Risk management in medicine: the process of identification, assessment and control of risks in medical practice

Gestão de riscos na medicina: o processo de identificação, avaliação e controle de riscos na prática médica

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Abstract

Risks accompany any activity of a person, company, or country throughout life. The healthcare industry is no exception, given the constant difficult situations that occur with patients, medical personnel, and healthcare facilities in general. All risks in medical practice can be divided into different groups according to the object in the risk zone: general risks (economic, financial, environmental, military, etc.), specific risks aimed at the patient (diagnostic, therapeutic, pharmacotherapeutic, etc.), and specific risks aimed at the healthcare employee (working conditions, contact with hazardous infections, etc.). Risk governance is one of the priorities of healthcare institutions in achieving their goals because there is always

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a chance that something will go wrong, not as it was planned. In the field of healthcare, as in other industries, to assess and analyze the risks one can use risk matrices. These matrices allow for quantitative, semi-quantitative, and qualitative risk analysis. The latter makes it possible to develop the right strategy for responding to and mitigating those risks. This study aims to conduct comprehensive research of the risk stages in medical practice, as well as to provide detailed recommendations for risk analysis and emphasize the importance of corporate risk governance in healthcare activities. The authors analyzed the data collected since 2013. It has been found that the study of the overall risk level assigned to each incident helps to determine the urgency and degree of control measures required.


**Resumo**

Os riscos acompanham qualquer atividade de uma pessoa, empresa ou país ao longo da vida. O setor da saúde não foge à regra, dadas as constantes situações difíceis que ocorrem com os pacientes, o pessoal médico e as instalações de saúde em geral. Todos os riscos na prática médica podem ser divididos em diferentes grupos de acordo com o objeto da zona de risco: riscos gerais (econômicos, financeiros, ambientais, militares, etc.), riscos específicos direcionados ao paciente (diagnósticos, terapêuticos, farmacoterapêuticos, etc.), e riscos específicos dirigidos ao trabalhador de saúde (condições de trabalho, contacto com infeções perigosas, etc.). A governação do risco é uma das prioridades das instituições de saúde para atingir os seus objetivos porque existe sempre a possibilidade de algo correr mal, não como foi planeado. Na área da saúde, como em outras indústrias, para avaliar e analisar os riscos podem-se utilizar matrizes de risco. Essas matrizes permitem análises de risco quantitativas, semiquantitativas e qualitativas. Este último permite desenvolver a estratégia adequada para responder e mitigar esses riscos. Este estudo tem como objetivo realizar pesquisas abrangentes sobre os estágios de risco na prática médica, bem como fornecer recomendações detalhadas para análise de riscos e enfatizar a importância da governança corporativa de riscos nas atividades de saúde. Os autores analisaram os dados recolhidos desde 2013. Verificou-se que o estudo do nível de risco global atribuído a cada incidente ajuda a determinar a urgência e o grau de medidas de controlo necessárias.

Introduction

One constantly meets risks in ordinary life, they are inevitable in any complex program, including medicine (Arimbi, Puspasari, & Syaifullah, 2019). Risk is defined as "the probability of something occurring that will influence the achievement of organizational objectives." The definition of risk governance in the literature is the following: "all activities related to identifying, assessing, selecting response options, and monitoring risks." The general risk governance pattern under international risk governance standards ISO 31000 consists of several vital stages (Spross, Olsson, & Stille, 2017), namely:

− Defining the organizational context;
− Risk identification;
− Risk analysis;
− Risk estimation;
− Risk treatment;
− Monitoring and review;
− Communication and consultation encompassing the entire process.

In this structure, risk estimation is a term that includes three consecutive stages: risk identification, risk analysis, and risk evaluation (ISO 31000, 2018; NSW Government, 2018). Risk identification is used to search, recognize, and describe hazards that may impact the achievement of goals. Risk analysis is proposed to define the nature, sources, and causes of identified risks and evaluate their levels. It is possible to use risk evaluation to understand the difference between the results of risk analysis with risk criteria to determine whether the specified risk level is acceptable or tolerable and to identify where additional actions are required (ISO 31000, 2018). Therefore, risk estimation gives possibilities to decision-makers to prioritize which risks will be considered and with what priority. It turns out to be a key part of the decision-making process, as it can help determine options for possible risk governance according to the specified risk level (Strametz, 2017).

Nowadays risk governance is a major task for organizations and governments in achieving their goals because there is a likelihood that things may go differently than planned. Organizations in the healthcare field are revealed as high-risk and highly complex, with a variety of interdependent dimensions. Therefore, risk governance in healthcare is critical, as even a low-risk event can have serious outcomes that affect patients, staff, costs, and, in general, the hospital's reputation. Risk estimation and ranking tools, developed in complex
and high-reliability sectors such as nuclear energy, manufacturing, and aviation, have been recently adopted to solve the problem of patient safety, specifically in the healthcare sector.

Different analytical methods focus on two general points - the presence and severity of hazards. They vary in the methodology of assessment and the combination of these two factors in the process of risk estimation (Van der Fels-Klerx et al., 2018). One of these ways uses a qualitative or semi-quantitative risk estimation matrix to determine, evaluate, and rank threats-related risks and define which of them needs to be controlled first. This treatment’s comparative simplicity and simplicity have likely promoted its worldwide adoption. This includes a common international standard for the methods of risk estimation in risk governance support (Gul & Ak, 2018; Li, Bao, & Wu, 2018; Vatanpour, Hrudey, & Dinu, 2015). In this context, hospital personnel often have to decide whether certain risks are high or low, but participants must clearly define what is considered "high" and what is "low." (Healthcare Insurance Reciprocal of Canada, 2014).

There are various risks related to healthcare institutions and hospitals. Healthcare organizations are engaged in highly complex surgeries that aim to provide high-quality patient care. As a sensitive service industry, it is exposed to significant risks from both the patient and staff perspectives. Risk governance in healthcare refers to processes that include monitoring, assessing, mitigating, and preventing clinical and administrative risks. Healthcare risk governance was traditionally focused on patient safety. Nevertheless, as healthcare services have expanded their role, the related risks have also increased. They relate to patient safety, business viability, and sustainability in financial, legal, and political areas. As a result, hospital services and other healthcare organizations are expanding their programs of risk governance that primarily support and promote patient safety but also actively protect other areas of business-related risks.

**Literature Review**

The quality of healthcare is an indicator of a society's level of development. Healthcare institutions play a key role in social and economic life (Kubar, 2016). As service-providing enterprises, healthcare organizations deliver medical services to meet societal needs by combining production factors (Türk & Ertaş, 2018). However, they are regarded as a distinct sector due to the social importance of their services, market size, and their unique features (Türk & Çil Kocyigit, 2020).
The activities of healthcare institutions are associated with encountering numerous risks, which occur continuously for both patients and healthcare professionals and the institutions themselves. All risks may relate to the healthcare institution, the patient, or the medical staff separately. Considering the significant number of threats in medical practice, risk governance is used to be a primary task, as there is a high likelihood that things may go differently than planned. Risk matrices are necessary for the estimation and analysis of risk levels and hazards in medicine, as well as in other fields. They enable quantitative, semi-quantitative, and qualitative risk analysis, allowing healthcare institutions to develop appropriate strategies for responding to and mitigating the outcomes of risks.

To understand the nature, evaluate the level of each risk, and provide a basis for risk estimation and decision-making it is important to be aware of all the risk matrix limitations. These limitations influence and impair the reliability of the provided information. There are traps for careless users of risk matrices (Baybutt, 2015). If risk matrices are not scientifically developed, the assessed risk evaluation may not be reliable (Chunbing, Dengshen, Wan, Li, & Chen, 2017). Despite widespread usage, an increasing number of authors identify, analyze, and discuss limitations and discrepancies in the risk matrix treatment, which are related to its development, utilization, and influence on risk governance decisions.

Cognitive limitations that affect a person's ability to elucidate and assess information can lead to errors and biases associated with the estimation of input data in risk matrices: impact-severity-consequence and probability-likelihood-frequency (Pascarella et al., 2021). People's risk aversion can complicate risk matrix results (Chunbing, Dengshen, Wan, Li, & Chen, 2017). The risk matrix is only one part of a broader process. The adequacy and reliability of information largely depend on the descriptions of outcomes and probabilities used by the matrix developer (Peace, 2017). Decisions based solely on the matrix can lead risk assessors to provide subjective and arbitrary judgments, rendering any risk estimations of dubious value. So, gathered information obtained from mapping with data on control measures, which are considered critical, can make the risk control activities more adequate and reliable.

Effective risk reduction measures cannot rely just on the risk matrix categories. They require additional quantitative information on the clamping of the budget and the interaction between control measures (Pascarella et al., 2021). In attempting to overcome decision-maker biases and competence during risk matrix result estimation, it is necessary to compare the risk level established by the risk matrix with the risk criteria set in advance by the healthcare
organization. Risk criteria are essential for information obtained from the matrix to be correctly applied (Peace, 2017).

The danger lies in the fact that hospitals may use the matrix as a means and assessment tool not just like a simple visualization tool, unintentionally ignoring all its restrictions, given the limitations that can significantly affect the experts' opinions in decision-making and risk analysis. Arguably, the most significant risk for healthcare organizations is the "bias and competence of the risk matrix developer." When the developer does not know matrix construction principles and their pitfalls, as well as unfamiliarity with relevant events in the sector, the most common mistake is borrowing a matrix from another organization without attempting to adapt or customize it to the specific context (Peace, 2017). Additionally, the use of a single corporate risk matrix should be avoided as it is challenging to find a universal matrix that can be applied uniformly to numerous events pertinent to the healthcare organization. It is necessary to elaborate an effective risk matrix for decision-making to suit specific circumstances. What may be an acceptable risk at the company level may be unacceptable at the department level and even more tragic at the organizational level (Duijm, 2015).

Many authors have proposed various solutions to avoid the restrictions of risk matrices. A described process for elaboration of an obscure risk matrix can be used for new obscure logic applications in different security analyses to model vaguenesses associated with severity and possibility concepts (Pascarella et al., 2021). Earlier, Gul and Guneri (2016) proposed an obscure treatment. It allows assessors to employ linguistic variables to eliminate the shortcomings of a crisp risk estimation calculation and reduce inconsistency in risk decision-making by weighting probability and severity factors through an obscure analytic hierarchy procedure. It can also be used when evaluating five risk parameters: severity, occurrence, detectability, sensitivity to maintenance, non-execution, and sensitivity to personal protective equipment non-usage (Gul & Guneri, 2016; Gul, Ak & Guneri, 2017). The authors provide some recommendations, including:

- the colouring of the components of the risk matrix;
- the choice of logarithmic scales for both outcomes and probability (it allows covering several orders of magnitude of probability and outcomes);
- determining (when aggregating risks) the rules for moving the aggregate probability of several separate events with similar solutions (outcomes) to the following probability category;
- avoiding the use of common corporate risk matrices;
– using the uninterrupted possibility-consequence diagram that employs uninterrupted scales instead of discrete ones as an alternative to the risk matrix;
– presenting ambiguity in risk charts in practical elaborations after estimating the advantages and disadvantages of existing proposals;
– modifying possibility-consequence charts with predisposal intervals and evidence estimation reliability (references not provided for the last part) (Duijm, 2015; Goerlandt & Reniers, 2016; Aven & Reniers, 2013; Abrahamsen, Amundrud, Aven & Gelyani, 2014).

A "consistent update treatment" has been proposed to overcome the limitations of the common risk matrix based on "modified weak sequence," "consistent internal consistency," and "continuous screening" (Li, Bao, & Wu, 2018). The last three comprise the principles that reliably characterize an excellent risk matrix rating scheme. They propose a global ranking algorithm to elaborate a framework that responds to the three principles. In a hypothetical case, it explains the implementability of a treatment where decision-makers need to evaluate project risks with the same outcomes but do not have sufficient risk data to determine how to prioritize these risks.

Several recommendations have been made to address the challenges, primarily related to the methodological treatment and how to manage a risk that generates multiple impacts in many areas (Kaya, 2019; Card, Ward, & Clarkson, 2014). The results showed a variety of risk matrices applied, primarily related to the size of the risk matrix (e.g., 3 × 3 or 5 × 5), the type of matrix (symmetric or asymmetric), and the number of coloured bands and risk score for each band, which can increase the likelihood of mis-prioritizing risk. In addition, the results demonstrate that hospitals may give insufficient manuals on how to assess probability and outcomes and action algorithms in response to existing criticisms of risk matrices.

So, despite the existence of many guidelines for risk identification, estimation, and management, there are many unresolved issues regarding risk analysis and management in medical practice. These issues are related to the clash of interests of three parties in this area: the patient, the healthcare worker, and the healthcare facility.

The article aims to highlight the key variables, advantages, disadvantages, strengths, and weaknesses of the entire risk analysis stage in healthcare organizations. It also seeks to provide guidance on risk analysis carried out using a risk matrix and emphasize the importance of enterprise risk governance in healthcare institutions.
Methods and Materials

For this complex search for relevant articles, the MEDLINE-PubMed and EBSCOhost databases were searched for relevant studies since 2013. A set of "MeSH terms" was created to remove a large number of irrelevant papers in the manual search: "Risks/healthcare industry"[Mesh] / "Risk matrix"[Mesh] / "Risk governance/medical practice"[Mesh]) / "Risk identification/healthcare"[Mesh] / "Risk estimation/healthcare"[Mesh]. The same search terms were used for the database (EBSCOhost). The current literature review includes studies that focus on identifying healthcare risks, their estimation, risk governance in medical practice, and risk mitigation.

Results

Analysis of risks in the healthcare sector involves examining risk sources, their outcomes, and the probability that these outcomes may accommodate patient safety, individuals involved in healthcare delivery, and the organization itself. The aim is to distinguish between admissible minor clinical risks and unadmissible major risks and give data to aid in further risk estimation and control (Strametz, 2017; Department of Health, Government of Western Australia, 2016).

The Risk Matrix Method, also known as the "decision matrix method for risk estimation," turns out to be a systematic treatment used in risk estimation to determine and rank the level of risk, compare different risks, and identify which threats have to be controlled at the first time to diminish the credibility of potential risks occurring. The level of risk depends primarily on two variables: the sternness of harm and the probability of its occurrence (Gul & Ak, 2018).

The Decision or Risk Matrix (Figure 1) is user-friendly and visually appealing. It can be applied even with limited data and does not require specialized knowledge, offering a quick graphical way to recognize risk issues, the seriousness of hazards, and their frequency/probability (Li, Bao, & Wu, 2018; Baybutt, 2015). The risk matrix is a two-dimensional lattice, with horizontal cells reflecting the chance of potential outcomes and vertical cells representing the severity categories of these events (U.S. Department Of Agriculture Forest Service, 2020). The intersection of cells helps to provide a relative ranking of various types of risks and establishes a baseline level from which progress and trends can be measured over time (Healthcare Insurance Reciprocal of Canada, 2014).
Matrices may have various designs based on an organization's risk pattern, and the desired number of cells depends on the scales of outcomes and probabilities used. A five-level scale for outcomes and probabilities is the most common, resulting in 25 cells. However, other combinations can be encountered (e.g., 3x3, 6x6, 7x10). It is essential to consider that 3x3 matrices may not provide sufficient detail for beneficial results, while 10x10 matrices might mislead users into believing they offer greater accuracy. It is claimed that a 5x10 matrix can allow the analysis of negative as well as positive outcomes and their influence on objectives (Peace C. 2017).

<table>
<thead>
<tr>
<th>Probability</th>
<th>Occurrence</th>
<th>0.1</th>
<th>0.3</th>
<th>0.5</th>
<th>0.7</th>
<th>0.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Often, under any circumstances</td>
<td>0.9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probably under most circumstances</td>
<td>0.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td>0.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very rarely, only under certain circumstances</td>
<td>0.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description of occurrence possibility</th>
<th>0.1</th>
<th>0.3</th>
<th>0.5</th>
<th>0.7</th>
<th>0.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not require treatment or first aid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimal injuries, requires first aid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The injury requires medical intervention and takes time</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Serious injury, requires in-patient treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death or permanent and severe disability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Color-coded risk gradation**
- 0.01-0.03 Very low risk
- 0.05-0.07 Low risk
- 0.09-0.27 Average risk
- 0.35-0.49 High risk
- 0.63-0.81 Very high risk

Figure 1. The risk matrix for quantitative, semi-quantitative, and qualitative risk analysis
Source: Authors' findings

The colour coding allows for a quicker estimation of the risk level. The risk levels and corresponding colour codes are categorized based on their evaluation or calculation, and the degree of loss can be defined in five levels:

1. very high-risk level – red,
2. high-risk level – orange,
3. moderate or average risk level – yellow,
4. low level of risk – green,
5. Very low level of risk – grey/blue.

The levels of description of the occurrence possibility can be expressed as percentages or in semantic terms. Risks with the same quantitative values should have the same qualitative ratings and colour.
The risk matrix is usually used in healthcare facilities because it can standardize the risk grading process and gives a visualization of the probability of an event occurring as well as of its outcomes if an event occurs. It provides a direct view of how these two elements affect the overall risk, facilitating stakeholder discussion about the identified risks (Van der Fels-Klerx et al., 2018; Kaya, Ward, & Clarkson, 2019). More than that, the risk matrix helps evaluate and document risk changes before and after the implementation of controls (World Health Organization, 2012).

A well-designed risk matrix (including its colour) should meet three axioms:

1. Weak consistency,
2. Interrelationship,
3. Axiom of consistent colour (Pascarella et al., 2021).

The Axiom of Weak Consistency requires that all risks in a cell with a higher rating be quantitatively greater than any risk in a cell with a lower rating. So, the smallest risk point in a cell with a higher rating must be quantitatively larger than the most significant one with a lower rating (Chunbing, Dengshen, Wan, Li, & Chen, 2017). This axiom shows that to satisfy weak order, any risk matrix must be performed by at least three colours (green, yellow, and red). Continuity means that the yellow risk category must be passed between a slight change in the probability or impact starting from the green risk category and ending in the red category. Sequential colouring means that risks with equal quantitative levels must have the same qualitative and colour estimations.

It is possible to use the risk matrix to assess the risk rating through quantitative, qualitative, and semi-quantitative methods (see Figure 1). The quantitative treatment calculates numerical values connected with each element, which is the result of risk estimation (Pascarella et al., 2021). Thus, the risk impact, probability, and level are determined by numerical values (Ayatollahi & Shagerdi, 2017). For instance, the level of risk of patient injury resulting from a specific medical procedure may be determined by assessing the chance based on historical frequency or accessible statistical data and numerical values expressing potential impacts, ranking from insignificant injuries to harsh ones leading to death (Pascarella et al., 2021).

In contrast to quantitative methods, qualitative methods do not express probability or outcomes with numbers. The values of probability and impact/outcomes of a particular event are presented by specification based on a pre-defined rating scale (Pascarella et al., 2021). This usually means imprecise risk determination and is used in all cases where the calculation of numerical risk values is impossible or complex (Ayatollahi & Shagerdi, 2017). For
example, when numerical data is insufficient or unavailable, resources are restricted (in terms of expertise or budget), and when time is constrained, a person or a team in such situations may gather information with the help of structured interviews/questionnaires (together with experts in the relevant field), expert opinions and estimations, evaluations involving multidisciplinary groups, and benchmarking methods (Department of Health, Government of Western Australia, 2016; Pascarella et al., 2021).

Semi-quantitative risk estimation represents an intermediate level between qualitative textual estimation and numerical quantitative risk evaluation, achieved through ranking risks according to a pre-defined scoring system, allowing the handling of information quantitatively. This treatment involves categorizing perceived risks, establishing a logical and clear hierarchy between categories, and reflecting on the sequence to be followed when considering them (Pascarella et al., 2021). After comparing the plus and contras of quantitative and qualitative methods, it can be concluded that this combination of the proposed two models may be a decision in the sector of healthcare. The semi-quantitative method combines the peculiar privileges of each, mitigating their drawbacks, As suggested by governmental and non-governmental practices guidelines, they have a restricted ability to correctly reproduce risk estimations anticipated by quantitative models (Peace, 2017).

The risk governance guidelines (Safe Work Australia, NSW Government, 2019) propose assessing the severity of detriment resulting from each risk, taking into consideration the following points:

- The type of detriment that may take place (physical, psychological, financial, legal, etc.).
- The seriousness of the detriment (death, serious traumas, severe illness, additional monitoring or minor treatment, minor budget losses, anxiety, fear, corruption, etc.).
- Factors that can influence the severity of harm (e.g., height in a fall, concentration of a particular substance, patient age, social culture regarding corruption levels, etc.).
- The number of people that may experience harm.
- The number of cases that may be related to the risk.
- The number of cases that may be linked to the risk more than once.
- The number of people exposed to the threat and the number that may be affected at the workplace and beyond.
- The need for specific implements or processes to evaluate the severity of detriment (e.g., samples for testing or organizing noise impact testing).
Multiple failure scenarios (e.g., low-quality medical services leading to a poor reputation).

The outcomes are categorized on a five-point scale:

1. insignificant/not significant,
2. minor
3. moderate
4. significant
5. catastrophic.

When assessing the impact, the expected outcome of the risk is evaluated on a scale from 1 to 5 points, where 5 points represent the most serious impact. In the case that such standardization is not revealed, there is no possibility of comparing risks to each other, and priorities cannot be adequately set (Healthcare Insurance Reciprocal of Canada, 2014). Each severity category is associated with a specific value and example. Thus, a risk is catastrophic if it results in death (harm impact), while it would be significant if it causes significant injury/prolonged disability/impairment, moderate if it causes mild injury or a disease requiring professional intervention, and so on. These categories can help users identify risk by providing examples of risk levels. Experts usually underline that consequence tables will never be excellent or universally agreed upon, but they acknowledge that if perfectly formed, they give the possibility for adequate comparisons between a variety of events (Department of Industry, Innovation and Science, 2016).

In healthcare, it is impossible to predict all possible risks, and events that have never occurred before constantly happen in life (Healthcare Insurance Reciprocal of Canada, 2014). In this case, it may be impossible to precisely predict a certain risk's outcome (and also the probability). Some risks may lead to more than one outcome, which also influences different areas. In such cases, a multiple risks analysis is required to identify the overall risk from several hazards, whereas eventual dangers and vulnerability interactions may occur simultaneously or just after each other or not coincide chronologically. The absence of reliable data and the fact that individual risks may relate to different time intervals, or the need to consider different impact typologies complicate, if not preclude, ranking, often requiring the use of software instruments, such as the system of decision support, to reflect scenarios of multiple risks (Pascarella et al., 2021).

Throughout the process of risk estimation analysis, probability is the assessment of the chances of an event or incident occurring, regardless of whether it is defined, measured, or objectively or subjectively determined, so it is usually referred to as likelihood.
Notwithstanding several terms are usually used interchangeably, some differences should be considered.

Probability is the chance that an event or something will happen, usually expressed qualitatively. Likelihood is a quantitative or numerical measure of the probability of something happening, expressed in percentages. Both concepts can be successfully used, but the diversity between chance and likelihood is critically important in the process of risk analysis (Popov, Lyon, & Hollcroft, 2016). Probability relates to feasible results (reciprocally exclusive and comprehensive), while outcome relates to hypotheses. This, unlike the results, is neither mutually exclusive nor comprehensive (Gallistel, 2015).

Additionally, while likelihood is explained with the help of the term "probability," it can also be clarified in terms of frequency over a certain period. Thus, frequency is a gauge of probability expressed as the number of instances (e.g., once a month or yearly) of an event over a specific time or number of observations. As with outcomes, one can use the probability scale in theory and practice to evaluate the likelihood of risk happenings, providing specialists with a more precise description of how often negative outcomes are likely to take place. In the semi-quantitative model, probability can be estimated on a five-point scale from 1 (the lowest possible rank) to 5, (the highest possible rank).

When analyzing risk, it is vital to take into consideration the present control measures, as a control failure could bring an outcome. Understanding the exact meaning of controls in place and the rate of their efficacy can help determine what further actions are needed (University of Adelaide, 2019). Each organization of Healthcare should have its treatment to assess control effectiveness guide the process and determine how controls should be evaluated. This will allow the organization to determine the rate of its exact control efficacy, and treatment for estimation, evaluate whether the control is effective, partially effective, or ineffective, and help decide what actions are needed (Victorian Managed Insurance Authority, 2016).

A healthcare organization can apply the control estimation questions proposed in the WHO Clinical Risk Management Guidelines to evaluate the exact control in place (depending on the varying degrees of documentation, agreement, etc.) and the appropriate answers to make some assumptions about the level of adequacy (Department of Health, Government of Western Australia, 2016). Controls may consist of legislation, policies, procedures, guidance materials, staff training, necessary education, segregation of duties, audits, inspections, investigations, personal protective equipment and facilities, checklists, etc. (The University of Adelaide, 2019; Victorian Managed Insurance Authority, 2016). The risk level is evaluated
Risk management in medicine: the process of identification, assessment and control of risks in medical practice

Risk governance is developing and implementing strategies to optimize patient well-being, avoid harm or diminish injury of patients, focusing on reducing errors to ensure the highest quality of healthcare services to patients, as well as reducing any financial loss and damage to the organization's viability. One can describe healthcare risk governance as a complex set of clinical and administrative systems, processes, procedures, and reporting structures elaborated to identify, monitor, evaluate, mitigate, and prevent patient risks.

Nowadays the majority of risk governance practices and processes taking place in the system of healthcare reflect the items in the Institute of Medicine's report entitled "To Err Is Human: Building a Safer Health System" (McGowan et al., 2023). The report by the Institute of Medicine indicated that every year merely 98,000 people die because of medical errors during hospitalization. As a result of the report, the U.S. Congress passed the Patient Safety and Quality Improvement Act in 2005.

Legal experts have analyzed the impact of this Law and formulated some of its main principles and responsibilities:

- ensuring certification and recertification of patient groups for safety
- collecting and disseminating information concerning patient safety;
- elaborating a database of patient safety;
- facilitating consensus building among healthcare professionals, patients, and other stakeholders on patient safety and recommendations for its improvement;
- provide technical contributions to conditions that have or elaborate medical error reporting systems to assist in developing standardized data collection methods and collecting data from state reporting systems for its incorporation into the database of patient safety.

The main purpose of this Law was to enhance general patient safety in the country by stimulating of confidential and voluntary reporting of unfavourable occasions affecting patients' health. Policy-makers theoretically believed that systematic data collection on medical errors could refine patient safety. In their view, Awareness of medical professionals and administrators regarding such error data would lead to error prevention and a significant reduction in their recurrence (McGowan et al., 2023).

At the core of risk in the system of healthcare lies the patient's and staff's safety. Healthcare facilities, being commercial enterprises, must have their financial, strategic, and operational processes under control (Özcan, 2018). Risk governance in healthcare facilities
focuses more on patient and employee safety rather than holistic treatment like corporate risk governance and risk-oriented management, inner control, and audit, neglecting the emergence of risks in neglected areas of activity. The appearance of missed or ignored risks can lead to adverse outcomes, including injuries and deaths within healthcare organizations. Such outcomes, affecting patients, employees, as well as third parties, also impact the organization's financial structure. Risk governance activities are crucial for operational-financial activity and financial stability, as the economic dimension of risk will influence the enterprise's financial activities (Türk & Eroğlu, 2021).

The risk governance process includes five essential and significant steps:

1. Risk identification.
2. Risk estimation.
5. Evaluation of strategies.

Risk identification primarily revolves around identifying potential organizational risks (Figure 2). Such risks are performed by four main categories:

- Safety risks, such as patient or staff injury.
- Operational risks, which include disruptions in circulation.
- Financial risks, such as a slowdown in the economy.
- Strategic risks, such as a decline in brand value or the emergence of new, more effective competitors.

It is important to identify the risks that pose a potential risk to the entire institution and patients.
Risk estimation involves measuring the frequency and severity of risks identified within an organization. Heat maps or risk maps are commonly used to visualize the occurrence frequency of risks within the organization. This helps determine the priority of actions essential for risk governance.

The development of risk governance strategies entails addressing potential hazards for the organization. These risks may be newly identified, or strategies previously used or proposed may be applied if relevant in the context.

The strategy implementation involves the adoption of these strategies at various levels of the organization. All staff and relevant stakeholders are oriented towards the strategies and changes implemented to take necessary steps in their activities. This process requires change management among employees to implement the devised strategies effectively.
Implemented strategies are evaluated over specific periods, such as monthly or quarterly estimations. It is recommended to ensure constant monitoring and evaluation of optimized functioning and to address any related issues.

Healthcare organizations face numerous potential risks during operations and patient care services. Depending on the organization’s size, different instruments are used to determine and evaluate these risks to determine the prioritization of actions and associated opportunities. While holistic risk governance programs may seem inadequate in healthcare settings, like in corporate risk governance treatments, many healthcare facilities realize risk governance strategies in clinical and patient safety programs, projects, and services. However, they may fail in enterprise risk governance’s financial success and stability (Aksoy, 2018; Alam, 2016).

The corporate risk governance treatment is recommended to improve value creation and a safer environment in healthcare organizations (Etges et al., 2018). The International Organization for Standardization (ISO) 31000 (ISO, 2018) defines common steps in corporate risk governance:

- identification;
- analysis;
- estimation;
- monitoring;
- control.

In financial risk governance research in healthcare organizations, they discuss the analysis of financial applications, financial distress, institutional efficiency, and bankruptcy prediction. In risk governance, some companies identify consequence categories related to the impact of hazards on human health, environmental harm, financial loss, and reputation. At the same time, governmental and the best non-governmental guidelines in healthcare organizations focus on the patient, staff, or public safety (physical/psychological harm), finance, assets, business continuity, etc. (Schwarz, Koerts, & Hoercher, 2019).

In the clinical practice of dental healthcare institutions of any form of ownership, whether public or private, preventive activity should play an important role. Preventive clinical activities are of vital importance, including social importance, due to the high prevalence of such dental diseases as dental caries and periodontal diseases in our country. They significantly threaten dental and somatic health, especially children (Yanchuk, A. O., Skiba, V. Ya., Katerinchuk, I. P., Kuznichenko, S. O., & Skiba, O. V., 2019; Glazunov, O.

The transition to economically rational market mechanisms for the operation of municipal dental health care institutions, which have acquired the status of municipal non-profit enterprises, has forced a slightly different treatment to risk estimation in clinical practice to reduce the likelihood of their occurrence (Lytvynova, L. A., Donik, E. N., & Artemchuk, L. I., 2020; Mazur, I. P., Lekhan, V. N., & Rybachuk, A. V., 2022). As a result, mass preventive measures against dental caries and periodontal diseases in organized groups of children have been reduced or made impossible due to the risk of high costs. The expected moderate effectiveness of the standard may not justify it. In other words, preventive measures that are the same for all children examined and treated are not effective, while the most effective is the most personalized prevention. In this regard, the importance of screening tests is growing significantly, as they can identify people with a significant risk of developing a particular dental disease.

Regarding dental caries, a range of clinical methods has been proposed for screening examinations of school-age children. These methods allow for determining the degree of individual caries resistance or susceptibility based on the condition of tooth enamel and predicting the likelihood of the development of this condition. The enamel resistance test is the most commonly used method for such rapid determination. This test has been included as a mandatory procedure for trainees in list No. 7 (dental procedures) of the Higher Education Standard for the speciality 221 Dentistry, field of knowledge 22 Health Care, for the second (master's) level (Order of the Ministry of Education and Science of Ukraine…., 2019). Due to numerous modifications, this test has reached a high level of standardization in terms of its conditions of performance and objectivity in the evaluation and interpretation of the results, achieved through the use of computer software for digital image analysis after the test (Udod, O. A., & Voronina, H. S., 2019). However, the test does not take into consideration the negative impact of orthodontic pathology, which is significantly prevalent among school-age children in our country. The test also does not consider the additional hazards associated with dental caries due to its presence and the typically prolonged orthodontic treatment. Therefore, these additional adverse factors should be considered when assessing caries resistance.

Determining the level of enamel caries resistance during screening examinations of children, considering orthodontic pathology and appropriate treatment allows the formation of groups of people at high risk of caries development. This allows for targeted and personalized caries prevention measures with periodic monitoring of the caries resistance.
level according to the enamel resistance test within specified periods. If there's an increase in resistance in certain people, it indicates the high effectiveness of the applied preventive measures and their exclusion from the risk groups. Such a selective treatment provides an opportunity to optimize the caries prevention system in organized children's communities by directing preventive measures only to those children who urgently need them. It significantly reduces the costs of caries prevention and thus reduces the clinical practice risks.

Healthcare is a high-risk industry that faces various threats daily. Risk governance in healthcare is a process used to prevent and mitigate threats and harm to patients, staff, and organizations. Reducing risk aims to avoid harm and minimize its outcomes through the estimation of patient, staff, safety, and organizational risks and safety events. Assessing past risk events allows organizations to develop an appropriate risk reduction plan, which can prevent or mitigate future threats.

The key risks in healthcare include cyber threats, physical threats, breaches of confidentiality, healthcare-associated infections, and non-compliance with requirements. Therefore, they conduct some solutions for emergency departments.

When assessing risk, it is recommended to:

1. Consider the competence of assessors, confirming the probability and outcomes of judgments (using three-dimensional risk matrices) withal to two classic input data (probability and consequences).

2. Introduce a manual on strategies when a risk has multiple outcomes in several domains, and explain how to assess risk when a range of outcomes may occur with different probabilities.

3. Explain which probability estimation scheme (i.e., nominal, temporal, and conditional) to use and under what conditions and how to prioritize risks that receive the same assessment.

4. Remind risk, assessors, that risk matrices are just one of several tools elaborated to support their decisions, not to make decisions exactly and that supplementary factors required for implementing any means of risk control should be considered in risk prioritization.

Finally, risk indicators may not reflect the actual risk rating, and the main recommendation, while making risk decisions, is a balanced and unbiased professional and subjective judgment.
Discussion

Hospitals should develop administrative activities to anticipate potential risks and turn them into opportunities to minimize potential losses. Hospitals with active risk governance will stay ahead compared to those that do not strive to ensure patient and staff safety and service quality. Possible risks and the outcomes of these risks can vary depending on the conditions, resources, and environmental factors. Risk governance is a proactive methodology for hospitals to address operational, clinical, and financial risks. However, risk diversity and estimation are complex. Self-awareness is crucial for organizations.

The determination of the risk level means understanding the consequences that this threat can lead to identifying acceptable minor clinical risks among those that are considered unacceptable. Risk ranking by multiplying outcomes by probability is an easy way to appoint a numerical value to any risk. The risk matrix turns out to be a useful instrument to evaluate probabilities and levels of consequences and to define the risk rating according to the proposal scale. It also helps the team prioritize risks that need to be addressed first. However, in the process of risk analysis, deviations that characterize the entire stage and, in particular, those affecting the development and employment of risk matrices must be considered.

When developing matrices, consideration should be given to the fact that developers may poorly understand the matrix design principles and catch, as different choices can lead to quite other representations of the risk matrix and, as a result, various decisions regarding risk acceptance. Present control measures also need to be considered, as they affect the probability and risk estimation.

Many authors describe issues of risk matrix use that can mislead risk assessors, misinform decision-makers, or lead to incorrect analysis, while some authors consider risk matrices to add little value to risk governance. Essentially, as soon as the matrix predicts the outcomes and probability of risk, its positions are tied to the judgment of the developer and user. Peace (2017) points out that few matrix developers or users may not understand the main idea while receiving training or supervising the elaboration or use of risk matrices (Peace, 2017). Duijm (2015) stresses that risk matrices are widespread and create uncertainty and ambiguity in results and limiting their use becomes challenging (Duijm, 2015). For these reasons, we also believe it is more productive to consider a priority to its limitations and inform risk assessors, designers, and decision-makers about these difficulties rather than obstructing their use.
According to the Food and Agricultural Organization, the choice of matrix style depends on the team's preferences. Colours play the role of a visual instrument to facilitate discussion and help risk assessors agree on the risk level. Thus, the matrix may not be necessary for some cases of lack of information, and the general risk value is evident. Healthcare organizations do not shy away from this logic and do not support their team members with appropriate organizational manuals to support risk control practices. In our opinion, critical questions related to the use of risk matrices may be unknown not only to developers and users but also to healthcare organizations to manage and govern risk (Card, Ward, & Clarkson, 2014). However, there is no data to confirm this conclusion.

The use of risk matrices is widespread and offers risk governance guidance for organizations of healthcare, possibly because not all assessors have the necessary skills and knowledge to propose risk analysis using more complex methods. Hence, they represent a widely accepted decision to ensure quick response and some rapid results in healthcare organization risk governance. Any organization is urged to develop (or assist in developing) one or more questionnaires to provide a more accurate calculation of the risk level by considering the probability category against the severity category of outcomes. The general risk value assigned to the event helps determine the urgency and degree of necessary control measures. Accordingly, various control measures with different levels of urgency will be introduced to counter this.

**Conclusions**

Risk governance is one of the primary challenges for healthcare institutions. It allows them to predict the facility's development and avoid or mitigate the outcomes of risks. The use of risk matrices helps both personnel and management to analyze risk, predict the possibility of a situation occurring and avoid the outcomes, if possible. All employees who conduct risk estimations should be trained in risk estimation as per the standards and institutional goals to improve basic awareness and enable the identification and management of risks in different departments, encouraging adequate pre-planning for potential threats.

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Submetido em: 29.09.2023
Aceito em: 30.10.2023