Research Article

Risk Management in a Clinical Biochemistry Laboratory

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Abstract

Introduction: To ensure compliance with new laboratory standards, it is imperative to adopt risk-based thinking, which involves a systematic examination of the functions, procedures, and activities associated with risks and opportunities. This article aims to explore the implementation of risk-based thinking in medical biology laboratories and to highlight the challenges inherent in this approach.

Materials and Methods: This descriptive study was conducted in the biochemistry laboratory of the Main Military Teaching Hospital of Tunis during the first half of 2024. A risk analysis was performed by a working group to identify failures by analyzing non-conformities recorded during the study period. The group adopted the Failure Mode and Effects Analysis (FMEA) methodology, an inductive approach well-suited to process analysis and mastered by all participants. Subsequently, a corrective action plan was developed for each process phase.

Results: Across the entire laboratory workflow, 33 distinct failure modes were identified and cataloged for each step, followed by a criticality analysis. The distribution of these failures was 36.36% in the pre-analytical phase, 33.34% in the analytical phase, and 30.3% in the post-analytical phase. A review of the severity of their effects revealed that a significant portion constituted major risks.

Conclusion: In response to the major risks identified at each stage of the laboratory workflow, a corrective action plan has been proposed. This plan outlines specific actions designed to reduce the criticality of these risks and enhance patient safety and quality of service.

Introduction

Risk management is a concept with ancient roots, first appearing around 3200 BC in the Tigris-Euphrates valleys under the guidance of the Asipu, who are considered among the earliest risk consultants [1, 2]. Following the Second World War, large corporations with diversified physical asset portfolios began to develop self-insurance mechanisms to cover the financial consequences of adverse events or accidental losses [3]. Modern risk management was implemented after 1955, initially within the insurance sector [4].

The concept of risk is not new to clinical laboratories, as it was implicitly addressed in previous versions of the ISO 9001 standard through preventive measures aimed at eliminating potential non-conformities and preventing their recurrence (ISO 9001:2008 [5], ISO/IEC 17025:2005 [6]). However, in the latest versions of standards such as ISO 9001:2015 [7], ISO/IEC 17025:2017 [6], and particularly ISO 15189:2022 [8], risk-based thinking is more pronounced and has become a mandatory requirement. Furthermore, the ISO 31000:2018 standard [9] defines risk management as the coordinated set of activities that an organization undertakes to direct and control risk.

Consequently, for a laboratory to achieve and maintain compliance with current standards, it is essential to understand and implement risk-based thinking by systematically examining its functions, procedures, and activities in relation to risks and opportunities. To address this need, this article explores the implementation of a risk-based framework in a medical biology laboratory and highlights the challenges posed by this approach.

Materials and Methods

Study Description

This descriptive study was conducted within the biochemistry laboratory of the Main Military Teaching Hospital of Tunis during the first half of 2024. A working group, composed of members from the laboratory's quality unit, was formed. The group convened on multiple occasions to analyze non-conformities recorded within the laboratory. The objective was to conduct a rigorous analysis of these failures to determine their root causes, evaluate their criticality, and implement preventive measures to mitigate associated risk factors.

Study Protocol

The working group first conducted a risk analysis by identifying failures encountered through the review of non-conformity records from the first half of 2024 related to the laboratory's core processes. The group selected the Failure Mode and Effects Analysis (FMEA) methodology, which is an inductive, process-oriented approach well-understood by all participants. In practice, the FMEA method was executed in five distinct steps:

- Step 1: Establish a working group. This crucial step involved forming a team of biologists and medical laboratory technicians who had received training in quality management.
- Step 2: Define the scope of the study. The scope was confined to the three core phases of the clinical biochemistry laboratory's workflow: pre-analytical, analytical, and post-analytical.
- Step 3: Describe the process. All steps within the workflow, from the pre-analytical phase to the final reporting of results, were mapped using flowcharts, specifying the personnel, documentation, and equipment required for each stage.
- Step 4: Analyze risks across the pre-analytical, analytical, and post-analytical phases. For each phase, the working group identified potential failure modes through brainstorming sessions and investigated their possible root causes. These causes were categorized using the 5M (Manpower, Method, Machine, Material, Milieu) framework and presented in Ishikawa (fishbone) diagrams. The group then assigned Severity (S) and Frequency (F) scores to each failure mode based on established quantification grids. The criticality of each failure was calculated using the formula:

  Criticality (C) = Severity (S) × Frequency (F)
- Step 5: Define the action plan. For each significant failure mode, one or two risk-reduction actions were identified and compiled into a comprehensive improvement plan.

Results

Risk Management

Across the entire process, 33 distinct failure modes were identified, for which a criticality analysis was performed. Table 1, 2, and 3 summarize the results of the FMEA conducted on the three phases of the laboratory workflow.

Table 1: Failure Modes and Associated Criticality in the Preanalytical Phase.

Step/Phase	Failure Modes	Effects / Impact	Potential Causes	S	F	C
Sample Registration & Labeling	Patient identification error	Result linked to the wrong patient identity	- Non-compliant test request form - Lack of concentration	4	2	8
	Failure to observe fasting conditions	Falsely elevated results for glucose and lipid panel	- Lack of patient information	3	3	9
	IT system failure	- Delay in registration - Congestion at the Central Specimen Reception	- Mismatch between workload and IT system capacity	3	1	3
Blood Collection	Collection by an unauthorized trainee	- Non-compliant collection - Risk of needlestick injury	- Non-adherence to trainee supervision protocols	3	4	12
	Expired collection tube	Ineffective anticoagulant	- Poor stock management	2	2	4
	Hemolyzed sample	- Sample rejection and re-collection - Delayed results	- Tourniquet applied for >1 min - Vigorous mixing	3	3	9
	Coagulated sample	- Delayed results	- Insufficient mixing of tubes - Incorrect blood-to-anticoagulant ratio	3	4	12
Sample Transport	Sample contaminated by anticoagulants	Certain parameters will be erroneous	- Incorrect order of draw	3	3	9
	Broken tube	- Risk of contamination from blood - Loss of sample	- Poor quality of tubes	4	2	8
	Tube soiled with blood	Occupational exposure to blood	- Incomplete tube closure before pneumatic transport	3	4	12
Hygiene and Safety	Inadequate cleaning of facilities/restrooms	Occupational exposure to pathogens	- Disproportion between high patient volume and sanitary facilities	3	3	9
	Improper waste management	Risk of sharps injuries for cleaning staff	- Lack of staff awareness on waste sorting protocols	4	2	8

SIL: Laboratory Information System

S = Severity, F = Frequency, C = Criticality

Table 2: Failure Modes and Associated Criticality in the Analytical Phase.

Step/Phase	Failure Modes	Effects / Impact	Potential Causes	S	F	C
Analyzer Maintenance	Missed maintenance	Erroneous calibration and/or controls	- Unauthorized personnel performing maintenance - Non-adherence to maintenance procedure	3	1	3
	Analyzer breakdown	Delayed results	- Mechanical or electronic failure	3	1	3
	Poor water quality	Erroneous calibration and/or controls	- Uncontrolled water quality - Damaged water station filters	3	1	3
Execution of Calibrations	Incorrect calibration	Erroneous quality control results	- Lack of personnel training - Expired or degraded calibrators	3	1	3
QC Execution & Validation	Unacceptable QC results	- Erroneous QC results - Delayed sample analysis - Incorrect Levey-Jennings charts	- Lack of personnel training - Poor organization - Expired or degraded control solutions	3	2	6
Analysis by Analyzer	Barcode reading error	- Analysis not performed - Delayed results	- IT network failure - Poor quality of barcode labels	3	1	3

	Mismatch between barcodes and requested tests					
	Sample/reagent pipetting error (e.g., air bubble)		- Blockage in the analyzer's pipetting system	2	2	4
	No automated transfer of results		- IT network failure	2	2	4
Technical Validation of Results	Failure to check patient's previous results	Validation of a result inconsistent with patient history	- High workload - Omission	4	3	**12**
	Delayed or absent validation	Delay in patient management		4	2	8

S = Severity, F = Frequency, C = Criticality

Table 3: Failure Modes and Associated Criticality in the Post-analytical Phase.

Step/Phase	Failure Modes	Effects / Impact	Potential Causes	S	F	C
Biological Validation	Lack of clinical information for interpretation	Erroneous interpretation	- Lack of a standardized, easy-to-use request form - High workload in clinical services	2	4	8
	Absent or delayed biological validation	Delayed patient management	- Lack of an on-call system for biologists at night	2	4	8
Electronic Result Reporting	IT network failure	Delayed result transmission	- Faulty or under-maintenance IT network	3	1	3
	Missing test method information in report	Misinterpretation of certain parameters	- Lack of a detailed procedure for communicating this information	2	4	8
	Insufficient reference values for interpretation	Misinterpretation of certain parameters		2	4	8
	No procedure for delayed results	Patients not informed	- Lack of a relevant procedure	2	2	4
	Issue with automated results distributor	Congestion at manual distribution counters	- Distributor out of service - Paper shortage	1	1	1
Critical Result Reporting	Non-communication of a critical result	Delayed patient management	- Lack of awareness - Omission	3	1	3
	Delayed communication of a critical result		- Lack of training	3	1	3
	Lack of communication traceability on log		- Omission of transcription on the register	1	1	1
Sample Storage	Non-compliance with storage conditions (temp, time)		- Lack of a detailed procedure for sample storage - Lack of dedicated storage areas	1	4	4

S = Severity, F = Frequency, C = Criticality

Discussion

This study aimed to implement a comprehensive and integrated risk management approach within our biochemistry laboratory to align with quality standards and foster a culture of risk mitigation. The FMEA methodology was applied across the pre-analytical, analytical, and post-analytical stages of the laboratory workflow. Our analysis identified 33 distinct failure modes.

The distribution of these failures revealed that 36.36% occurred in the pre-analytical phase, 33.34% in the analytical phase, and 30.3% in the post-analytical phase. This finding is consistent with a large body of literature demonstrating that the pre-analytical phase is responsible for 60% to 70% of laboratory errors. This is partly due to the involvement of multiple

stakeholders (physicians, nurses, trainees, phlebotomists, technicians) in this phase [10]. Our results align with a study in Morocco on pre-analytical risks in hemostasis, which reported a rate of 39.58% [11], and another FMEA study in Lyon, which found that 36.36% of risks (48 out of 132) in hemostasis testing were pre-analytical [12].

Indeed, the majority of non-conformities affect the pre-analytical phase, the mastery of which is strongly recommended by the ISO 15189 standard. It is increasingly evident that quality improvement efforts must be directed toward this phase, especially since many pre-analytical variables are not under the direct control of the laboratory. Regarding the severity of these failures, our study found that over 58.33% of failure modes had a high criticality score ($C \geq 9$). The combination of FMEA with Ishikawa cause-and-effect analysis led to the conclusion that human factors ('Personnel') are the primary root cause of the identified issues. This highlights the critical role of human intervention in pre-analytical errors. Implementing a robust quality assurance system requires the laboratory to be fully aware of the risks inherent in this phase.

The primary solution, as outlined in paragraph 5.4.1 of the ISO 15189 standard, is for the laboratory to "have documented procedures and information for pre-examination activities to ensure the validity of the results" [8]. The standard requires not only the creation of these procedures but also their dissemination to internal and external collectors and prescribing physicians. To address this, our laboratory has developed and maintains a comprehensive, up-to-date phlebotomy manual. This document contains specific instructions for sample collection and handling, conforming to best practice recommendations. Despite the availability of this manual in both paper and digital formats, failures associated with high criticality persist.

To further mitigate these risks, continuous training sessions on best practices for the pre-analytical phase are included in the hospital's professional development program, along with periodic reviews of phlebotomists' certifications. A second major improvement has been the implementation of a pneumatic tube system for transporting blood samples, which helps control and reduce transport times. While this system has resolved many issues related to transport delays, it remains unsuitable for certain tests, such as blood gases and cerebrospinal fluid analysis. Moreover, the system can be a source of occupational exposure to blood if tubes are not hermetically sealed. In this regard, ISO 15189 (paragraph 5.4.5) mandates that samples be transported within a suitable timeframe and at an appropriate temperature to ensure their integrity and the safety of all personnel [8].

To ensure robust control over the pre-analytical process, written criteria for sample acceptance and rejection must be defined. Any sample not meeting these criteria must be rejected, and the non-conformity must be formally documented.

(The full action plans derived from this study are detailed in Table 4, 5, and 6.)

Table 4: Action Plan for the Preanalytical Phase.

Failure Mode	Corrective/Preventive Action	Responsible Party	Resources/Tools
Patient identification error	Scan barcodes before collection, verifying patient ID	Supervisor of Collection Unit	Barcode scanner
Non-adherence to fasting	Educate staff responsible for registration		Awareness sessions
Collection by unauthorized trainee	Prohibit trainees from performing collection without direct supervision		Meetings, Protocols
Expired tube	Implement stock management training		Deploy stock management software
Hemolyzed sample	"Update procedures and instructions for blood collection		
Ensure continuous training for phlebotomists"	"Laboratory Biologist		
Phlebotomist"	Procedures, Instructions, Training		
Coagulated sample			
Contaminated sample			
Broken tube	Prioritize use of high-resistance materials	Laboratory Biologist	Call for tenders
Soiled tube	Do not transport tubes that are not hermetically sealed via pneumatic system	Technicians	Instructions
Poor waste management	Perform daily cleaning of all facilities	Cleaning Staff	Cleaning Procedure

Table 5: Action Plan for the Analytical Phase.

Failure Mode	Corrective/Preventive Action	Responsible Party	Resources/Tools
Missed maintenance	Adhere to manufacturer's instructions for maintenance Apply the pre-established maintenance schedule	Planning Manager, Technical Staff Biologists	Technical Docs, Planning Schedule
Analyzer breakdown	Apply the pre-established maintenance schedule Draft a procedure for IT-related failures	Technical Staff	Planning, Procedure
Poor water quality	Change filters periodically	Technical Staff	Procedures, Instructions
Incorrect calibration	Respect calibration procedure Respect instructions for preparation and storage	Technicians Biologists	Procedures, Instructions
Barcode reading error	Improve the print quality of labels	IT Service	High-quality printer and labels
Pipetting system error	Implement metrological control of pipetting systems	Technical Staff Biologists	
Delayed/absent validation	Sensitize technicians on the need for proper organization	Biologists	SIL

Table 6: Action Plan for the Post-analytical Phase.

Failure Mode	Corrective/Preventive Action	Responsible Party	Resources/Tools
Lack of clinical information	Implement a standardized request form to be completed by clinicians	Clinician-Pharmacist Collaboration, Hospital Admin	Update hospital's IT system
Absent/delayed biological validation	"Improve biologist involvement in on-call system		
Sensitize biologists to the impact of validation speed"	Head of Service, Biologists	Awareness meeting	
IT network failure	Create a documented procedure for communicating results during system downtime	Quality Unit	Procedure
Insufficient reference values	Conduct studies to adapt reference values to the local population	Biologists	
Non-communication of critical result	Sensitize biologists on the importance of rapid communication of critical results	Biologists, IT Service	Awareness meeting

Conclusion

In a medical biology laboratory, mastering the three phases of the workflow is an essential requirement to limit non-conformities that compromise not only the analytical process but also patient and clinician satisfaction.

Based on the major risks identified at each stage of the laboratory workflow, corrective actions have been proposed in an action plan. These actions, such as continuous training, staff sensitization, and the creation and dissemination of communication procedures, are designed to reduce the criticality of major risks. The implementation and monitoring of these measures must be part of a continuous improvement cycle to yield satisfactory results. Consequently, during subsequent evaluations, some risks may remain priorities while

their criticality is reduced, others may be eliminated, and new ones may emerge. This underscores the dynamic nature of risk management and the necessity for ongoing vigilance and adaptation.

Conflicts of interest

We have no conflicts of interest to disclose, and all authors have approved the manuscript for submission.

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Ethical considerations

This study protocol was conducted according to the principles of the Declaration of Helsinki and was approved by the Ethics Committee of the Military Hospital of Tunis.

Data Availability Statements

Data sharing is not applicable to this article as no new data were created or analyzed in this study. All sources analyzed are cited in the references.

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