenges, reduced financial liquidity, and other situations that may threaten the development, smooth operation, and sustainability of healthcare objectives. The work defines "Risk" as an intangible and multifaceted concept, explaining that the only way to assess it is through a systematic evaluation process. This evaluation must be conducted in a well-defined, rational, and standardized manner, as Risks are typically associated with negative events, situations, or conditions that can adversely impact desired outcomes and the achievement of healthcare goals. It highlights the extensive variety of regulatory, environmental, financial, geopolitical, and internal corporate factors that can significantly influence the success or failure of a Healthcare Unit. These factors include Natural or Anthropogenic Catastrophes, supply chain disruptions, industry developments, and legal and regulatory changes, all of which can pose substantial threats to the organization. When Corporate Risks become apparent, administrators and senior managers—namely, hospital management and medical staff—must recognize and record them to enable systematic assessment and informed decision-making for Effective Management and Mitigation. The present paper proposes a comprehensive Risk Management Methodology, encompassing Hazard Assessment and Risk Management, as a crucial approach for healthcare businesses to navigate and mitigate the risks that threaten their development, proper functioning, and long-term sustainability.

Keywords: Intensive Care Unit; Risk Assessment; Risk Management; Risk Matrix; Greece

1. Introduction

1.1. Emergency and Intensive Care Units (ICU)

"Without health, life is not life. It is only a state of agony and pain - an image of death" said, in a free translation, the American writer Shel Silverstein, trying to emphasize that Health is the most precious

gift to human. The commodity of health is influenced by two main factors, the “Hereditary” the transmission of certain diseases from the parents to the offspring, and the “Acquired” which are related to the development of certain diseases during the course of someone’s life, without transmission to future generations through reproduction [1]. Since there is no doubt that health not only encompasses the dimension of the absence of disease or the absence of disability, but also has the dimension of complete physical, mental and spiritual well-being, every modern and favored social state should ensure the extension of the life of its citizens [2]. In other words, ensuring health should be on the top of the priority of every government.

The National Health Service (NHS) has taken on the role of organized and equal provision of healthcare to all citizens without discrimination, which was established by the Law 1397/1983 within the framework of upgrading - reforming the pathogenic public health until then and the functional unification of public care infrastructures [3]. The NHS consists of seven Health Regions which oversee three levels of healthcare. Specifically, the levels of healthcare are:

- Primary Health Care: Includes 322 Health Centers and 239 Local Health Units and aims at prevention, hospitalization, and rehabilitation of patients.
- Secondary and Tertiary Health Care: Includes 73 Hospital Units with the purpose of inpatient care of patients. The difference between these two levels is that the 3rd concerns specialized provision of healthcare. The Third Level includes Emergency and Intensive Care Medical Services that will be referred to in this paper.

The Intensive Care Unit (ICU) is a critical and special department of Secondary Health Care, and for this reason it is considered the center of a hospital. The goal of the ICU is highly significant and concerns the uninterrupted, multidisciplinary, and specialized provision of individualized intensive care and hospitalization to high-risk patients with reversible damage, complications, or dysfunctions of vital organs [4]. Subsequently, we will refer to the factors that can reduce the effectiveness of the mission of an ICU, bringing entropy to its operation and consequently the creation of crisis incidents.

1.2. Factors Reducing the Efficiency of ICUs

In an ICU, there are numerous factors that can negatively impact the expected efficiency of its operation. Some of the key factors are focused on the [5,6,7]:

- Pathologies of a chronically weak healthcare system.
- Underinvestment in the healthcare sector.
- Aging infrastructure of most hospital units in the country and the need for extensive structural renovations and maintenance.
- Lack of weighted and multi-scenario action plans for emergency situations.
- Understaffing of units with healthcare personnel of various specialties, especially in geographically decentralized units, inadequate training, aging and fatigue of human resources.
- Difficulty in transitioning to digital transformation and cutting-edge technologies.

It is evident that in a dynamically changing environment, where the concept of Crisis is always present, the only line of defense for such an outstandingly important entity, as health, is the establishment of a structured Risk Assessment and Management Process. Some of the benefits that can be achieved are the reduction of the Vulnerability of citizens, increase of the Resilience of the system, regulatory compliance with the legal framework, and improvement of reputation.

2. The Necessity of a Risk Assessment Process in the ICU As a Tool for Systemic Crisis Management

The effective management of crisis incidents is a complex and multifaceted challenge, as it involves numerous stakeholders who often perceive and assess the events differently, leading to the emergence of conflicting interests due to individual biases or pursuits. As a result, coordinating an effective response can be extremely difficult. The management of such problems requires a holistic approach, where through a scientific framework of action and experiential involvement in complex scenarios, the system can be dynamically fed with new knowledge and self-regulated, providing sustainable solutions.

Consequently, effective risk management:

- Addresses the Risk holistically and systemically rather than a unilateral approach, focusing on the broader concept of risk rather than individual risks.
- Particularly recognizes the two main Dimensions of Risk: probability/likelihood and severity/consequence.
- Is considered an appropriate and ideal tool for the management of any type of risk, as it combines both qualitative and quantitative elements.

It is important to note that each Crisis Incident is unique, as it is the result of a multi-factorial process. However, some common characteristics may emerge, the examination of which would initially help in understanding the crisis and further facilitate the development of a customized emergency response plan for each Intensive Care Unit. This holistic and systematic approach to risk management is crucial in the context of ICUs, where the protection of the health and safety of extremely vulnerable patients is of the utmost importance. By adopting such a framework, ICUs can enhance their preparedness, improve coordination, and develop sustainable solutions to effectively manage crisis situations, ultimately enhancing the quality of care and patient outcomes.

According to Meena, the common characteristics of crisis situations are [8]:

- Physical risk and psychological risk that may include anxiety, pressure, confusion, etc. due to the sense of loss of control.
- Causing material damage to state property.
- Sudden interruption of daily activities.
- The need to support the affected by third parties or emergency agencies.
- Increased search for information, increased activity on social media.
- Lack of information, provision of vague or ambiguous information, or even misinformation.
- Significant interest from the mass media to increase viewership and listenership.
- The need for immediate decision-making.
- Difficulty in predicting the onset and intensity of the crisis.
- Difficulty in controlling or managing the crisis due to its uniqueness.
- The progression/escalation of the crisis over time.

Building on the rationale of Meena, a series of prominent authors have argued that an emergency situation can have the following additional characteristics [9,10]:

- The crisis is a milestone in an evolutionary sequence of events or actions.
- The crisis is an exceptional situation in which the demand for action by the involved parties is of the utmost importance and priority.

- The crisis provides a significant lesson from the outcome, which will catalytically shape the future of the parties involved (lesson learned).
- The crisis is a combination of many incidents, the combination of which results in the creation of a new and possibly different set of incidents.
- The crisis exponentially increases the complexity, uncertainty, and anxiety regarding the way it is evaluated and the finding of the best solutions for its mitigation or management.
- The crisis, at the moment it occurs, is a phase where control over the events and their consequences is essentially from minimal to impossible.
- The crisis is characterized by a sense of urgency, resulting in mostly anxiety for all parties involved.
- The crisis can be the result of a single event or even multiple events together, where in most cases the information that the involved parties have is generally poor or inadequate.
- The crisis involves time pressure.
- The crisis puts a strain on the relationships between the participants.
- The crisis increases the tension among citizens.

From all the above, it becomes clear that the existence of a continuous process of formal risk assessment is a fundamental element of a knowledge base through which it will become clear that the term “risk” does not constitute a measurable quantity, e.g., it does not have dimensions as it is not something “tangible”. It is an 'intangible' quantity and therefore the only possibility we have for the assessment of a risk is only its estimation.

An assessment should not be done in a random, shallow, hasty, and generally without norms that establish in some sense the rationale of each assessment regarding the severity of a risk. A risk is always associated with something negative (event, situation, incident, condition, circumstance, fact, etc.) that has significant impacts and consequences on an ICU. If we introduce the logic that in ICUs the probability of the occurrence of some undesirable negative event during its 24-hour operation is high, the conclusion is that a series of risks exist on a continuous basis. Furthermore, the complex and intricate operation of the ICU and the process of service delivery further exacerbates the probability of the occurrence of negative events.

3. Risk Categorization

In the light of the above, it is not surprising that the systemic risk assessment is the only way to quantitatively and qualitatively measure the hazards and their potential consequences on patients, staff, and infrastructure, through which the effectiveness and efficiency of existing control methods can be examined. Risk assessment can also provide valuable information to decide on an action plan that will greatly mitigate risks, improve existing control systems, and design appropriate responses. The method we propose is called Failure Mode and Effects Analysis through risk assessment, as we believe it is one of the most effective risk assessment methods.

A relatively comprehensive categorization of the hazard groups that need to be weighed and monitored is considered to be the following:

- Operational (quality of services provided, patient service, etc.) [11].
- Financial (credit, liquidity, cash flow, cost of services, cost of patient stays in the ICU) [12,13,14].
- Chronical (patient transfer and length of stay in the ICU).

- Reputational (positioning, competition and reduced demand if we are talking about a private institution) [15].
- Natural disasters, health & safety (environment, geographical location of the unit, hygiene, pandemics, earthquakes, hurricanes, safety, disposal) [11,15,16].
- Social (strikes, attitudes, terrorism, resignations of executives or doctors, job satisfaction, stakeholder reactions, etc.) [16,17].
- Technological (work equipment, more attractive health products, new technologies, alternative services, etc.) [13,15].
- Hazardous and chemical substances (flammable, explosive, carcinogenic, biological, etc.).
- Horizontal risks (psychosocial & ergonomic factors, adverse working conditions, etc.).

For these categories, where risks may be either predictable or not, the starting point for their management, i.e. for identification, estimation and evaluation, can be done in a timely manner, provided that the institution, management, and staff are imbued with a basic foresight, vigilance, and alertness. The signs for their appearance in many cases are visible and can be diagnosed well before their occurrence. This means that an early response plan should be planned and implemented. It should also be noted that in some cases, potential hazards, in addition to being addressed, have also revealed some opportunities that were utilized in the past by some healthcare units, ultimately leading to results that could not have been initially predicted [18].

3. Case Study - Proposed Risk Management Model

3.1. Characteristics of the Examined ICU

The hospital unit under examination has been operating from the 1960s. It was originally established as an anti-cancer institution, providing specialized healthcare services in the field of oncology. The management's objectives are the continuous modernization and improvement of services, the improvement of the working conditions and environment for the staff, and the absolute respect and protection of patients' rights.

The Intensive Care Unit (which also operates a High Dependency Unit - HDU) has been functioning since 1990. It has six ICU beds and 5 HDU beds. The ICU admits patients who require care because their life is at high risk and they need continuous monitoring of vital functions and intensive care from specialized medical and nursing staff for as long as their condition is critical. The patients treated in the ICU may come either from the various departments of the Hospital, or they may be transferred from other Hospitals through the national Emergency Aid Centre (EMS) [3].

3.2. ICU Risk Management Plan

The risk management advisory team, leveraging a comprehensive suite of management methodologies and tools, has conducted a thorough "written risk assessment" for the Intensive Care Unit. This assessment encompasses all the potential sources of risk, including:

- Affected human resources: Medical staff, nursing staff, administrative staff, technical staff, cleaning staff. Affected stakeholders: Patients, visitors.
- Physical infrastructure and technological assets: Building structures, medical equipment and devices.

- Operational procedures and protocols: Existing measures and controls, additional measures that need to be implemented.
- Risk re-evaluation and mitigation: Reassessment of risk levels, Timeframe for completing the necessary measures. Responsible parties: Individuals or teams tasked with the implementation and completion of the risk mitigation measures.

By adopting this holistic and structured approach, the risk management advisory team has been able to identify, assess, and address the multifaceted risks inherent in the ICU environment. This comprehensive risk assessment serves as a foundation for the development of a robust and effective risk management strategy, ensuring the safety and well-being of both the ICU staff and the patients under their care. The systematic documentation of the risk sources, existing controls, and required actions, along with the clear assignment of responsibilities, enables the ICU to maintain a proactive and coordinated approach to risk management. This, in turn, enhances the ICU's overall resilience and preparedness in the face of potential crisis situations, ultimately contributing to improved patient outcomes and the delivery of high-quality healthcare services.

At this point, it should be made clear that the services provided by the risk management team are advisory and,

- Does not exercise authority over the organizational units, departments or individuals who have been tasked with the responsibility to complete some of the proposed measures, nor do they substitute them.
- Does not record the potential risks. The recording - assessment and identification of all potential risks emerge from the organizational units, in this case the ICU, as the staff who manage it (director, head, etc.) have better knowledge of the subject and therefore of the risks.
- Must be independent so that it can carry out its work objectively and effectively. In other words, during the execution of their work, there should be no manipulation, but on the contrary, they should have full freedom of movement and access to any activity that is a potential risk.
- Must have the full and written support of the management. This means that for effective risk management and the implementation of the team's findings, the management's commitment to the action plan, and all kinds of resources (financial, technical, human resources) that will assist in the full implementation of the measures, is essential.

A good practice as a safeguard for the implementation of all these recommendations proposed is the creation of a "Risk Management Regulation (RMR)" which the entire human resources of the ICU must compulsorily comply with. The RMR should be an official document that will define the mission, activities, and risk management procedures within the ICU and will specify the scope of these management activities. It is also important to have a provision for the annual review of the RMR, simply because in an extremely dynamic environment characterized by regulatory changes and a multitude of crisis events, the regulation will need to be updated.

3.3. Methodology – Risk Data Quality Assessment

The risk management team had a series of methodologies and tools at their disposal that they could use in the overall cycle of such an effort. When we refer to tools, we mean the way the team utilized the available management means such as:

- **Technology:** How they used technology for data collection, analysis, and communication.
- **Data Collection Methodology:** The approach they took to systematically gather relevant information and evidence.
- **Communication and Persuasion:** The way they interacted with and convinced the organizational unit under review to cooperate.
- **Evaluation and Utilization of Evidence:** How they assessed and leveraged the collected data and documentation.
- **Formulation of the Final Findings:** The process they followed to develop the final risk management recommendations.

The goal was to enable a comprehensive assessment and estimation of the potential risks faced by the ICU. The specific phases of this process are presented below.

3.3.1. Identification, Definition, and Interpretation of Risks

For an entity, in this case the ICU, risk is the threat where a critical event, incident, or activity can negatively impact the achievement of its objectives. Risk threatens all the operations of an entity, regardless of the subject matter, but some functions present higher risk compared to others, as they are more vulnerable/susceptible to that particular risk [19]. The success of management is therefore the ability to properly and systematically manage the risks.

The first phase was the identification of potential hazards that could affect the mission and the uninterrupted operation of the ICU. The process started with a series of meetings, where through the brain-storming method with the ICU management and the attending physicians, all available information regarding the potential hazards was gathered. This knowledge emerged from the staff's experiences, the regulatory framework governing this organizational unit, and the historical data that had occurred in this particular ICU. Based on the input provided, the risk assessment team prepared the following Cause and Effect Diagram with all the potential risks that could arise (Figure 1).

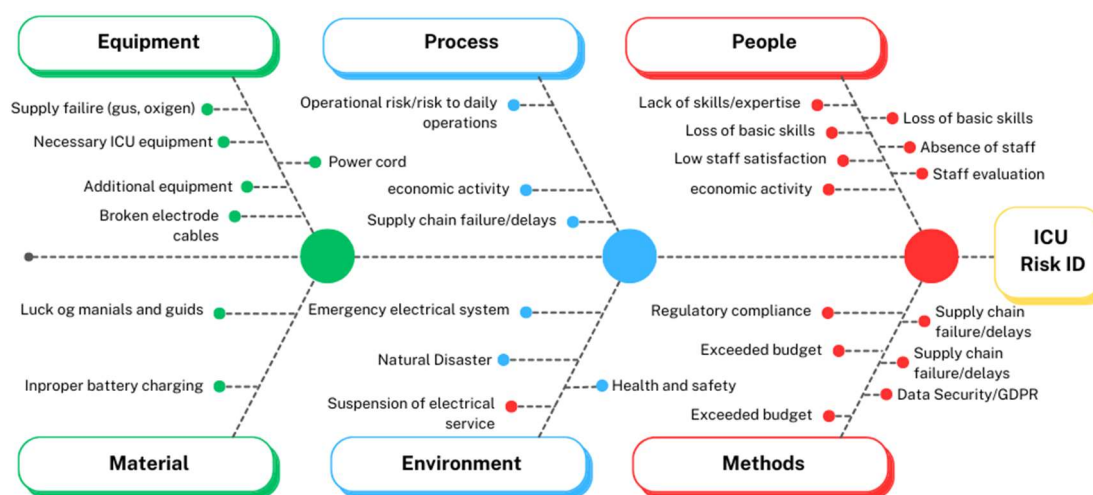


Figure 1. Cause and Effect Diagram (Ishikawa).

3.3.2. Determining the Significance and Calibration of Risks

The second phase involved determining the degree of significance for each risk factor identified in the first stage (Figure 1). In other words, the risks were evaluated based on a rating scale from 1 to

5 in terms of their level of significance. Observing Image 1, the management team had recorded six main areas from which business risks could potentially arise. For each of these risk sources, the team identified subcategories, according to which twenty-seven (27) hazards could emerge and could bring entropy to the operation of the ICU, with all the implications this would have for the effectiveness of its mission. These hazards are presented in the Risk Collection and Preliminary Assessment Table (Table 1). Additionally, the table shows both the variable of the significance (likelihood) of each hazard and the probability of its occurrence, as assessed by the evaluation team.

The key points regarding the determination of risk significance and calibration are:

- Establishing a 1-5 rating scale to assess the level of significance for each identified hazard.
- Identifying six main risk source areas and further breaking them down into 27 specific hazards.
- Documenting the risks in a Risk Collection and Preliminary Assessment Table.
- Capturing both the significance level and the probability of occurrence for each hazard.

This structured approach allows the team to systematically evaluate and prioritize the identified risks based on their potential impact and likelihood of materializing.

Table 1. Risk Collection and preliminary assessment table.

ICU	HAZARD	Likelihood	Potential Consequences	Product
1	Necessary ICU equipment	3	5	15
2	Additional equipment for ICUs of at least 6 beds	3	5	15
3	Necessary amenities per bed	2	4	8
4	Medical risks	4	4	16
5	Natural Disaster	3	2	10
6	Land/Real Estate/Assets	2	3	6
7	Use of Electrical Equipment	3	5	15
8	Use of oxygen/risk of fire	2	8	16
9	Operational risk/risk to daily operations	3	3	9
10	Health and safety	2	4	8
11	Installation/equipment failure	2	5	10
12	Exceeded budget	2	3	6
13	Emergency and Evacuation	3	5	15
14	Regulatory compliance	2	5	10
15	Data Security/GDPR	2	3	6
16	Lack of skills/expertise	2	5	10
17	Loss of basic skills	2	3	6
18	Low staff satisfaction	3	3	9
19	Supply chain failure/delays	2	5	10
20	Staff evaluation	3	3	9
21	Absence of staff	4	3	12
22	Failure - disruption of information systems	3	2	6
23	Hospital Waste Management	5	5	25
24	Hostage situation	1	5	5
25	Bomb treat	1	5	5
26	Terrorism, biological	1	5	5
27	Terrorism, chemical	1	5	5
28	Airplane attack	1	5	5

3.3.3. Analysis, Classification and Risks Mapping

The third phase of the methodology concerns the visual representation of the probabilities and impacts of the risks, the risk collection and preliminary risk assessment table, in the risk matrix [20]. In other words, when the risks are identified and evaluated, they are hierarchized according to the urgency and prioritization of their mitigation, which we consider to be very important since resources and time should not be wasted by devoted on a small risk. It would be a serious omission not to emphasize that risk management increases costs, which should be considered together with the cost of the risk and the benefit that will result from an investment for risk management, which benefit should be multiple times the investment that will be made. Examples are hazards 23, 24, 25, 26 and 27, which have a very low probability of occurrence up to zero, resulting in their treatment not being deemed necessary by the team (Table 1).

More specifically, the proposed technique, by combining the probability and impact scores of the individual risks (hazards), grades them according to their severity using the simple equation:

$$\text{RISK} = \text{LIKELIHOOD} \times \text{POTENTIAL CONSEQUENCES}$$

For a better understanding of our methodology, we will present the case of Hazard No. 1 regarding the "Necessary equipment of the ICU". The Likelihood for this particular hazard was judged to be '3', meaning a 40% to 59% chance of occurrence, while the Potential Consequence was judged to be 5, in other words, it will have a Severe impact on the effective operation of the ICU. Calculating their product will result in the number 3x5=15. Therefore, in the Risk Matrix table, we find the coordinates (3,5) and in the corresponding field, we insert the ordinal number of the respective hazard, which is '1'.

We follow the same process for the remaining hazards, compiling the following table (Table 2).



Table 2. Risk matrix.

				Likelihood				
				P1	P2	P3	P4	P5
				Rare	Unlikely	Possible	Likely	Almost Certain
				0 – 19%	20 – 39%	40 – 59%	60 – 79%	80 – 100%
				1	2	3	4	5
Potential Consequences	S1	Not Significant	1	1	2	3	4	5
	S2	Minor	2	2	4 (22)	6 (5)	8	10
	S3	Moderate	3	3	6 (6,12,15,17)	9 (9,18,20)	12 (21)	15
	S4	Major	4	4	8 (3,8,10)	12	16 (4)	20
	S5	Severe	5	5 (23,24,25,26,27)	10 (11,14,16,19)	15 (1,2,7,13)	20	25 (23)
The numbers refer to the product between Likelihood and Potential Consequence. The numbers in parentheses characterize the Hazards of the Table 1.								

In the table below (Table 3), it was deemed appropriate to mention the proposed actions that

should be taken by the risk management team, based on the risk level resulting from the Risk Matrix.

Table 3. Recommended action depending on the level of risk.

Risk level	Recommended actions	Indicator
1 - 6 Minor	Accept and monitor low priority risks. Manage through routine processes where possible. Monitoring through regular internal reporting mechanisms.	
7 – 12 Moderate	Develop and implement a Treatment/Action Plan for high-risk areas. Consider alternative activities unless the necessary controls are in place. Allocate actions and budget to minimize risk, with ongoing monitoring of implementation. Report to management on the effectiveness of the controls in place.	
13 – 25 Major	This rating level is deemed unacceptable. Report this issue to Senior Management without delay for consideration of additional controls. Consider alternative activities unless the necessary controls are implemented. Create a specific treatment/action plan for immediate implementation to address extreme risks. Allocate actions and budget for implementation within one month.	

3.3.4. Defining a Risk Management Strategy

Another challenge for the entity, which is part of the fourth phase, is the decision on whether a risk should be managed under the responsibility of a department of the entity (risk acceptance), or if the management responsibility should be transferred to an external partner (risk transfer). The degree of responsibility for a risk depends on the size of the entity, the willingness, and ability of the management to take on responsibility, and the available resources of the entity. With the oversight of the Risk Matrix, each risk becomes immediately understandable at a glance within the framework of a larger project, so if it occurs, either there will be a plan for effective prioritization of its management, or not, in the logic where the hospital management will decide whether some risks will not be accepted, taking the risk of their potential occurrence, but through the evaluation of a series of criteria, such as the operational objectives and the available resources.

Based on this position, each of the risks must be realistic, and then the basic risk management strategies (risk) to be followed should be decided [21,22]. In this context, Table 4 was compiled.

The basic strategies are:

- **Risk Avoidance: Avoiding undertaking activities that involve high risk.** Modifying processes or products to reduce risk.
- **Risk Transfer:** Transferring the risk to third parties, such as insurance companies. Using contracts, agreements or other means to transfer the risk.
- **Risk Reduction:** Implementing control and risk mitigation measures. Improving processes, training personnel, installing security systems.
- **Risk Acceptance:** Accepting the risk when it is low or the cost of mitigation is high. Maintaining adequate reserves to address the risk.

Table 4. Hazards realism table.

NO.	HAZARD	REALISM	STRATEGY
1	Necessary ICU equipment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
2	Additional equipment for ICUs of at least 6 beds	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
3	Necessary amenities per bed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
4	Medical risks	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
5	Natural Disaster	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
6	Land/Real Estate/Assets	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Transfer
7	Use of Electrical Equipment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
8	Use of oxygen/risk of fire	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
9	Operational risk/risk to daily operations	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
10	Health and safety	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
11	Installation/equipment failure	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Transfer
12	Exceeded budget	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
13	Emergency and Evacuation	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
14	Regulatory compliance	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
15	Data Security/GDPR	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Transfer
16	Lack of skills/expertise	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Transfer
17	Loss of basic skills	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
18	Low staff satisfaction	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
19	Supply chain failure/delays	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Transfer
20	Staff evaluation	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
21	Absence of staff	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Reduction
22	Failure - disruption of information systems	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Transfer
23	Hospital Waste Management	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Risk Transfer
24	Hostage situation	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Risk Acceptance
25	Bomb treat	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Risk Acceptance
26	Terrorism, biological	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Risk Acceptance
27	Terrorism, chemical	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Risk Acceptance
28	Airplane attack	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Risk Acceptance

3.3.5. Proposed Preparation and Implementation of An Annual Action Plan

As mentioned, several times in this paper, the benefits of systemic and organized risk management are numerous, including an increased likelihood of achieving ICU goals, more efficient cost management, improved transparency, reduced losses, focused attention on important functions, and the creation of a safe environment for staff and patients by significantly minimizing surprises. The table below (Table 5) summarizes all the risks under consideration, the measures that have been decided to be taken within a specified time frame by the owners responsible for the implementation, as well as the individual risk analysis. In other words, we are referring to the action plan for the implementation of the risk management strategy, defining responsibilities, resources, and timeline.

During the implementation phase of the action plan, it is worth noting that it is vital to have continuous monitoring of the effectiveness of the measures, so that there is the ability to adapt the risk management strategy in cases where subsequent dramatic changes in the environment have emerged.

3.3.6. Updated Risks Mapping



The next phase of our methodology is the depiction of the ICU's picture based on the updated values of the Likelihood and Consequences dipole (Table 6).



Based on the table, we observe that if the proposed measures of the action plan are fully implemented, the mitigation of the risks will be impressive. Given that the risk cannot be eliminated, the risks under evaluation have been significantly reduced.





3.3.7. Communication and Training



All stakeholders should be informed about the proposed action plan, the risks and the measures to be taken. Information and understanding are critical to the success of risk management; therefore, we consider it imperative to provide training to all ICU employees.







Table 5. Risk management table.


RISK MANAGEMENT										
Risk Assessment of the Intensive Care Unit (ICU) in Healthcare Facilities. Attention! The activities mentioned in the following table may vary significantly depending on the type, nature, and specifics of each ICU. Therefore, all events must be evaluated individually to address the relevant risks and related control measures. Consequently, there may be additional or alternative risks and control measures applicable to each Intensive Care Unit, which should be examined more thoroughly.										
Recommendations for assessing and controlling liability risk										
Organizational unit: Intensive Care Unit (ICU)				Date: ____ / ____ / ____				Time: __: __		
Risk description	Consequence	Initial risk assessment			Identification of control measures Actions to mitigate the risk e.g. reduce the likelihood.	Owner Responsible for Implementation	Date/Time	Final risk assessment		
		Likelihood	Consequences	Level of risk				Likelihood	Consequences	Level of risk
1. Necessary equipment for ICUs	Damage to reputation. Cancellation, reduction, or inability to provide medical services. Increase in mortality rates. Reduction in patient satisfaction. Reduction in staff satisfaction. Increase in the rate of complaints.	3	5	15 	Bed status Electrocardiogram (ECG) Blood pressure equipment. Central venous pressure equipment. Channels for measuring various pressures, such as intracranial pressure, wedge pressure, etc. Temperature Oximetry Non-invasive blood pressure measurement Cardiac output and hemodynamic parameter calculator Recording and storage of alarms to allow documentation of all monitored parameters ventilators.	ICU Director Nursing Director Procurement Director Finance Director		1	3	3 









<p>2. Additional equipment for ICUs with at least 6 beds</p>	<p>Damage to reputation. Cancellation, reduction, or inability to provide medical services. Increase in mortality rates. Reduction in patient satisfaction. Reduction in staff satisfaction. Increase in the rate of complaints. Quality of services provided.</p>	<p>3</p>	<p>5</p>	<p>15 </p>	<p>One volume and pressure ventilator with continuous patient ventilation monitoring capabilities for each bed, with one backup ventilator for every 3 beds. One or two portable transport ventilators. One or two monitors for transporting patients to other departments and laboratories for necessary diagnostic tests. Blood electrolyte analyzer, lactate, glucose, hemoglobin, hematocrit, and blood gas analyzer. Two ventilators suitable for non-invasive ventilation. Two continuous renal replacement therapy (CRRT) machines. An equal number of specialized ICU beds with the unit's capacity, with an integrated scale for patient weight measurement. Electrocardiograph. Defibrillator with rechargeable battery, screen, and recorder. Hypothermia/hyperthermia a device (1 for every 3 beds). External pacemaker. Mobile emergency cart with an extensive range of medications, laryngoscopes, intubation, and resuscitation devices (1 for every 8 beds). Bronchoscope with a cold light source. Resuscitation bag with oxygen reservoir for each bed. Ultrasound with transesophageal echocardiography capability. Six infusion pumps for fluid and medication administration per bed. Intracranial pressure monitoring system, if the ICU treats neurosurgical cases.</p>	<p>ICU Director Nursing Director Procurement Director Finance Director</p>	<p>2</p>	<p>3</p>	<p>6 </p>
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<p>3. Necessary amenities per bed</p>	<p>Damage to reputation. Cancellation, reduction, or inability to provide medical services. Increase in mortality rates. Reduction in patient satisfaction. Reduction in staff satisfaction. Increase in the rate of complaints. Quality of services provided.</p>	<p>2</p>	<p>4</p>	<p>8</p> 	<p>Electricity: 16-20 grounded sockets per bed. 1 socket for the X-ray machine in each patient area. All ICU equipment must be supported by an uninterruptible power supply (UPS) system. Vacuum: 3 vacuum outlets per bed, connected to low-vacuum devices. Oxygen: 4 outlets per bed, two on each side with flowmeters. Compressed air: 3 outlets per bed with one flowmeter. Piping for an additional medical gas: Installation of appropriate piping and a corresponding cleaning system is required. Water supply: In each patient area, there should be 2 sinks with a large range and depth, as well as faucets that can be operated with the elbow or foot to prevent the spread of microorganisms.</p>	<p>ICU Director Nursing Director Director of Technical Services</p>	<p>1</p>	<p>2</p>	<p>2</p> 
<p>4. Medical risks Spread of Mult resistant microbes. Increased rates of adverse drug reactions. Increased mortality rate. Increased incidence of Delirium. Increased re-intubation rates. Increased rates of tracheostomy. Increased hospital</p>	<p>Quality of services. Reduction in staff satisfaction. Reduction in patient satisfaction. Increase in the rate of complaints.</p>	<p>4</p>	<p>4</p>	<p>16</p> 	<p>Updates to sedation medications that cause less delirium, communication interventions with patients, and lighting adjustments. Re-examination and adjustment of problematic extubating protocols. Re-examination and adjustment of problematic weaning protocols. Staff training and education. Procurement of modern equipment that makes the process safer. Collection of sufficient data on the disease, diagnosis, average length of stay, mortality, and expected mortality. Collection of data on complications during the ICU stay.</p>	<p>ICU Director Nursing Director</p>	<p>2</p>	<p>3</p>	<p>6</p> 

days. Increased complications in procedures performed in the ICU by intensivists Adverse effects from administered drugs.										
5. Natural Disaster	Disruption, postponement, or cancellation of activities. Safety issues, injury to staff and patients. Damage to equipment or facilities.	3	2	 6	<ul style="list-style-type: none"> Identification of physical hazards Measuring vulnerability to physical hazards Connection to early warning systems Using forecasts to measure proximity of risk, e.g. weather forecasts Creating disaster response plans Obtaining insurance policies Unexpected events due to inclement weather Proper infrastructure dimensioning Infrastructure destruction Available first aid Insuring electrical equipment Adequate water/heating Obtaining insurance policies to cover all necessary areas 	ICU Director Nursing Director Director of Technical Services		3	1	 3
6. Land/Real Estate/ Assets	Loss or damage.	2	3	 6	<ul style="list-style-type: none"> Conducting a thorough inspection of the premises Providing fencing and signage for unsafe or critical areas Adherence to Fire and Building Regulations Implementation of Early Warning Systems Acquisition of Insurance Policies 	Director of Technical Services Finance Director		2	1	 2
7. Use of Electrical Equipment	Electrocution. Slipping. Falling. Increase in the rate of complaints.	3	5	 15	<ul style="list-style-type: none"> Electrical cables and devices must have current test certification and labeling. All electrical conductors should be kept away from areas with potential 	ICU Director Nursing Director Director of Technical		1	3	 3

					water/rain exposure. Outlets should be properly placed or taped down to reduce the risk of electrocution. Only use specialized electricians where electrical work is required. Adhere to the equipment maintenance schedule. Maintain a backup of critical equipment essential for patient survival. Obtaining insurance policies to cover all necessary areas	Services Finance Director				
8. Use of oxygen/risk of fire	Burns. Explosion. Property damage. Increase in the rate of complaints.	2	4	8 	Inspection of oxygen cylinders Oxygen cylinders must have the current seal Inspection of facilities/components/piping for damage before use Secure storage of flammable materials (e.g. chemicals, etc.) Fire extinguishing equipment on site Restricted access to critical facilities Obtaining insurance policies to cover all necessary areas	ICU Director Nursing Director Director of Technical Services Finance Director		1	3	3 
9. Operational risk/risk to daily operations	Organizational impacts. Operational impacts. Work climate. Quality of services. Reduction in staff satisfaction. Reduction in patient satisfaction.	3	3	9 	Existence of a recognized Operational Risk Management (ORM) process Existence of written operating procedures Risk assessment for each operational area, e.g. doctors, nurses, finance, security Automation of operational workflows Improvement of human resource management Additional training Investment in infrastructure	ICU Director Nursing Director		2	2	4 
10. Health and safety	Safety issues, injury to staff and patients. Reduction in staff satisfaction. Reduction in patient satisfaction.	2	4	8 	Creating a health and safety policy. Identification and assessment of written risk assessment. Providing staff training. Existence of written incident reporting	ICU Director Nursing Director Finance Director		2	2	4 

	Increase in the rate of complaints.				procedures. Provision of personal protective equipment in accordance with risk assessments. Obtaining insurance policies to cover all necessary areas.					
11. Installation /equipment failure	Failure of communication. Cancellation, reduction or inability to provide scheduled activities. Increase in mortality rates. Damage to reputation. Quality of services. Reduction in staff satisfaction. Reduction in patient satisfaction. Quality of services.	2	5	10 	Inspection of facilities/equipment for damage or faults before use. Use of equipment in accordance with manufacturer's instructions. Adherence to recommended service and maintenance programs. Maintaining spare parts inventory. Existence of contracts with 24/7 emergency repair services. Training employees on safe use, maintenance and basic repair.	ICU Director Nursing Director Director of Technical Services		2	2	4 
12. Exceeded budget	Damage to reputation. Cancellation of an event or reduction or inability to provide scheduled activities.	2	3	6 	Agreed budget predetermined. Regular review of the budget. Contingencies included in the budget.	ICU Director Nursing Director Finance Director		1	2	2 
13. Emergency and space evacuation	Disruption of services provided. Injury or death. Damage to reputation. Mass movement of the crowd. Financial implications.	3	5	15 	Preparation of an evacuation plan including refuge points. Establishment of emergency procedures prior to the event. Training of medical and nursing staff on the evacuation plan. Designation of medical and nursing staff to provide first aid on-site. Availability of first aid materials on-site and Availability of portable life support equipment on-site, especially for high-vulnerability patients.	ICU Director Nursing Director		2	3	6 

4. Regulatory compliance	Damage to reputation. Fines and penalties from governmental authorities.	2	5	10 	Training and professional development of employees. Availability of legal advice regarding patient record keeping, new legislation and industry-specific regulations. Creation of a quality assurance team. Implementation of quality and safety controls.	ICU Director Administration Office		2	2	4 
15. Data Security/GDPR	Damage to reputation. Increase in the rate of complaints. Fines and penalties from governmental authorities. Lawsuits. Legal Actions.	2	3	10 	Creation of a GDPR policy. Existence of necessary security measures in place e.g. virus protection, firewalls, use of passwords, allowlist, access control. Encryption of network and data. Risk assessment based on data and systems. Conducting security audits. Locking down hardware e.g. company laptops, disable USB. Existence of a procedure that will be activated in case of loss or suspected attack. Obtaining insurance policies to cover all necessary areas.	ICU Director Nursing Director IT Director		2	2	4 
16. Lack of skills/experience	Damage to reputation. Professional exposure. Professional errors. Staff satisfaction.	2	5	10 	Use of government schemes e.g. apprenticeship. On-the-job training. Automation. Offering upskilling packages for doctors and nurses. Outsourcing. Creation of an annual mandatory training program for all staff.	ICU Director Nursing Director		1	2	3 
17. Loss of basic skills	Damage to reputation. Professional exposure. Professional errors. Staff satisfaction.	2	3	6 	Use of employee incentive programs or bonuses. Identification of top employees through rewards and offering incentives to retain them. Existence of different incentives such as parking spots, flexible work, etc.	ICU Director Nursing Director		1	2	3 

18. Low staff satisfaction	Organizational impacts. Operational impacts. Work climate. Damage to reputation. Physical and psychological burnout. Professional exposure. Professional errors.	3	3		Identification of sources of low satisfaction. Use of employee relationship management software. Quality control of the work environment. Implementation of surveys to monitor sentiment. Investing in the employee, including their training. Existence of clear objectives. Regular (6-monthly) review of the employee relations strategy. Existence of meritocracy and fairness in decision-making.	ICU Director Nursing Director		2	2	
19. Supply chain failure/delays	Damage to reputation. Organizational impacts. Operational impacts. Disruption of services provided. Resource allocation.	2	5		Registry of the location of suppliers and their facilities. Contact with suppliers for re-routing and creation of risk management procedures. Verification of suppliers' regulatory compliance. Diversification of approved suppliers. Maintaining a safety stock. Diversification of the supply chain. Adapting the supplies to seasonal fluctuations e.g. holiday periods.	ICU Director Nursing Director Procurement Director		2	2	
20. Staff evaluation	Operational impacts. Work climate. Staff turnover - resignations. Staff satisfaction.	3	3		Use of a TISS or OMEGA staff evaluation system. Measuring the medical or nursing workload per shift (satisfactory workload 40 - 50 points on the TISS measurement). Collecting sufficient nursing data.	ICU Director Nursing Director		2	2	
21. Absence of staff	Organizational impacts. Operational impacts. Work climate. Damage to reputation.	4	3		Establishing a staff absence policy. Examining the factors behind staff absences. Separating sick leave from annual leave, so that they can be monitored separately.	ICU Director Nursing Director		3	2	
22. Failure - disruption of information	Organizational impacts. Operational impacts. Damage to	2	2		Creation of a data backup policy. Existence of backup power and cooling sources e.g. generators.	ICU Director IT Director		1	1	



n systems	reputation. Disruption of services provided.				Investment in monitoring and early warning systems. Existence of a business continuity plan through a contract with an external company (e.g. Google, Amazon, etc.).					
23. Hospital Waste Management	Damage to reputation. Fines and penalties for environmental violations. Lawsuits. Legal Actions. Safety issues to staff and patients. Reduction in staff satisfaction. Reduction in patient satisfaction.	5	5	 25	There should be a dedicated corridor and lift in hospitals for the transport of waste. General waste must be disposed of at municipal dumps. Waste designated for autoclaving and incineration should be taken to a separate location for external transport, using distinct colored plastic bags for these types of waste. Transportation must be carried out in sealed containers, and the sanitation supervisor should ensure there are no leaks. Implementation of RFID (Radio Frequency Identification) technology. Implementation of Geographic Information System (GIS) applications. Implementation of Internet of Things (IoT) technics.	ICU Director Nursing Director		5	1	 5

Table 6. Updated risk matrix.

		Likelihood						
		P1	P2	P3	P4	P5		
		Rare	Unlikely	Possible	Likely	Almost Certain		
		0 – 19%	20 – 39%	40 – 59%	60 – 79%	80 – 100%		
		1	2	3	4	5		
Potential Consequences	S1	Not Significant	1	1 (22)	2 (6)	3 (5)	4	5
	S2	Minor	2	2 (3,12,16,17)	4 (9,10,11,14,15,18,19,20)	6 (21)	8	10
	S3	Moderate	3	3 (1,7,8)	6 (2,4,13)	9	12	15
	S4	Major	4	4	8	12	16	20
	S5	Severe	5	5 (23)	10	15	20	25

The numbers refer to the updated product between Likelihood and Potential Consequence from table 5, after the proposed measures take place.

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