ORIGINAL ARTICLE

Enhancing pre-analytical phase efficiency in a tertiary Parasitology-Mycology Laboratory: A methodological approach

Amélioration de l'efficacité de la phase pré-analytique dans un laboratoire tertiaire de Parasitologie-Mycologie: Une approche méthodologique

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Abstract

Introduction: The pre-analytical phase is a crucial step in the workflow of medical laboratories, as errors during this stage can significantly impact the subsequent analytical and post-analytical phases.
Aim: This study provides a comprehensive analysis of the causes of pre-analytical non-conformities and the corrective procedures implemented in the Parasitology-Mycology Central Laboratory of the Ibn Sina University Hospital Center in Rabat.
Methods: Over a 30-month period, we evaluated compliance with ISO 15189:2022 standards using a self-assessment grid to identify areas for improvement. Non-conformities were categorized based on their root causes to gain insight into the underlying issues. We conducted a Pareto analysis to identify the most significant problems in the pre-analytical phase. Additionally, we employed Failure Modes and Effects Analysis (FMEA) to assess potential risks associated with these non-conformities.
Results: The most frequent non-conformities identified included delays in sample transportation, reagent shortages, and identification-prescription errors. The FMEA categorized these non-conformities as high-risk, leading to several proposed corrective actions: enhancing transport protocols, implementing automated alerts for reagent shortages, improving staff training, and establishing better communication between departments and the laboratory.
Conclusion: This study emphasizes the need for a comprehensive approach to managing non-conformities in the pre-analytical phase. Involving everyone in the process and creating a culture of quality and responsibility are essential for improving laboratory efficiency and ensuring better patient outcomes. Additionally, continuous monitoring and evaluation through established quality indicators will support ongoing improvements in laboratory practices.

Key words: Pre-analytical phase, Medical laboratory, Parasitology, Mycology, Quality Improvement

Résumé

Introduction: La phase pré-analytique représente une étape déterminante dans le fonctionnement des laboratoires médicaux, car les erreurs survenant à ce niveau peuvent affecter de manière significative la fiabilité des phases analytique et post-analytique qui suivent. Cette étude s'intéresse aux non-conformités observées dans le laboratoire central de Parasitologie-Mycologie du Centre Hospitalier Universitaire Ibn Sina à Rabat.
Objectif: Identifier et d'analyser les causes profondes des non-conformités pré-analytiques, d'évaluer leurs risques potentiels, et de proposer des procédures correctives adaptées pour améliorer l'efficacité globale de cette phase critique.
Méthodes: Pendant une période de 30 mois, une grille d'auto-évaluation basée sur la norme ISO 15189 :2022 a été utilisée pour évaluer la conformité. Les non-conformités ont été catégorisées selon leurs causes sous-jacentes, puis analysées via une approche de Pareto pour repérer les problèmes les plus fréquents. Une analyse des modes de défaillance, de leurs effets et de leur criticité (AMDEC) a permis d'évaluer les risques associés.
Résultats: Les non-conformités majeures identifiées sont les retards dans le transport des échantillons, les pénuries de réactifs et les erreurs d'identification-prescription, toutes classées à haut risque par l'AMDEC. Les mesures correctives incluent l'amélioration des protocoles de transport, la mise en place d'alertes automatisées pour anticiper les pénuries, un renforcement de la formation du personnel et une communication optimisée entre les départements et le laboratoire.
Conclusion: Une gestion globale des non-conformités, impliquant tous les acteurs et favorisant une culture de qualité, est essentielle. Un suivi régulier via des indicateurs de qualité établis soutiendra les efforts d'amélioration continue des pratiques.

Mots-clés: Phase pré-analytique, Laboratoire médical, Parasitologie, Mycologie, Amélioration de la qualité

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Introduction

Laboratory diagnostics play a crucial role in clinical decision-making, with the accuracy of laboratory results being essential to the diagnostic process(1). The performance of medical laboratories is directly linked to the quality maintained throughout the entire testing cycle, with particular focus on the control of the pre-analytical phase(2).

The pre-analytical phase includes all procedures performed before the actual testing, from the clinician's request, including the examination requisition, patient preparation, patient identification, specimen collection, labelling, transportation, handling and storage(3).

Errors or inefficiencies during this step are a significant concern, as they often require resampling and result in additional costs(4). Moreover, if abnormalities go undetected, they can compromise patient safety and lead to misdiagnosis(5).

Studies have shown that up to 61.9% of errors in the total testing process occur during the pre-analytical phase(6). A quality assurance system focused on this phase must be implemented, with the first step being the identification of potential sources of error(7).

The aim of this study is to analyse the pre-analytical processes at the Parasitology-Mycology Laboratory of Ibn Sina University Hospital through a methodological approach. This approach incorporates ISO 15189:2022(8) recommendations and adopts fundamental quality tools such as the Ishikawa diagram, the Pareto principle, and Failure Modes and Effects Analysis (FMEA)(9).

By identifying key factors contributing to inefficiencies and prioritizing areas for improvement, this study seeks to propose actionable solutions to enhance the efficiency and quality of the pre-analytical phase. This, in turn, aims to improve laboratory performance and promote better patient care.

Methods

Study Setting and Design

This study was conducted at the Parasitology-Mycology Laboratory of Ibn Sina University Hospital in Rabat, which serves all ten hospitals within the center. The laboratory provides diagnostic services for a wide range of parasitological and mycological infections and plays a crucial role in supporting clinical decision-making(10). The study adopts a descriptive and analytical design, focusing on the pre-analytical phase of laboratory operations. The objective is to identify inefficiencies, determine their root causes, and propose solutions using a structured methodological approach.

Evaluation Grid Based on ISO 15189

An evaluation grid was developed in alignment with ISO 15189 standards, which provide requirements for the quality and competence of medical laboratories(11). This grid was used to assess the compliance of pre-analytical processes, and to identify any deviations from standard recommendations(12).

Data Collection

Data were retrospectively collected over a 30-month period from January 2022 to June 2024, focusing on all samples received for analysis. Non-conformities in the pre-analytical phase were identified and categorized into several types, such as sample labelling errors, transportation delays, improper storage, and incomplete patient information. These non-conformities were recorded and analysed based on their frequency and impact on laboratory performance.

Root Cause Analysis Using the Ishikawa Diagram

The Ishikawa diagram, also known as the fishbone or cause-and-effect diagram, was employed to identify the root causes of pre-analytical inefficiencies. The diagram helped visually map out the potential causes of non-conformities, enabling a clearer understanding of their underlying sources(13).

Pareto Analysis for Prioritization

Pareto analysis was used to prioritize the identified causes of pre-analytical inefficiencies. According to the Pareto principle «80/20 rule», 20% of causes often lead to 80% of problems(14).

Failure Modes and Effects Analysis (FMEA)

Failure Modes and Effects Analysis (FMEA) was conducted to assess the potential risks associated with the identified non-conformities. Each failure mode was evaluated based on three key criteria: severity, occurrence, and detectability(15). A risk priority number (RPN) was assigned to each failure mode to prioritize non-conformities presenting the highest risk to laboratory operations and patient outcomes(16).

Results

During the study, data were retrospectively collected over 30 months, and a total of 1,647 non-conformities (NCs) were recorded, representing 7.86% of the 20,954 total analyses received and processed during the same period.

The self-assessment grid revealed that the laboratory fully complies with the pre-analytical phase requirements of ISO 15189 version 2022, section 7.2, demonstrating effective procedures and protocols across all assessed areas. Notably, there are no non-conformities in the handling of test specimens for superficial mycology, indicating a strong operational foundation. However, the assessment identifies the need for improved communication and dissemination of information among staff and other departments to enhance compliance further and ensure consistent adherence to established procedures.

According to statistics based on the hospital of origin, 82% of NCs were traced to Ibn Sina Hospital (41.04%) and

the Children's Hospital of Rabat (41.71%).

The percentage of NCs in outpatient samples was 24.22%, compared to 75.61% in inpatient samples. In contrast, samples collected within the laboratory's own sampling room for mycological analysis showed no non-conformities.

Non-conformities in the pre-analytical phase were primarily recorded for the stool ova and parasite test (50.88%), followed by toxoplasmosis serology (19.13%) and aspergillosis serology (12.81%).

Throughout the study period, several types of non-conformities were identified in the pre-analytical phase. The most common issues observed included delays in sample transportation, reagent shortages, haemolysed samples, incorrect sample labeling, and incomplete patient information. Each category of non-conformity was quantified, and its frequency was recorded.

The Ishikawa diagram allowed for a systematic exploration of the root causes behind these non-conformities. Factors related to personnel, methods (lack of standardized protocols), and communication (poor coordination between clinical services and the laboratory) were identified as primary contributors.

The different types of pre-analytical non-conformities are presented in Table 1, which summarizes the frequency and percentage of each non-conformity, along with their corresponding root causes, providing insight into the prevalent issues and areas for improvement within our laboratory processes.

Table 1. Frequency, Percentage, and Root Causes of Pre-Analytical Non-Conformities.

Non-conformity	Frequency	Percentage (%)	Root Cause
Transportation delay	641	38.92	Miscommunication, understaffing, poor time management, lack of transportation coordination.
Reagents shortage	269	16.33	Failure to report or manage reagent shortages, poor coordination with suppliers, insufficient stock management.
Haemolysed sample	187	11.35	Improper collection technique, delayed processing, improper sample storage.
Unidentified sample tube	146	8.86	Lack of labeling protocols, failure to double-check sample identification, inadequate staff training.
Mismatch between sample and requested analysis	90	5.46	Lack of attention in matching samples to requests, insufficient verification processes, human error.
Patient ID mismatch between prescription and sample	87	5.28	Manual data entry errors, insufficient verification procedures, lack of training on patient identification.
Non-compliant tube	86	5.22	Use of improper tubes, failure to follow tube specifications for specific analyses, lack of communication.
Damaged tube (vial)	31	1.88	Improper handling or storage by personnel, lack of care during transport or storage, inadequate packaging.
Absent sample	25	1.52	Miscommunication, errors in tracking or collecting samples, oversight in sample management.
Insufficient quantity	22	1.34	Failure to follow collection guidelines, lack of staff experience, miscommunication about required sample volumes.
Misidentified sample tube (ID error)	22	1.34	Human error in labelling, lack of double-checking identification, inadequate verification procedures.
Illegible prescription	11	0.67	Printing errors in electronic prescriptions, poor handwriting.
Transportation error	9	0.55	Mistakes in transport logistics, failure to follow standardized protocols for sample transport, miscommunication between departments.
Missing prescription	6	0.36	Failure to ensure the prescription is attached to the sample, lack of coordination between departments.
Contamination of prescription form by biological product	6	0.36	Lack of care in handling samples and forms, failure to separate forms and samples during transport or storage.
Empty tube	5	0.30	Failure to verify sample collection before submission, miscommunication during the collection process.
Coagulated blood	4	0.24	Improper handling, failure to use anticoagulants correctly, delays in processing or incorrect sample storage.
Total	1647	100	

Prioritization of Causes Using Pareto Analysis

Applying Pareto analysis, we found that the most impactful factors included delays in transportation, lack of reagents, haemolysed samples and identification-prescription errors, accounting for most inefficiencies.

A Pareto chart highlighting the distribution of non-conformities is displayed in Figure 1, illustrating the contribution of each factor to the overall problem.

Risk Assessment Using FMEA

Using Failure Modes and Effects Analysis (FMEA), we assigned Risk Priority Numbers (RPN) to each identified non-conformity. The highest RPN values were associated with: reagents shortage, transportation delay, Haemolysed sample and identification-prescription errors, indicating that these issues pose the greatest risk to laboratory operations.

The following table outlines the scoring criteria for calculating the Risk Priority Number (RPN) in Failure Mode and Effects Analysis (FMEA), categorizing severity, occurrence, and detection on a scale of 1 to 5.

Table 3 shows the RPN values for the top-ranked non-conformities, along with their severity, occurrence, and detectability ratings.

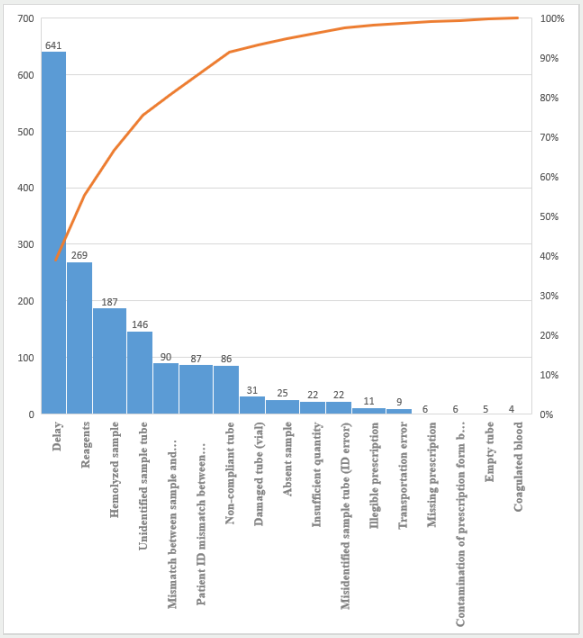

Figure 1. Pareto Chart Showing the Distribution of Pre-Analytical Non-Conformities by Frequency.

Discussion

Quality management of the preanalytical phase in parasitology-mycology cannot be approached in the same way as in other disciplines. This discipline fundamentally focuses on living microorganisms, which are inherently characterized by multifactorial variability.

The fact that a significant part of the pre-analytical process takes place outside the laboratory, the involvement of multiple operators not always affiliated with the laboratory, and the multitude of successive actions governing the preanalytical process add an additional level of complexity to managing this critical phase.

During the study, 1,647 preanalytical non-conformities (NCs) were recorded, representing 7.86% of the total 20,954 analyses received and processed over the 30-month period. Similar findings have been reported in previous studies, including a Tunisian study (17). However, other studies documented a lower percentage of NCs (18–20). This discrepancy may be attributed to the centralized model implemented in our laboratory, which serves 10 hospitals within the Ibn Sina University Hospital Center.

Table 2. RPN calculation score scale for FMEA

Criteria	1	2	3	4	5
Severity (S)	Minor impact, no significant effect.	Low impact, minor delay or rework.	Moderate impact, noticeable delay or need for retesting.	High impact, significant patient care or operational delay.	Critical impact, potentially life-threatening or major harm.
Occurrence (O)	Rare (very infrequent).	Unlikely (infrequent).	Occasional (moderately frequent).	Likely (frequent).	Very Likely (very frequent).
Detection (D)	Very easily detected (high detection rate).	Detected with regular controls.	Moderate detection ability (sometimes missed).	Difficult to detect (often missed).	Very difficult to detect (rarely detected).

Table 3. FMEA results – Risk Priority Numbers for pre-analytical non-conformities.

Non-conformity	Frequency	Severity (S)	Occurrence (O)	Detection (D)	RPN	Potential Effect
Transportation delay	641	4	3	3	36	Degradation of sample quality, risk of false negatives (for parasitology)
Sample identification and prescription errors	345	4	3	3	36	Misidentification, risk of incorrect treatment or need for recollection
Reagents shortage	269	4	3	3	36	Analyses delayed or not performed, affecting clinical decision-making
Haemolysed sample	187	4	2	3	24	Compromised sample integrity, unreliable results or inability to analyse
Non-compliant tube	86	3	3	2	18	Inaccurate results due to the use of incorrect containers
Damaged tube	31	3	2	2	12	Delayed analysis due to transport issues
Absent sample	25	4	2	1	8	Sample not available for analysis, delaying diagnosis
Insufficient quantity	22	3	2	2	12	Insufficient sample volume, requiring recollection
Illegible prescription	11	3	1	2	6	Delayed analysis due to unclear prescription
Transportation error	9	3	1	3	9	Delays in sample arrival due to transportation mistakes
Missing prescription	6	3	1	3	9	Missing paperwork leads to delays in processing samples
Contamination of prescription form by biological product	6	3	1	1	3	Risk of contamination affecting documentation and laboratory safety
Empty tube	5	4	1	1	4	Tube received empty, no analysis possible
Coagulated blood	4	4	1	2	8	Blood coagulated, making sample unusable

This structure contributes to a higher proportion of non-conformities due to logistical challenges and communication gaps with peripheral clinical teams, particularly those located far from the core laboratory. Specifically, 58.96% of the non-conformities originated from peripheral collection sites, with 41.71% of these errors arising from Children's Hospitals.

Interestingly, no non-conformities were recorded for superficial specimens. This can be explained by the fact that these specimens are collected in the laboratory's dedicated sampling room, an area directly supervised by laboratory staff. This setup ensures immediate error correction and proper patient guidance, thereby minimizing collection mistakes.

A root cause analysis, combined with a Pareto analysis, highlighted that the most common preanalytical errors were delayed sample transportation, reagent shortages, haemolysed samples, unidentified sample tubes, and mismatches between samples and requested analyses.

Sample transportation remains a major preanalytical challenge, where time is a critical factor in preserving sample integrity (17,20,21). According to ISO 15189 requirements, biological samples must be transported to the laboratory as quickly as possible while following all necessary precautions to ensure their quality and safety (11). Optimizing the transportation system involves reducing transit times and increasing the frequency of deliveries. Implementing a dedicated courier service for urgent samples could further ensure timely processing. A lack of training in these standards may contribute to delays. Regular workshops, continuous updates on best practices, and close supervision could help maintain high standards(22).

Another significant issue is the suspension of routinely requested tests due to reagent shortages, which can significantly disrupt patient management. To mitigate this, laboratories should provide consultancy services to adapt test prescriptions and minimize unnecessary testing (23). Additionally, implementing an automated real-time inventory monitoring system with alert triggers for low stock levels can improve supply chain efficiency. Regular updates to clinicians regarding reagent availability are also essential to facilitate informed decision-making.

In our study, the third most common preanalytical error was haemolysed samples, which accounted for 11.35% of all errors. Previous studies (18,24) have shown variations in hemolysis rates across different laboratory settings, particularly between emergency and routine laboratories(19,25). Undetected hemolysis can lead to incorrect immunoassay results, impacting clinical decisions(4). Therefore, corrective actions targeting blood collection techniques, sample transportation, and proper storage conditions can significantly reduce this issue(17).

Unidentified samples represented 8.86% of the total non-conformities recorded. Literature reviews indicate that the use of a structured labeling system significantly reduces this type of error(18,24). However, higher rates have been reported in other studies(17,20). Given both the frequency and severity of this issue, it is essential to label all specimen containers with at least two patient-specific identifiers. Additionally, implementing barcode or radio-frequency identification (RFID) systems at the time of collection, along with periodic staff training and awareness campaigns, can minimize these critical errors (26–28).

5.46 % of preanalytical non-conformities are related to a mismatch between the type of sample submitted and the analysis request. This error can arise during the sampling or transportation phases due to insufficient attention to matching samples with requests. To address it, a verification process must ensure that each container is placed with the requisition sheet in a securely closed double bag. Errors can sometimes be related to the prescription phase due to frequent confusion between stool ova and parasites testing and stool culture, which can result in sample rejection(22).

The ISO 15189 standard is essential for ensuring quality in medical laboratories by providing a framework for competence and continuous improvement. Our findings show that while the laboratory's internal collection procedures closely adhered to ISO 15189 recommendations, external departments encountered significant challenges in meeting the same standard. Non-conformities such as sample misidentifications, transportation delays, and inappropriate sample handling were notably more prevalent in external departments.

This disparity highlights the need for targeted interventions to bring external departments up to the same standard of practice. Enhancing training programs, improving coordination, and implementing stricter monitoring of pre-analytical procedures are critical measures to address these issues. Achieving compliance in these areas would align external collection practices with the high-quality standards observed in the internal laboratory environment, thereby improving overall service reliability and patient outcomes.

Corrective Actions

Based on these analyses, several corrective actions are recommended to improve pre-analytical processes and reduce non-conformities:

1. **Staff Training and Supervision**: Ensuring that all personnel, particularly in external departments, receive comprehensive training in sample collection, identification, and transportation is critical. Regular workshops, updates on best practices, and close supervision would help maintain high standards.
2. **Improved Sample Transport Logistics**: Optimizing the transportation system by reducing transit times and increasing the frequency of deliveries would help prevent delays and the resulting sample degradation. A dedicated courier service for urgent samples could be introduced to ensure timely processing.
3. **Automated Labeling and Identification Systems**: Introducing barcoding and automated identification systems across all departments would minimize identification errors. These systems ensure that all samples are accurately labeled and matched with their corresponding requests, reducing the risk of misidentification.

4. Inventory Management for Reagents: Implementing an automated inventory management system would ensure that reagent levels are continuously monitored. Alerts would be triggered when stocks are low, preventing shortages and ensuring that analyses are not delayed due to a lack of necessary materials.

5. Feedback and Continuous Monitoring: Establishing a real-time feedback system for non-conformities, combined with continuous monitoring, would enable the laboratory to detect and address issues as they arise. This approach ensures a dynamic quality control process and allows for rapid responses to emerging challenges.

By implementing these corrective actions, the laboratory can significantly reduce the rate of non-conformities, improve overall efficiency, and ensure adherence to ISO 15189 standards across all departments.

Limitations

While this study provides valuable insights, it has several limitations. The data collection was retrospective, which may have resulted in the underreporting of certain non-conformities. Additionally, the study was conducted in a single hospital laboratory, potentially limiting the applicability of the findings to other settings. Future studies could benefit from a prospective design and the inclusion of multiple laboratories to provide a broader perspective on pre-analytical issues.

Conclusion

This study highlights the critical need for addressing inefficiencies in the pre-analytical phase at the Parasitology-Mycology Laboratory of Ibn Sina University Hospital. By identifying the root causes of these inefficiencies and prioritizing solutions using a structured methodology, we have demonstrated that targeted interventions can significantly improve laboratory performance and patient outcomes. Implementing these changes will not only enhance the quality of diagnostic services but also promote better overall patient care.

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