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Implementation of risk management in a public health laboratory

Processo de implantação da gestão de riscos em um laboratório de saúde pública

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ABSTRACT

Introduction: Managing risks means, in case of risks with negative effects, having them under control to mitigate or eliminate them, if possible, or in case of risks with positive effects, turning them into opportunities. The Adolfo Lutz Institute (IAL) establishes documents and implements and maintains a management system in accordance with option A of ISO/IEC 17025: 2017. Thus, risk management is one of the requirements to be met. In order to fulfill this requirement, the IAL has started the implementation of the risk management process using the Failure Mode, Effect and Criticality Analysis (FMECA) tool. As the methodology was considered complex by the collaborators, this tool was abandoned and only the brainstorming was used for the identification step, and the probability and impact analysis at the risk analysis for the assessment stage. **Objective:** To assess the implementation level of the risk management process in the IAL and identify the main difficulties involved in this process. **Method:** 74 risk matrix forms filled out by many sectors of the institution were analyzed. **Results:** There was a 76.3% adherence to the implementation of risk management and the main difficulties encountered in the risk management process were: identification of the risks, including identification of risks with positive effects, selection of an indicator associated with risk, and proposal of actions to treat risks. **Conclusions:** To implement the risk management process, the use of simpler tools should be recommended when the team maturity level is low or intermediate. Another point to be considered for the successful implementation of this process is strengthening of the understanding of risks by everyone in the organization. In IAL, the risk management process is in the risk monitoring phase; the next step is to review the risk mapping initially done.

KEYWORDS: Risk Management; Quality Improvement; Public Health Laboratory

RESUMO

Introdução: Gerenciar riscos significa, no caso de riscos com efeitos negativos, tê-los sob controle de forma a mitigá-los ou eliminá-los, se possível, ou, no caso de riscos cujos efeitos são positivos, transformá-los em oportunidades. O Instituto Adolfo Lutz (IAL) estabelece, documenta, implementa e mantém um sistema de gestão de acordo com a opção A da norma ABNT NBR ISO/IEC 17025:2017. Dessa forma, a gestão de riscos é um dos requisitos a ser atendido. Para cumprir esse requisito, o IAL iniciou a implantação do processo de gerenciamento de riscos utilizando a ferramenta Análise de Modo, Efeito e Criticidade da Falha (FMECA), porém a metodologia foi considerada complexa pelos colaboradores e, por isso, houve a necessidade de abandoná-la e utilizar apenas o *brainstorming*, na etapa de identificação dos riscos, e a análise de probabilidade e impacto, na etapa de análise e avaliação dos riscos. **Objetivo:** Avaliar o nível de implantação do processo de gestão de riscos no IAL e identificar as principais dificuldades envolvidas nesse processo. **Método:** Analisou-se 74 formulários de matriz de risco preenchidos pelos diversos setores da instituição. **Resultados:** Verificou-se uma adesão de 76,3% pelos setores, e as principais dificuldades encontradas no processo de gestão de riscos foram: identificação dos riscos

propriamente dita, incluindo a identificação de risco com efeito positivo, seleção de um indicador associado ao risco e proposta de ação para tratar o risco. **Conclusões:** Para a implantação do processo de gestão de riscos, a utilização de ferramentas mais simples deve ser preconizada quando o nível de maturidade da equipe ainda é baixo ou intermediário. Outro ponto a ser considerado para o sucesso da implantação desse processo é o fortalecimento da compreensão dos riscos por todos da organização. No IAL, o processo de gerenciamento de riscos encontra-se na fase de monitoramento dos riscos, sendo que a próxima etapa consiste na revisão do mapeamento de riscos feito inicialmente.

PALAVRAS-CHAVE: Gestão de Riscos; Melhoria de Qualidade; Laboratório de Saúde Pública

INTRODUCTION

Organizations of all kinds and sizes are vulnerable to influences and external and internal factors that cast doubt on the achievement of their goals[1]. Any decision or choice made by an organization is exposed to risks. Therefore, it is important to understand that risks are inherent in any business. In this context, there is a necessity for risk management, since an organization that remains indifferent to the risks to which it is exposed is vulnerable to unforeseen events.

Risk management is a process that helps organizations to reduce as much as possible the failures that can affect their processes. Once the risks are identified in advance, actions can be taken to reduce the occurrence probability of these events or minimize their negative effect, if they occur. With risk management, the opportunities can be also maximized by identifying strengths or room for improvement.

Once the risks are known, it is also possible to have a better management of financial, human and environmental resources and also protect the institutional reputation with customers[2]. In this way, risk management is combined with the best strategic decisions and institutional planning[3,4].

Risk concept and risk management

According to the Institute of Risk Management (IRM)[3], the general definition of risk is the combination of the probability of the occurrence of an event and its consequence, whether positive or negative. The standard of the Brazilian Association of Technical Standards (ABNT) NBR ISO 9001:2015[5] and the Project Management Institute (PMI):2004[6] define risk as the uncertainty effect, in other words, the positive or negative deviation of the expected objective of a project, process, operation or service of the organization[4].

Considering these definitions, we conclude that risks are future circumstances or conditions that may have favorable or unfavorable impact on a given objective. Risk is also related to choice, rather than chance, because it stems from the uncertainty inherent in the set of possible consequences (losses or gains) resulting from decisions made by organizations[7].

Since the publication, in 2000, of the *To err is human* report[8], which estimated that 44,000 to 98,000 deaths per year in the United States were due to adverse events, caused by errors or failures, the concept of risk has been gaining importance in the agenda of healthcare organizations[9,10]. Several studies have shown that about half of the adverse events could be prevented[11,12]. In Brazil, the numbers are also alarming; 2017 data from the Institute of Supplementary Health Studies revealed that more than 54,000 deaths from adverse events occurred and about 30% of these events could have been prevented[13]. In order to prevent these events from happening, it is essential that organizations adopt risk management.

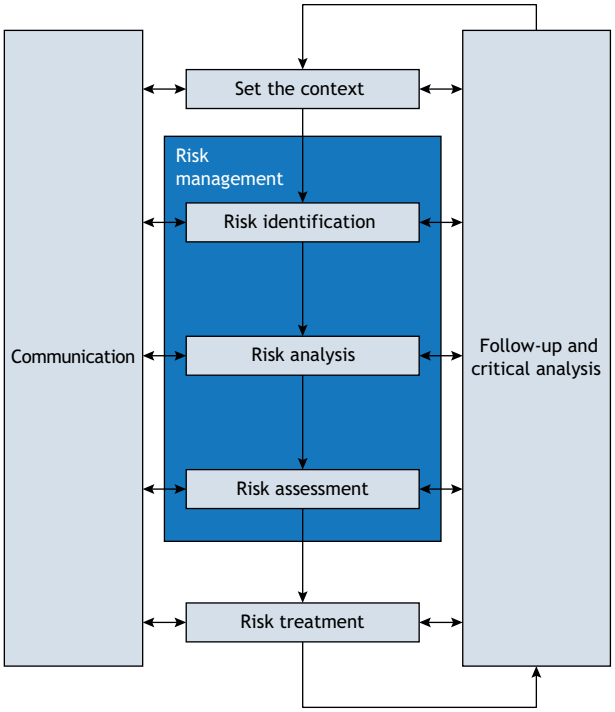
Risk management is the set of coordinated activities that aim to manage and control an organization in relation to potential threats[1].

The ABNT NBR ISO/IEC 17025:2017[14] standard does not recommend any formal risk management methods. Therefore, it is up to each company to decide what methodology to adopt to implement risk management. This decision must take into account the characteristics and complexity of the business, and the magnitude and typology of the risks existing in its segment. Thus, the ABNT NBR ISO 31000: 2018[1] standard can be used. This standard addresses risk management guidelines and fundamentals applicable to all types of organizations and processes in general terms.

Figure 1 depicts the steps involved in the risk management process, according to ABNT NBR ISO 31000:2018. This scheme can be the basis for the implementation of risk management by organizations of any type, size and industry.

According to the scheme presented in Figure 1, the preliminary step to the management itself consists of determining in what sectors of the organization risk management will be implemented, determining policies and procedures that will be adopted, in addition to assessing the internal and external factors that may affect the objectives. This is the phase of setting the context for the implementation of the risk management process. Then, the team must be informed of this decision and collaborate in the risk survey. The engagement and support of the stakeholders contribute to effective risk management initiatives, since this enables the inclusion of their expertise and perceptions in the pursuit of better management[1].

In risk management, risk identification is the initial step of the process. For this survey, risks that are more likely to occur and



Source: Adapted from ABNT NBR ISO 31000[1].

Figure 1. Stages of the risk management process.

that significantly impact the organization's business should be considered. Anything that does not reflect the reality experienced or that offers extremely low impact should be left out.

For effective risk management, attention must be paid to the identification of new risk situations or changes in the risks already mapped. It is worth mentioning that a risk is not the same thing as a problem, because the latter is an existing event that already threatens the fulfillment of the objectives. A problem should be corrected and avoided. Risk, in turn, should be managed.

The second stage of the process refers to the risk analysis, which is done by classifying the level of risk through the assessment of the probability of occurrence and the possible impact that can be caused, thus composing the degree of criticality of the identified risk[7]. Estimates for probability and impact can be made from qualitative or quantitative analyses[15]. Scales can be found in the literature to guide these estimates[16,17,18,19].

In the next step, risks are assessed based on the level of criticality obtained by determining a "response" to those risks. This "response" may include the need for treatment, that is, whether the identified risks should be "minimized", "eliminated" or "accepted" or whether the risks should be seen as opportunities rather than threats. In short, the treatment of risks involves the definition of actions to modify these risks. It is at this stage that organizations should determine which risks will take priority. Usually, risks with a higher level of criticality are addressed first.

Finally, the identified risks must be monitored to verify whether the actions implemented were effective and led to a decrease in the effects or a decrease in their occurrence. According to Watson and Jones[20], risk management is not a "do and forget" process, it is a continuous improvement process, just like the Plan, Do, Check, Action (PDCA) cycle.

Implementation of risk management at the Adolfo Lutz Institute

In view of the important role of the Adolfo Lutz Institute (IAL) as a Central Public Health Laboratory, the requirements of reliability, traceability and excellence of its results are strict and, for this reason, the IAL meets the requirements of the quality standards adopted at the institution.

One of the challenges related to meeting the requirements of ABNT NBR ISO IEC 17025: 2017[14], the standard adopted at the institution, is the implementation of risk management.

At the IAL, the implementation of risk management began in 2017 under the guidance of a consultancy firm, which proposed the use of the Failure Mode, Effect and Criticality Analysis – FMECA tool. At first, this tool was selected because it offers a structured approach to assessing the risks associated with the processes. In general, the FMECA tool identifies potential failures, their causes and consequences in the performance of processes. The application of this tool requires knowledge about the process that is being evaluated in order to adequately survey the failure modes, that is, how a process, system or product can fail to meet specific requirements.

The first step taken to implement risk management at the IAL was the selection of the tool to be used in the process. Then, the risk management policy was established and a procedure was designed in which the responsibilities of the stakeholders were assigned and the scope of application of risk management for all organizational units was established, regardless of whether they were technical-administrative or technical-laboratory areas. It also established the risk assessment process, the definition of risk probability and severity scales, criticality matrix and periodicity of risk mapping review.

Once the policy had been determined and the risk management procedure had been prepared, communication and training were provided for all the Organizational Units (OUs) of the institution.

After the training program of April 2017, the OUs started the process of implementing risk management. For this, each OU met with its team and held a brainstorming session to break down their processes and identify their critical activities.

For the application of the FMECA tool, the OUs should identify: all possible failure modes of each critical activity (i.e., what is observed when failing or performing incorrectly), the effects of failure modes (the effects that these failures can have, that is, the consequence of the failure), the nature or type of risk (assistance, financial or reputation), the controls to avoid the failures or mitigate the effects of the failures, the controls to monitor the failures, analyze the criticality

Chart 1. Risk probability and severity scale.

Probability scale			Severity scale		
Level	**Descriptor**	**Probability (Frequency)**	**Level**	**Descriptor**	**Severity**
4	Frequent	It can occur immediately or after a short interval (it can occur several times in 1 year)	4	Catastrophic	It can cause catastrophic damage
3	Occasional	Probably will occur (it can occur several times in 1 to 2 years)	3	Major	It can cause major damage
2	Unlikely	Possibly will occur (it can happen in 2 to 5 years)	2	Moderate	It can cause moderate damage
1	Rare	Unlikely (it can occur sometime in 5 to 30 years)	1	Minor	It can cause minor damage

Source: Adapted from the INPI Risk Management Manual[22].

of each failure mode identified, in addition to informing the phase of the process (administrative, pre-analytical, analytical, post-analytical or support) and in which activity of that phase the failure could occur. This information should be recorded on a form called risk matrix.

Despite the assistance of the consultancy firm, the OUs found the process of filling out this form difficult and tedious, which led to the decision to simplify the risk matrix form with the elimination of the fields intended for information about the process phase where the failure could occur; critical activities in which failures could occur, type of risk and the effects of failure modes.

For the risk assessment stage, possible failures should be assessed from the perspective of the probability and impact of their occurrence. Thus, OU teams should assign a score according to a predetermined scale, for the probability of occurrence and the severity of the risk (Chart 1). The level of risk resulting from combining these scores in a matrix would determine the criticality of the identified risks (Table 2). The higher the score given to the severity and frequency of occurrence of the risk, the higher the level of the risk. At this stage, many OUs struggled to assign a score, since they had never measured these parameters and there was no historical data to help them measure the frequency.

ABNT NBR ISO 31000:2018[1] does not determine what the risk analysis process should be like. According to the standard, depending on the availability of information and necessary resources, among other issues, this step can be done in a more detailed and complex way and the approaches to the risk analysis can be: qualitative, quantitative or semi-quantitative[1,21]. Taking this into account and due to the difficulties pointed out by the OUs, it was determined that the best way to carry out the risk analysis was the qualitative approach, in which the risks would be classified by nominal scales. Thus, in 2018, the probability and severity scales and the risk criticality matrix were abandoned, the risk matrix form was revised and a field was included to classify the level of risk as low, medium or high. The revised risk matrix form is shown in Figure 2.

Thus, the objective of this work was to analyze the use of the form reviewed by the OUs and to identify the challenges in the implementation of risk management in the IAL.

Chart 2. Risk criticality matrix.

Criticality matrix				
	Severity			
Probability	Catastrophic (4)	Major (3)	Moderate (2)	Minor (1)
Frequent (4)	16	12	8	4
Occasional (3)	12	9	6	3
Unlikely (2)	8	6	4	2
Rare (1)	4	3	2	1

Unacceptable	8 to 16
Somewhat acceptable	4 to 6
Acceptable	1 to 3

Source: Adapted from the INPI Risk Management Manual.

METHOD

This study with a descriptive and exploratory approach was carried out with data obtained in 2018.

The techniques used for risk management were brainstorming, in the risk identification stage, and the probability and impact analysis (performed qualitatively), used in the risk analysis and assessment stage.

For the risk assessment, the OU teams, made up of quality representatives, the unit director and the technical team, met to identify the risks that could hinder the objectives of each process, as well as the opportunities. The identified risks were to be recorded on the revised risk matrix form (Figure 2).

After the identification stage, OUs should estimate the criticality level of the risks by classifying them into levels (low, medium or high), based on the probability of occurrence and the impact of the risks, should they occur. The organization of risks into levels would result in an order of prioritization for the treatment of risks. Thus, higher priority should be given to the treatment of risks classified as high, followed by medium and low. For the treatment stage, OUs should propose initiatives to reduce the occurrence and/or the impact of risks. Additionally, OUs should adopt indicators to assess the effectiveness of the initiatives to address risks, including decisions as to whether the remaining risk would be acceptable.

OU:

Risk identification	Effect of the risk		Classification of level of risk			Initiatives proposed to address the risk	Indicator	Comments
	+	-	Low	Medium	High			

Source: Quality Management System of the Adolfo Lutz Institute.
OU: organizational unit.

Figure 2. Risk matrix form.

The situational diagnosis of the implementation of risk management in the institution was based on the evaluation of the risk matrix forms filled out by the OUs. The 97 IAL OUs (54 technical-laboratory OUs and 43 technical-administrative OUs) were asked to fill out the form. Each OU filled out a single form.

The risk matrix form (Figure 2) adopted at the institution consists of the following fields:

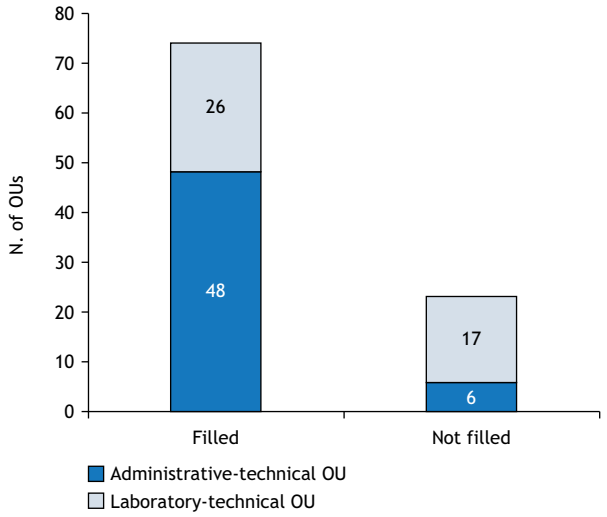
- risk identification;
- classification of the risk effect (either positive or negative);
- classification of the level of risk (which may be low, medium or high);
- action proposed to address the risk;
- indicator (to be used to measure the frequency of occurrence of the risk or level of impact of the risk); and
- comments (on the frequency of indicator monitoring, priority actions to deal with risk, or any other necessary piece of information).

With the analysis of the forms, we intended to assess the risk management implementation process, which includes the stages of risk identification, analysis, assessment, treatment and monitoring.

RESULTS

Of the total of 97 OUs, 74 OUs (76.3%) filled out the risk matrix form (Figure 3).

The risks were identified by analyzing the processes of the activities performed by the OUs, taking into account the risks that could really impact the achievement of their objectives. For example, in the case of OUs that performed laboratory activities, risks associated with the pre-analytical, analytical and post-analytical phases were identified. Subsequently, the identified risks were qualitatively classified into levels (high, medium or low), according to their probability of occurrence and the



Source: Prepared by the authors, 2019.
OU: organizational unit.

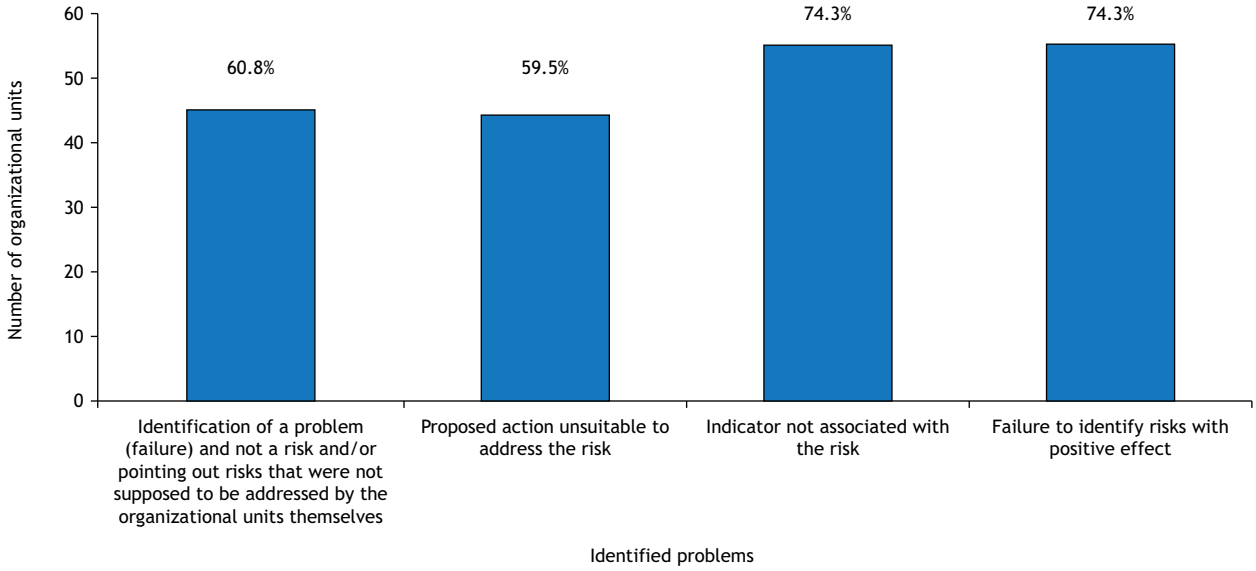
Figure 3. Rate of risk matrix form completion by organizational units.

impact of their consequences, should they occur. This analysis was made subjectively by the OU teams, since there were no previous records of these events. We found that of the total identified risks (n = 398) by the OUs, 37.0% were classified as high risk, 36.0% as medium risk and 27.0% as low risk.

The next step was the risk assessment, that is, based on the levels assigned to the risks, actions were planned in response to those risks, which could be to mitigate, eliminate, accept or maximize and, also, to prioritize actions for the identified risks. The predominant strategy adopted by the OUs was to mitigate risks. Higher-level risks were to be prioritized.

To monitor risks, the OUs should select specific indicators to ascertain whether the implemented actions were contributing to risk control in terms of mitigating events, consequences or impacts of risks with negative effects or maximizing risks with positive effects.

Figure 4 shows the main problems identified in the risk matrix form completion process:



Source: Prepared by the authors, 2019.

Figure 4. Percentage of the main problems identified in the risk matrix form filled out by the organizational units.

- Pointing out problems instead of risks and/or pointing out risks that could not be addressed by the OUs themselves;
- Inappropriate proposal of actions to minimize the occurrence or the effect of the risk;
- Indicator not associated with the identified risk; and
- Failure to identify risks with positive effect (opportunities for improvement).

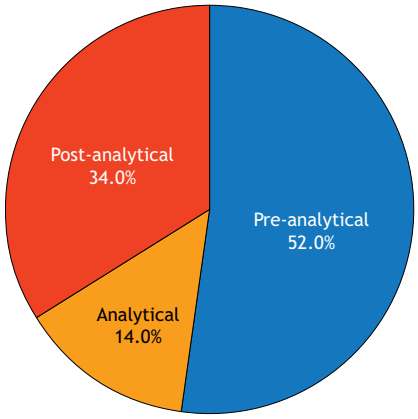
The risks identified by the technical-laboratory OUs were sorted into pre-analytical, analytical and post-analytical phases and are presented below:

Pre-analytical:

- Failure in sample registration;
- Receipt of samples and supplies that were not compliant with the established conditions;
- Storage of samples in inadequate conditions;
- Accident during sample transportation;
- Forwarding samples to the incorrect sectors;
- Incorrect identification of samples and supplies; and
- Failure to plan the purchase of inputs and failure to specify the purchase item.

Analytical:

- Failure of traceability in results, inputs and processes;
- Testing in equipment with expired calibration; and
- Cross contamination.



Source: Prepared by the authors, 2019.

Figure 5. Percentage of laboratory risks with a negative effect.

Post-analytical:

- Delay in the release of reports;
- Error in the transcription of results and data in the analytical reports; and
- Error in the interpretation of results.

Figure 5 presents the percentages of risks of the pre-analytical, analytical and post-analytical phases.

Of the 74 risk matrix forms filled out by the OUs (technical-laboratory and technical-administrative), three pointed out risks to impartiality and 27 pointed out opportunities for improvement. Among the risks identified by the technical-administrative OUs, the most frequently reported were failure

to index the quality management system documents; failure to prepare documents; and incorrect or incomplete records in documents (physical or electronic).

DISCUSSION

The initial decision to adopt the FMECA was based on the fact that this tool provides a structured assessment to identify how processes can fail and thereby identify the risks associated with them. However, the application of this tool was considered a tedious and time-consuming task, which discouraged the teams.

The FMECA tool recommended the mapping of risks by: phases of the process, classification of the type of risk, description of the consequences that could arise from the occurrence of the failure, definition of actions to prevent the occurrence of failures (preventive actions), definition of corrective actions to be implemented in the event of failure and definition of indicators for risk monitoring. In view of the OUs' difficulty in understanding this information and because it was considered a lengthy task, adherence was low, less than half of the total OUs filled out the risk matrix form. In view of this, there was a proposal to streamline and simplify the risk matrix form.

With the revised form, the OUs' adherence increased substantially (76.3%), with the highest adherence by technical-laboratory OUs (89.0%), while adherence by technical-administrative units was 60.0%. Therefore, we consider that the proposed modification of the strategy to carry out the assessment of the risk level in a qualitative way and with subjective data contributed to the risk management implementation process. This finding is in line with the results obtained in the study by Silva et al.[23], who observed that the analysis of risk levels based on subjective data contributes to greater team commitment and engagement in this process. Quantitative assessment methods enable more reliable analyses[24]. Nevertheless, in the context of the IAL, this is not yet feasible due to the level of maturity of its risk management implementation process.

Although the simplification of the risk matrix form contributed to the greater adherence of the OUs, rethinking all the components of the previous structure is fundamental. Encouraging a risk mindset in the organization means guiding it to think about what threats and opportunities are there and what should be done in these situations, thus making the company better prepared, stronger and with good results in the long term. At any rate, a culture of prevention should be established[25]. This involves not only technical concepts of how to do things, but also effective communication so that people adopt risk-based thinking and always consider the possibility that something may go wrong in their actions[26]. To prevent risks, it is necessary to identify and analyze the origin of the event so that actions can be proactively systematized[27].

Analyzing the forms we've found some problems in the completion of the forms. Among the causes for the incorrect completion of the risk matrix form are the flawed conceptual understanding of the risk management methodology and the concept of risk itself, which creates difficulties for the OUs at the critical stage of risk identification. This result agrees with Monteiro[28], who reported that the lack of a risk management culture is a barrier to its implementation. Another difficulty presented by the OUs was to find an appropriate indicator to measure the occurrence of risks, as shown in Figure 3. With an inadequate indicator, there is no monitoring of the situation of the indicated risk. Risk monitoring is essential to avoid recurrence and to ensure that all possible threats are identified and will be dealt with appropriately, in addition to giving fluidity to the cycle of continuous improvement of the risk management process.

After the analysis of the completed forms, we gave some feedback to the areas requesting the correction of the problems identified in the completion of the forms.

The risks identified by the technical-laboratory OUs were sorted into pre-analytical, analytical and post-analytical phases. Figure 4 shows that the pre-analytical phase concentrates 52.0% of the risks, which confirms the study by Kalra[29], which shows a range of 46.0 to 68.2% for errors at this stage in clinical laboratories and other critical healthcare areas. It is followed by the post-analytical stage, with 34.0% of the risks, again within the percentage indicated by the author, from 18.5 to 47.0% and, finally, the analytical stage, with 14.0% of the identified risks. This is due to the fact that laboratories focus their attention on quality control methods and quality assessment programs[30,31]. The pre and post-analytical phases have the highest error rates because they are more susceptible to factors from outside the laboratories. Therefore, these are the stages in which the laboratory must strive to minimize or mitigate risks.

As established in the IAL management system, OUs should identify the risks to their impartiality, including the risks arising from their activities, their relationships or the relationships of their staff[25]. Of the 74 risk matrices filled out, only three included risks to impartiality. In a next update of the document, this should be reconsidered by the areas. There are several initiatives that can be adopted by laboratory personnel to minimize risks to impartiality, such as tagging the sample with the registration code instead of using the client's name or, as suggested by Wong[25], using a computer system for sample management, generation of barcode labels and sample tracking.

It was observed that 74.0% of the OUs did not inform risks with a positive effect. This is due to the fact that OUs associate risks only with negative effects or associate the identification of opportunities for improvement only with the application of resources for this purpose.

Nowadays the risk management implementation process at IAL is currently in the risk monitoring phase. Therefore, the first management cycle will soon be completed and a new cycle should start. In order to identify new risks, the current internal and external contexts of the institution must be taken into account, since risks may emerge, change or disappear as contexts change[1]. Effective risk management must be dynamic, that is, if the organization's objective or guidelines are changed,

it foresees, detects, recognizes and responds to these changes and events, so it is necessary to map new risks and/or reassess those already mapped[1].

Monitoring the risks that are inherent in an activity improves the conduction of the processes and enables us to foresee potential problems, which, after early identification, can be mitigated or even removed from the process, thus ensuring the achievement of the expected performance. In this context, it can be said that the variability of the quality attributes of processes and products tends to decrease, reducing costs and increasing efficiency[32].

Risk management is a dynamic, continuous and essential process for the good governance of any organization. Therefore, the organization must have the ability and competence to diagnose, prioritize, monitor and address its risks. Ávila[33] stated that the vision of those involved in the process can be expanded based on the consolidation of risk management concepts, training, advisory, case studies and some goodwill. With that, a risk analysis environment will be quickly created, matrices will be implemented and criteria will be determined.

Some of the benefits that can be achieved with the implementation of risk management are the reduction or elimination of errors, quality improvement, effective management of processes, reduction of costs and resources, proactive and preventive management, more assertive decision making, among others.

CONCLUSIONS

Several tools can be used to implement risk management. However, the choice of the tool must take into account the human factor, which plays an active role across the process. The use of simpler tools should be recommended when the team's maturity level is still low or intermediate.

The IAL is currently in the final phase of the first cycle of the risk management process. The next steps are to identify potential new risks and improve proposals for action that were unsatisfactory. There are many challenges involved in risk management. Overcoming them requires a stronger understanding of risks by the personnel, that is, the consolidation of the concept of risk, differentiating it from a problem; the implementation of a risk monitoring system through appropriate indicators and the understanding that risk management is a continuous process that implies periodic reviews and updates of the risk matrix.

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Authors' Contribution

Fonseca LG - Acquisition, analysis, interpretation of data and writing of the paper.

Kira CS - Conception, planning (study design), acquisition, analysis, interpretation of data, writing and proofreading of the paper. All authors approved the final version of the paper.

Conflict of interest

The authors report that there is no potential conflict of interest with peers and institutions, nor political or financial conflicts in this study.