

Hospital Risk Management and Patient Safety “Analytical Study” Compared to the Iso 31000:2018 Standard

Youness CHBAB^{1,2}, Soumia EL GHAZA², Brahim OUA KHZAN², Aziz.

ELOUAKFAOUI², Brahim ZAADOUD², El Mahjoub AOUANE²

¹Higher Institute of Nursing Professions and Health Techniques, Ministry of Health and Social Protection, Rabat, Morocco.

²Laboratory of Natural Resources and Sustainable Development, Faculty of Science, Ibn Tofail University, Kenitra, Morocco.

Abstract

The management of hospital risks and the safety of care are major concerns for healthcare establishments. The ISO 31000 version 2018 standard provides a reference framework for risk management across the organization. The analytical study of this standard in the management of hospital risks and the safety of care shows that the implementation of this standard can help healthcare establishments to identify, assess, treat and monitor the risks associated with healthcare. The main key elements of ISO 31000 include risk assessment, communication and consultation, planning and implementation, and monitoring and review. The study highlights the importance of collaboration and communication between the various actors involved in hospital risk management, including healthcare professionals, patients and their families, providers and regulatory authorities. Analysis of the ISO 31000 standard also shows that risk management and healthcare safety must be integrated into the organizational culture of the healthcare establishment. This involves putting in place effective risk management systems, monitoring and continuous improvement processes, as well as training and awareness programs for all involved. In conclusion, the ISO 31000 version 2018 standard provides a useful reference framework for the management of hospital risks and the safety of care. Its implementation can help healthcare institutions improve the quality of care, reduce risk to patients and strengthen their culture of safety.

Keywords: Care, service, risk, management, safety, ISO 31000, performance, hospital

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*Corresponding Author, e-mail: younesschbab@gmail.com

1. Introduction

The discourse on risk management and patient safety in healthcare facilities has been a subject of several emerging studies. From a perspective, the tools, methods, and approaches of risk management as well as the implementation in Moroccan healthcare establishments are still underdeveloped to ensure an overall performance of patient safety. The framework law 34-09, concerning the healthcare system and care provision, demands adherence to patient safety standards and safety standards for facilities, equipment, and personnel [1]. Similarly, law 43-13, pertaining to the nursing profession, emphasizes the development of nursing research to ensure and promote the quality and safety of care [2]. Indeed, risk management is both a regulatory and normative requirement and remains a matter of concern for Moroccan healthcare establishments and authorities [3].

The evaluation of the compliance of healthcare facilities' risk management systems with the requirements of ISO 31000 : 2018 standard revealed a significant gap of approximately 70%. This result will impact patient safety and

risk management practices focused on the performance of healthcare establishments. Improvement measures have been implemented to address identified non-conformities and adopt a risk management system that is an integral part of governance and leadership and holds fundamental importance in the way healthcare facilities are managed at all levels [4].

2. Risk Management Associated with Care

Several international organizations place great emphasis on the strategic importance of risk management associated with care as a promising approach to ensuring patient safety and care quality. Effective nursing care has become an essential and universal concern related to patient safety.

- **Concept of Risk:** The concept of risk is defined by ANAES as "an undesirable situation with negative consequences resulting from the occurrence of one or more events where uncertainty exists" [5]. According to Déroches and colleagues, the notion of risk is "the characteristic of an event, jointly defined by its

likelihood of occurrence and the severity of its consequences" [6].

- **Concept of Risk Management:** On the other hand, risk management is "a process of making arrangements to reduce the occurrence of risks or to mitigate the severity of the consequences" [7]. Risk management focused on patient safety lies at the heart of the daily concerns of healthcare facility managers, physicians, and caregivers. Generally, medical and paramedical activities are characterized by a high degree of uncertainty. Zero risk does not exist, and errors are inseparable from human activity. In healthcare structures, many procedures, whether professional, administrative, or regulatory, aim to control different types of risks. These risks are apprehended and classified in a very conventional manner, such as [8].

Thus, risk management associated with care encompasses three main axes:

- Prevention of risk through the implementation of preventive measures.
- Evaluation and analysis of risks to determine the criticality and severity of potential risks related to care.
- Treatment of risk through the establishment of corrective actions to improve the risk management system and ensure the safety and quality of care services.

3. Requirements of ISO 31000 Standard in Healthcare Services

Risk management is an iterative activity that helps organizations, especially healthcare establishments, develop strategies and make evidence-based decisions to enhance governance and leadership at all levels. Risk management is based on the principles, organizational framework, and process described in Figure 1. These elements may already exist, either in whole or in part, within the organization; however, they may require adaptation or improvement to ensure that risk management is efficient, effective, and coherent [9]. The ISO 31000 standard provides guidelines for risk management that organizations can apply to various contexts, including healthcare. It offers a generic approach to managing all forms of risk, be it organizational, medical, care-related, operational, etc.

- Principles of Risk Management in a Healthcare Establishment An effective risk management system within a healthcare establishment should consider the following elements:
- It must be integrated into all organizational, medical, and paramedical activities of the establishment.
- It should ensure consistent results through a structured and comprehensive approach, including all administrative, medical, and nursing care areas. The organizational framework and risk management process must be tailored to the context and strategic objectives of the Ministry of Health and Social Protection.
- Appropriate involvement of stakeholders, leading to a better-informed and relevant risk management process.
- It should anticipate, detect, recognize, and respond to changes and events in a timely and appropriate manner.
- Improved information and availability of up-to-date data accessible to relevant stakeholders.
- The culture and human behavior towards risk management at each level and stage.

- Continuous improvement through learning and experience.
- By adhering to these principles and applying the risk management process outlined in ISO 31000, healthcare establishments can enhance their ability to identify, assess, and mitigate risks effectively. This proactive approach fosters a safer environment for patients and improves the overall quality of healthcare services. Additionally, involving all relevant stakeholders ensures that risk management efforts are well-informed and tailored to the specific needs and goals of the healthcare organization.

4. Organizational Framework

The purpose of the organizational framework for risk management within a hospital establishment is to assist healthcare professionals in integrating risk management into all routine activities and functions. It involves considering how to steer a safety system in the face of multidimensional risks within a hospital setting. Hospital risk management, by definition, encompasses all methods of identifying, evaluating, treating, and prioritizing risks inherent in the activities and existence of healthcare facilities [10].

This organizational approach should be cross-functional, based on collaboration, and foster information exchange among all stakeholders involved in ensuring safety. The effectiveness of hospital risk management depends on its integration into the governance of the establishment, including the decision-making process. This requires support and involvement from stakeholders, particularly from the leadership. The development of the organizational framework includes integrating, designing, implementing, evaluating, and continuously improving the effectiveness of the decisions made [11]. By establishing a comprehensive organizational framework, healthcare facilities can ensure that risk management becomes an integral part of their daily operations. This approach enables proactive identification and management of potential risks, leading to improved patient safety, care quality, and overall performance of the healthcare organization. Moreover, fostering a culture of collaboration and information sharing among all stakeholders helps in creating a more resilient healthcare system capable of effectively addressing and mitigating risks as they arise.

5. System and Approach for Preventing Risks Associated with Care

The objective of hospital risk prevention is to ensure the safety and quality of care and services and thus avoid any patient or healthcare professional being affected by a malfunction in the hospital service [12]. One of the weaknesses of hospitals is the poor knowledge of potential risks they may harbor. Therefore, it is essential to have an early and systematic reporting of adverse events, an essential tool to precisely identify dysfunctions. Emphasis should be placed on the necessary comprehensiveness of reporting, which should encompass all activities within the establishment, including medical, nursing, technical, and administrative activities. The system and approach for preventing risks associated with care (RAC) aim to ensure patient safety and minimize errors and incidents that may occur during medical treatment. Here are the key steps of this approach:

1. Identification of risks: This step involves collecting data on risks associated with care and identifying the contributing factors to these risks. Techniques such as adverse event analysis, safety inspections, patient and staff surveys can be used to identify risks.

2. Risk assessment: This step involves assessing the probability and impact of each identified risk. Techniques such as risk matrices, risk impact analysis, and root cause analysis can be used to evaluate risks.

3. Planning prevention measures: This step involves planning and implementing measures to prevent identified risks. Measures may include the implementation of standard operating procedures, staff training, the use of checklists, the establishment of safety barriers, the implementation of monitoring and reporting systems, and the use of advanced technologies to reduce errors.

4. Implementation and monitoring of prevention measures: This step involves implementing the planned prevention measures and regularly monitoring them to ensure their continued effectiveness. Monitoring and reporting systems should be used to identify incidents and adverse events and continuously improve prevention measures.

5. Evaluation of the effectiveness of prevention measures: This step involves regularly evaluating the effectiveness of implemented prevention measures to ensure their continuous effectiveness and make improvements if necessary.

The approach to preventing risks associated with care should be integrated into the culture of the healthcare facility and supported by committed leadership and motivated healthcare teams. It should also be based on effective communication and interprofessional collaboration to ensure coordinated and safe patient care. By systematically applying this approach, healthcare establishments can significantly improve patient safety, reduce adverse events, and enhance the overall quality of care provided.

6. Materials and Methods

The evaluation of healthcare establishments in relation to ISO 31000 risk management standard can be conducted following the following steps:

- Preparation stage: Clarify the evaluation objectives, form an evaluation team, and collect necessary information about the healthcare establishment being evaluated.
- Identification of risks: Identify potential risks that the healthcare establishment faces using techniques like SWOT analysis, stakeholder surveys, inspections, and risk assessments.
- Risk assessment: Evaluate the probability and impact of each identified risk using methods such as risk matrix, risk impact analysis, and root cause analysis.
- Risk management: Implement risk management measures to mitigate identified risks. These measures can include the establishment of standard operating procedures, staff training, updating risk management policies, and improving existing processes.
- Monitoring and review: Monitor managed risks and regularly evaluate risk management measures to ensure their continued effectiveness.

The necessary materials for conducting an evaluation of healthcare establishments in relation to ISO 31000 may include documents such as the ISO 31000 standard, guides and manuals on the use of the standard, risk

information collection sheets, risk matrices, tools for evaluating the probability and impact of risks, risk management plan templates, risk monitoring and tracking tools, as well as guides for analyzing the root causes of risks. The methods used may vary depending on the specific healthcare establishment being evaluated and the specific evaluation objectives. It is recommended to engage risk management experts to conduct a thorough and reliable evaluation in line with ISO 31000 standard.

Questionnaire for Evaluation Adaptation of Evaluation Criteria from the Reference Framework A comprehensive review of hygiene reference frameworks and standards was conducted to identify evaluation criteria suitable for school meal services. A questionnaire containing over 200 hygiene-related criteria across various dimensions was established. The table below represents the model of the evaluation grid used in our study. Planning and Conducting Evaluation Visits The baseline assessment was scheduled at three establishments. During the evaluation process, we adopted various methods to collect information about hygiene practices in the study sites. Interviews were conducted with responsible personnel overseeing the meal preparation operations and cleaning staff.

Additionally, observations were made to visually assess compliance with good hygiene practices during meal preparation, equipment washing, and cleaning operations. The collected responses were recorded on evaluation grids. Subsequently, we defined a scoring method to calculate conformity and non-conformity rates and draw conclusions about the level of adherence to hygiene criteria.

6.1. Method of Scoring

In the evaluation grid, we assigned a coefficient of (0), (1) and (2) to each response to quantify and present the results in a graphical form. We gave a score of (2) to criteria that were fully compliant, a score of (1) to criteria that were partially compliant, and a score of (0) for non-compliant criteria. The rates are calculated using the following formulas:

These rates provide a clear representation of the level of adherence to the hygiene criteria evaluated. The conformity rate indicates the percentage of fully compliant criteria, the partial conformity rate shows the percentage of partially compliant criteria, and the non-conformity rate reveals the percentage of criteria that are not compliant at all. By using this scoring method, you can effectively assess and visualize the compliance level with the hygiene standards being evaluated.

7. Results, Evaluation Findings and Discussions

7.1. Principles

Here is the analysis of the evaluation results for the principles related to risk management in the 5 hospital establishments, based on the average compliance and non-compliance rates:

7.1.1. Integrated

- The average compliance rate is 30,15%, indicating that only one-third of the establishments have fully integrated risk management principles into their operations.
- The average non-compliance rate is high, at 69,85%, suggesting that the majority of establishments still have room

for improvement in effectively integrating risk management across their activities.

7.1.2. *Structured and comprehensive*

- The average compliance rate is 41,25%, showing that less than half of the establishments have implemented a structured and comprehensive approach to risk management.
- The average non-compliance rate is 58,75%, revealing that more than half of the establishments have not yet implemented a comprehensive risk management approach.

7.1.3. *Adapted*

- The average compliance rate is 21,85%, indicating that most establishments struggle to adapt their risk management practices to their specific context.
- The average non-compliance rate is high, at 54,14%, highlighting a need for improvement in the establishments' ability to adapt their risk management practices.

7.1.4. *Inclusive*

- The average compliance rate is 45,86%, showing that less than half of the establishments have embraced an inclusive approach to risk management, involving all relevant stakeholders.
- The average non-compliance rate is 54,14%, indicating that more than half of the establishments still face challenges in involving all stakeholders in risk management.

7.1.5. *Dynamic*

- The average compliance rate is 41,02%, suggesting that the majority of establishments still need to make efforts to adopt a dynamic approach to risk management, capable of adapting to changes and events in a timely manner.
- The average non-compliance rate is 58,98%, indicating that the majority of establishments have risk management practices that lack dynamism.

7.1.6. *Better information*

- The average compliance rate is 52,41%, indicating that more than half of the establishments have implemented measures to improve information availability related to risk management.
- The average non-compliance rate is 47,59%, showing that some establishments still need to ensure better information related to risk management.

7.1.7. *Human and cultural factors*

- The average compliance rate is 67,12%, revealing that the majority of establishments give importance to human and cultural factors in their risk management.
- The average non-compliance rate is 32,88%, indicating that some establishments still need to strengthen their consideration of human and cultural factors in their risk management approach.

7.1.8. *Continuous improvement*

- The average compliance rate is 31,12%, showing that less than one-third of the establishments have implemented actions for continuous improvement in their risk management.

- The average non-compliance rate is high, at 68,88%, indicating that the majority of establishments have opportunities for improvement in risk management.

In summary, these results show that there are areas where hospital establishments have made significant progress in their risk management, particularly concerning the consideration of human and cultural factors. However, there are also aspects that require improvement, particularly in terms of integration, adaptation, and continuous improvement of risk management practices. These findings will enable establishments to implement targeted actions to strengthen their risk management and improve the safety of the care they provide.

7.2. *Organizational Framework*

7.2.1. *Clarification of Risk Management Responsibilities*

- The average compliance rate is 28,75%, indicating that only a minority of establishments have effectively clarified risk management responsibilities.
- The average non-compliance rate is high, at 71,25%, suggesting that most establishments need to improve in clearly defining risk management responsibilities.

7.2.2. *Integration into Governance and Leadership*

- The average compliance rate is 42,50%, showing that less than half of the establishments have successfully integrated risk management into their governance and leadership structures.
- The average non-compliance rate is 57,50%, revealing that a significant number of establishments still need to better integrate risk management into their governance and leadership practices.

7.2.3. *Involvement of Relevant Stakeholders*

- The average compliance rate is 20,15%, indicating that the majority of establishments struggle with involving relevant stakeholders in risk management processes.
- The average non-compliance rate is high, at 79,85%, highlighting the need for improvement in involving relevant stakeholders in risk management.

7.2.4. *Adequate Resources Allocation*

- The average compliance rate is 46,25%, showing that less than half of the establishments have adequately allocated resources for risk management.
- The average non-compliance rate is 53,75%, suggesting that there is room for improvement in resource allocation for risk management.

7.2.5. *Risk Management Policy and Procedures*

- The average compliance rate is 39,40%, indicating that less than half of the establishments have established comprehensive risk management policies and procedures.
- The average non-compliance rate is 60,60%, revealing that a significant number of establishments need to enhance their risk management policy and procedure framework.

In summary, the results highlight several areas in which the 5 hospitals establishments need to improve in their organizational framework for risk management.

Conformity Rate:

$$\% C = (\text{Number of fully compliant criteria} * 2) / (\text{Total number of criteria} * 2) * 100$$

Partial Conformity Rate:

$$\% CP = (\text{Number of partially compliant criteria} * 1) / (\text{Total number of criteria} * 2) * 100$$

Non-Conformity Rate :

$$\% NC = 100 - (\% C + \% CP)$$

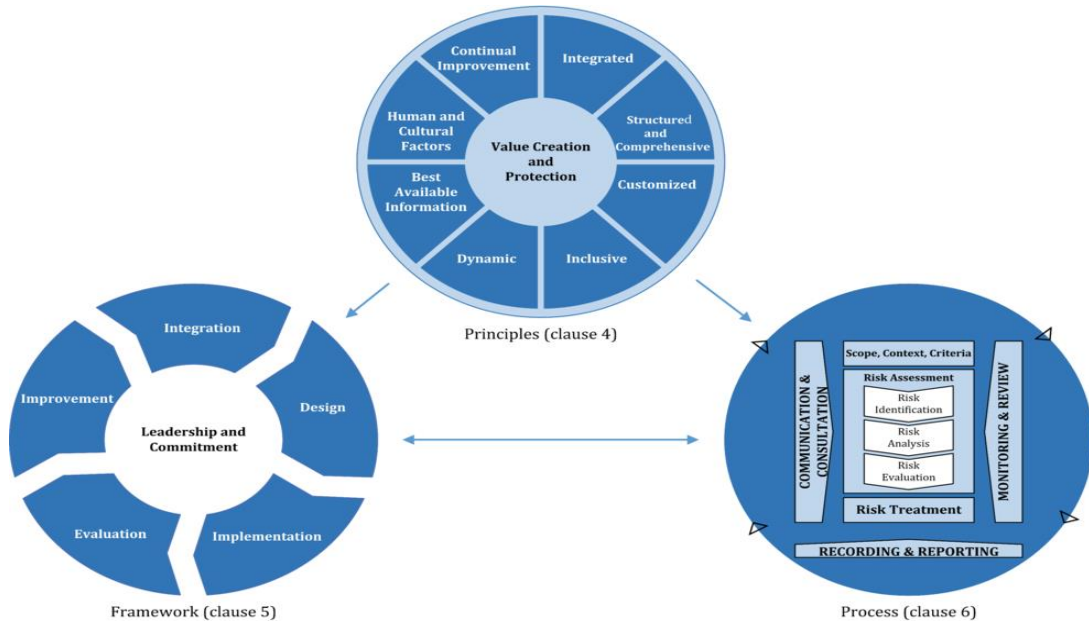


Figure 1. Principles, Organizational Framework, and Process (Source: ISO 31000/2018)

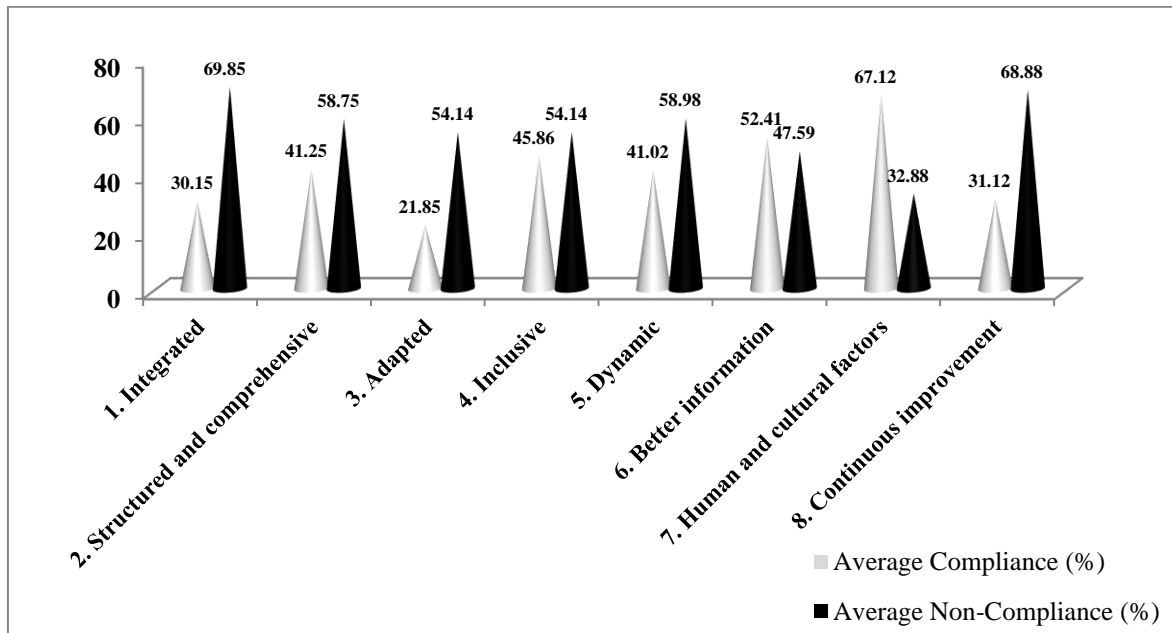


Figure 2. Graphical representation of the evaluation results of the compliance with risk management principles in the 5 hospital establishments

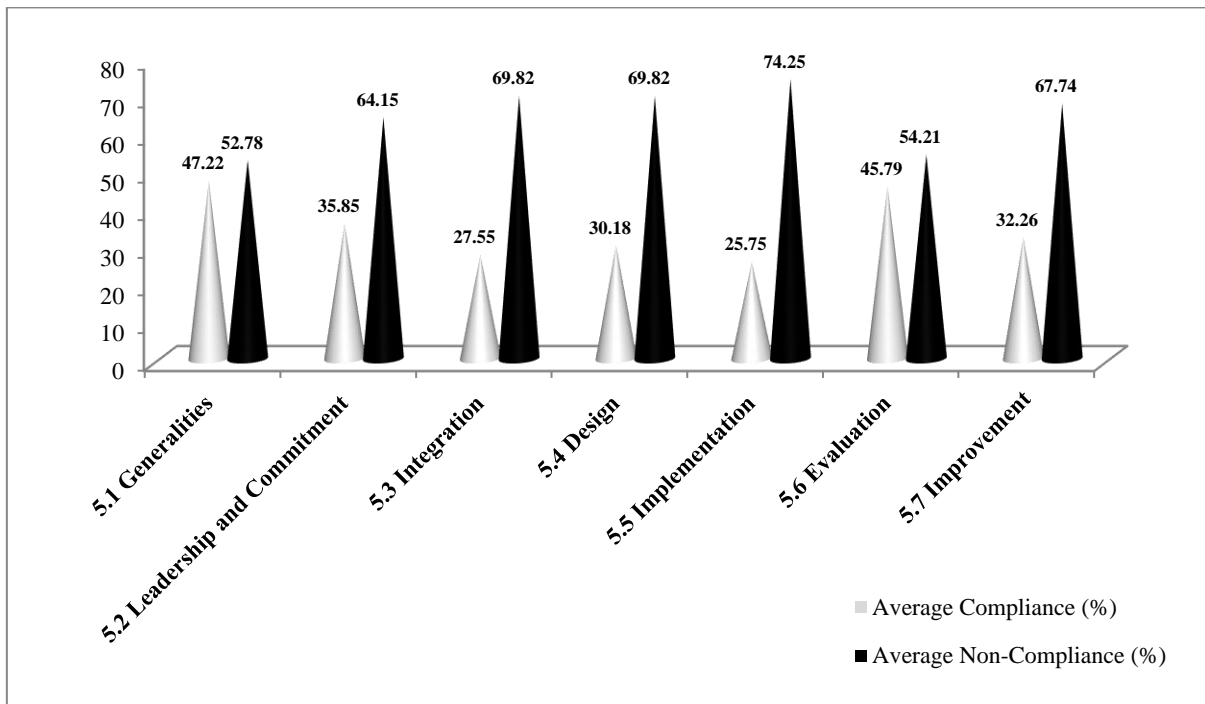


Figure 3: Evaluation results of the compliance with the organizational framework of risk management in the 5 hospital establishments

Table 1. Evaluation results of the compliance with risk management principles in the 5 hospitals establishments

Principles	Average Compliance (%)	Average Non-Compliance (%)
1. Integrated	30,15	69,85
2. Structured and comprehensive	41,25	58,75
3. Adapted	21,85	54,14
4. Inclusive	45,86	54,14
5. Dynamic	41,02	58,98
6. Better information	52,41	47,59
7. Human and cultural factors	67,12	32,88
8. Continuous improvement	31,12	68,88

Table 2. Evaluation results of the compliance with the organizational framework of risk management in the 5 hospitals establishments.

Organizational Framework	Average Compliance (%)	Average Non-Compliance (%)
5.1 Generalities	47,22	52,78
5.2 Leadership and Commitment	35,85	64,15
5.3 Integration	27,55	69,82
5.4 Design	30,18	69,82
5.5 Implementation	25,75	74,25
5.6 Evaluation	45,79	54,21
5.7 Improvement	32,26	67,74

Table 3. Evaluation results of the compliance with the organizational framework of risk management in the 5 hospitals establishments

Processus	Average Compliance (%)	Average Non-Compliance (%)
6.1 Generalities	51,41	48,59
6.2 Communication and Consultation	42,62	57,38
6.3 Scope of Application	25,25	74,75
6.4 Risk Assessment	65,68	34,32
6.5 Risk Treatment	58,01	41,99
6.6 Monitoring and Review	50,45	49,55
6.7 Recording and Reporting	62,75	37,25

Clarification of risk management responsibilities, involvement of relevant stakeholders, and establishment of comprehensive risk management policies and procedures are some of the critical areas requiring attention. Enhancing the integration of risk management into governance and leadership practices and adequately allocating resources for risk management are also important aspects for improvement. These findings will aid the establishments in developing targeted strategies to strengthen their organizational framework for risk management and enhance patient safety.

7.3. Processus

To analyze the evaluation results of the compliance with the risk management framework in the 5 hospital establishments, let's examine the average compliance and non-compliance rates for each aspect:

7.3.1. Generalities

- The average compliance rate is 37,20%, indicating that there is room for improvement in addressing general aspects related to risk management in the establishments.
- The average non-compliance rate is 62,80%, highlighting the need for better adherence to general principles of risk management. This suggests that the establishments may need to focus on establishing a clear and comprehensive risk management policy and guidelines.

7.3.2. Communication and Consultation

- The average compliance rate is 48,75%, showing that the establishments have made some progress in implementing communication and consultation practices related to risk management.
- The average non-compliance rate is 51,25%, indicating that there is still work to be done in enhancing communication and consultation efforts. This aspect is crucial for involving all stakeholders in the risk management process and ensuring effective communication channels.

7.3.3. Scope of Application

- The average compliance rate is 41,60%, indicating that the establishments have partially defined the scope of application for risk management practices.
- The average non-compliance rate is 58,40%, suggesting the need for further efforts in clearly defining the scope of risk management to encompass all relevant areas and activities within the establishments.

7.3.4. Risk Assessment

- The average compliance rate is 30,95%, showing that there is significant room for improvement in implementing effective risk assessment methodologies.
- The average non-compliance rate is 69,05%, signifying the need for better risk assessment practices. This aspect is critical for identifying and prioritizing potential risks accurately.

7.3.5. Risk Treatment

- The average compliance rate is 45,10%, indicating that the establishments have partially implemented risk treatment measures.
- The average non-compliance rate is 54,90%, highlighting the need for more effective risk treatment strategies and actions to mitigate identified risks appropriately.

7.3.6. Monitoring and Review

- The average compliance rate is 37,90%, suggesting that the establishments have made some progress in monitoring and reviewing risk management efforts.
- The average non-compliance rate is 62,10%, indicating that there is room for improvement in establishing robust monitoring and review mechanisms. Regular evaluation is essential for ensuring the effectiveness of risk management measures.

7.3.7. Recording and Reporting

- The average compliance rate is 52,05%, showing that the establishments have implemented recording and reporting practices for risk management to some extent.
- The average non-compliance rate is 47,95%, indicating the need for more comprehensive and accurate recording and reporting of risk management activities. Clear documentation is crucial for accountability and learning from past experiences.

Overall, the evaluation results suggest that the 5 hospital establishments have made progress in some aspects of risk management, particularly in areas related to communication, involvement of stakeholders, and recording and reporting practices. However, there are areas that require significant improvement, such as risk assessment, scope definition, and continuous monitoring and review of risk management efforts. To enhance risk management practices, the establishments may need to focus on establishing comprehensive risk assessment methodologies, defining the scope of risk management clearly, and implementing effective monitoring and review mechanisms. Additionally,

enhancing communication channels and involving all stakeholders in the risk management process can further improve patient safety and overall quality of healthcare services. By addressing these areas of improvement, the establishments can create a more robust and effective risk management framework to safeguard patient well-being and provide high-quality healthcare services.

Hospital risk management and patient safety are critical issues for healthcare facilities. Patients have the right to receive safe and effective care, and hospitals have the responsibility to ensure the safety of both patients and staff. To address these challenges, hospitals often use risk management standards such as ISO 31000. ISO 31000 is an international framework for risk management that provides guidelines for identifying, analyzing, evaluating, treating, and monitoring risks. The 2018 version of this standard is particularly relevant for hospitals as it emphasizes the importance of risk culture and transparent communication. By using ISO 31000, hospitals can establish a structured process to manage risks and improve the safety of care.

This process includes several steps, namely:

1. Risk identification: Hospitals must identify all potential risks related to their activities, including risks to patient and staff safety.
2. Risk analysis: The identified risks must be assessed in terms of probability and severity to determine their significance.
3. Risk management: Hospitals must implement strategies to manage risks, including reducing their probability or impact.
4. Monitoring and ongoing evaluation: Hospitals must continuously monitor risks and evaluations to ensure that risk management strategies are effective.

By implementing these steps, hospitals can enhance the safety of care for patients and staff, reduce costs associated with medical errors, and strengthen patient confidence in their healthcare facility. However, applying ISO 31000 in hospitals can be complex and requires strong commitment from hospital leadership and staff. It is crucial that the teams responsible for risk management receive proper training and have the necessary resources to implement an efficient process.

In conclusion, hospital risk management and patient safety are crucial issues for healthcare facilities. The ISO 31000 version 2018 provides a valuable framework to assist hospitals in managing risks and enhancing patient safety. However, the successful implementation of this standard requires strong commitment from hospital leadership and staff to ensure its effectiveness. By embracing ISO 31000 and adopting a systematic approach to risk management, hospitals can proactively identify and mitigate potential risks, leading to improved healthcare outcomes and a safer environment for both patients and healthcare professionals. It is essential for hospitals to prioritize risk management as an integral part of their operations, and to continually monitor and review their risk management practices to achieve the highest level of safety and quality of care.

In conclusion, hospital risk management and patient safety are critical issues for healthcare quality. The analytical study of ISO 31000 version 2018 highlights the importance of risk management in ensuring patient safety, healthcare quality, and the sustainability of healthcare facilities. ISO 31000 provides a robust framework for risk management, *CHBAB et al., 2023*

focusing on risk assessment, communication, and consultation, planning and implementation, as well as monitoring and review. Its implementation can help healthcare facilities adopt a systematic and consistent approach to risk management, involving all relevant stakeholders and integrating patient safety into the organizational culture. Ultimately, hospital risk management and patient safety are shared responsibilities among all stakeholders in the healthcare system. Implementing ISO 31000 version 2018 can promote a culture of safety and healthcare quality within healthcare facilities, fostering collaboration, communication, and engagement among all those involved in delivering quality healthcare services.

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