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# A Comprehensive Evaluation of the Preanalytical Phase in Laboratory Medicine, Nephrology, Emergency Specialties, Visceral Surgery, Pediatrics, Internal Medicine and Neonatology Hospital Departments: In-Depth Insights derived from an analysis of practices at a Medical University Centre in Morocco

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## Abstract

**Background and Aims:** The precision of biological examination results hinges on meticulous preparatory measures before analysis, known as the pre-analytical phase. This phase contributes significantly to error rates (48-68%). Our study assessed the pre-analytical phase in seven hospital departments at Mohammed VI University Hospital. The objective was to address key causes of pre-analytical nonconformities.

**Materials and Methods:** During this investigation, we observed 331 samples from various departments: Central Laboratory, Nephrology, Internal Medicine, Visceral Surgery, Emergency Specialties, Paediatrics, and Neonatology. Our evaluation identified 4945 instances of pre-analytical nonconformities. These cases encompassed issues with the prescription sheet (501), patient preparation (848), equipment preparation (295), sampling process (1957), waste management (323), and sample transfer (422).

**Results:** Our analysis highlighted a multitude of pre-analytical nonconformities within the surveyed hospital departments. These discrepancies illuminated the critical areas where corrective and preventive measures were imperative to adhere to the standards set by the International Standard ISO15189 and to optimize patient care.

**Conclusions:** The findings from this study underscore the paramount importance of the pre-analytical phase in ensuring accurate biological examination results. By implementing a series of targeted actions in the concerned hospital departments, we addressed the identified nonconformities. These actions encompassed ongoing education, staff awareness and support, regular audits, provision of technical resources such as manuals and sample catalogues, as well as the utilization of appropriate equipment for sample collection and transportation. Continuous learning remains essential, encompassing proper sampling techniques, packaging and transportation requisites, as well as procedures for identifying and rectifying biological sample nonconformities.

**Keywords:** Preanalytical phase, patient care, hospital departments, nonconformities, quality management.

## INTRODUCTION

Medical biology, a complex multidisciplinary field, generates clinically and public health-relevant test results. Given its significance, ensuring high-quality laboratory tests is paramount for optimal patient care. Quality in this context refers to meeting both stated and implied user needs. In medical biology, quality translates to the precision and reliability of test outcomes [1]. Reliable biological examination results hinge not only on technically sound analysis but also on proper preparation prior to analysis. This essential process is termed the preanalytical phase. Our study concentrates on this phase, which is divided into two stages: one external to the laboratory and the other within it. External preanalytical phase includes steps outside the laboratory: prescription, collection, identification, preservation, transportation beyond the medical laboratory technologist control. Studies reveal preanalytical error rates of 48% to 68% [2], with over two-thirds linked to the external phase [3]. The medical laboratory technologist is responsible for the entire process, including sample conditions, transportation, and rejecting unsuitable samples [4].

Due to the significance and direct impact of the preanalytical phase on laboratory results, we have chosen to conduct a study within the Mohammed Sixth University Medical Hospital in Morocco. The objectives of this study are as follows:

- To describe the process of the preanalytical phase in six hospital departments and the central laboratory.
- To identify the causes and origins of the nonconformities;
- To implement an improvement plan including corrective and preventive actions to address preanalytical errors and nonconformities.

An error is a deviation from the intended or specified behavior. It represents a mistake or flaw in a process, system, or product that may lead to undesired outcomes. Errors can occur due to various reasons, including human factors, system malfunctions, or external influences.

Nonconformity refers to a deviation from established standards, specifications, or requirements. It indicates a situation where a process, product, or system does not meet the defined criteria or does not conform to the expected norms. Nonconformities can encompass errors but also extend to situations where certain requirements are not met without necessarily implying a mistake.

## MATERIALS AND METHODS

This is a prospective, descriptive, observational, and quantitative study conducted in the central medical biology laboratory, nephrology, internal medicine, visceral surgery, pediatrics, neonatology, and adult emergency departments. The study involved substantial qualitative and quantitative sample collection to enhance anomaly detection. Collaboration with these departments aimed to improve preanalytical phase quality for better patient care. Observations occurred in the mornings across departments due to high sample volume. The study lasted 4 months, from February 23, 2023 to June 28, 2023 with two stages: eight weeks of departmental observations and two months of central laboratory data analysis.

- Inclusion criteria:

This study targets the observation of samples collected by any specimen collector working in the aforementioned services.

- Exclusion criteria:
  - Collectors unwilling to have us present during the sampling (a few cases);
  - Patients who declined to undergo

sampling;

- Catheter-based sampling.

The data collection started with permissions from directors of inpatient services. Clearances were also secured from supervisors and collectors to observe all relevant study services. A comprehensive form by medical biology staff detailed the preanalytical phase steps and was carefully completed. Triage area visits noted sample acceptance, times, and assigned codes for forms. Incomplete forms were removed before data work in EXCEL 2013. Results were presented as tables and histograms.

## RESULTS

In the study, 331 samples were observed: thirty-one from outpatients at the central medical biology laboratory; sixty seven from Adult Department patients; thirty nine from Nephrology patients; eighty two from Internal Medicine patients; thirty five from Visceral Surgery patients; thirty nine from Pediatrics patients and 38 from Neonatology patients. Of the 331 patients, 176 (53%) were female and 155 (47%) were male.

In our study, out of 331 sampled patients, thirty-eight (11%) were newborns; thirteen (4%) were infants; thirty-one (9%) were children; 145 (44%) were adults; and 104 (31%) were elderly individuals. During the study, we found 4,945 cases of preanalytical nonconformities. These were distributed as follows: central laboratory (214 cases, 4%); neonatology (460 cases, 9%); visceral surgery (548 cases, 11%); pediatrics (581 cases, 12%); nephrology (611 cases, 12%); specialty emergency (1,225 cases, 25%); and internal medicine (1,306 cases, 26%). Table 1 below presents the completed form with the non-conformity results across hospital departments.

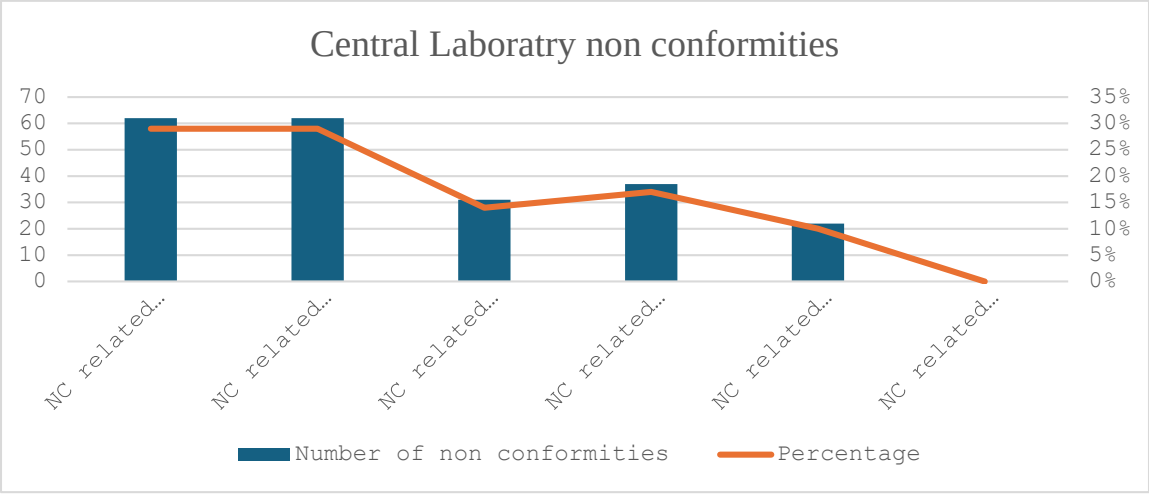


**Figure 1. Global representation of preanalytical NC collected within the central laboratory**

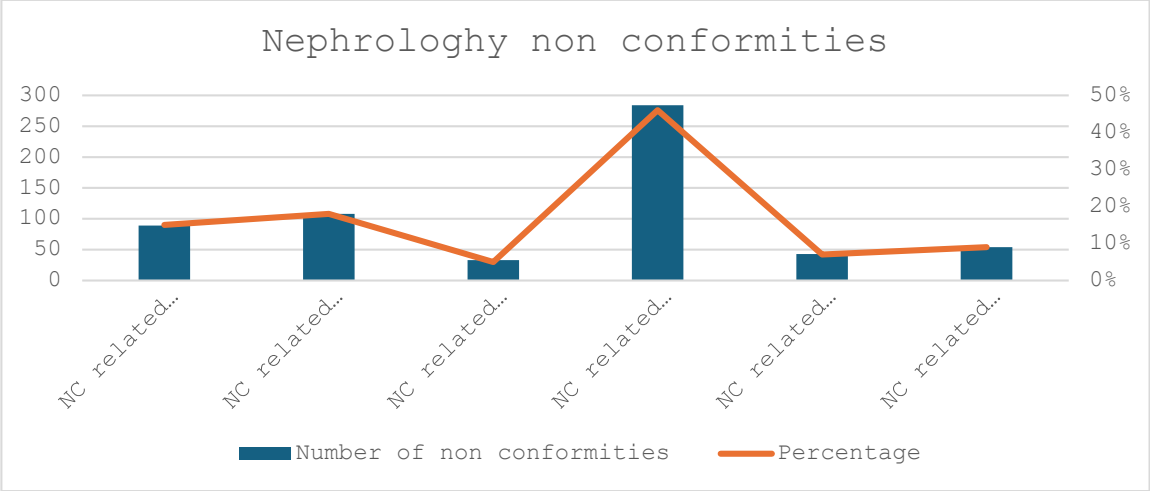


**Figure 2. Global representation of preanalytical NC collected within the Nephrology Department**

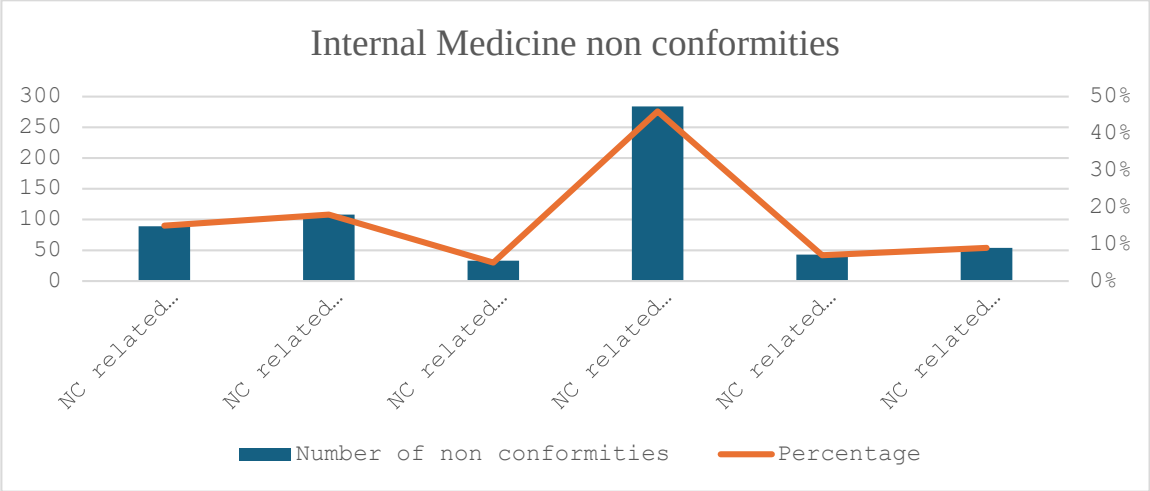


**Figure 3. Global representation of preanalytical NC collected within the Internal Medicine Department**

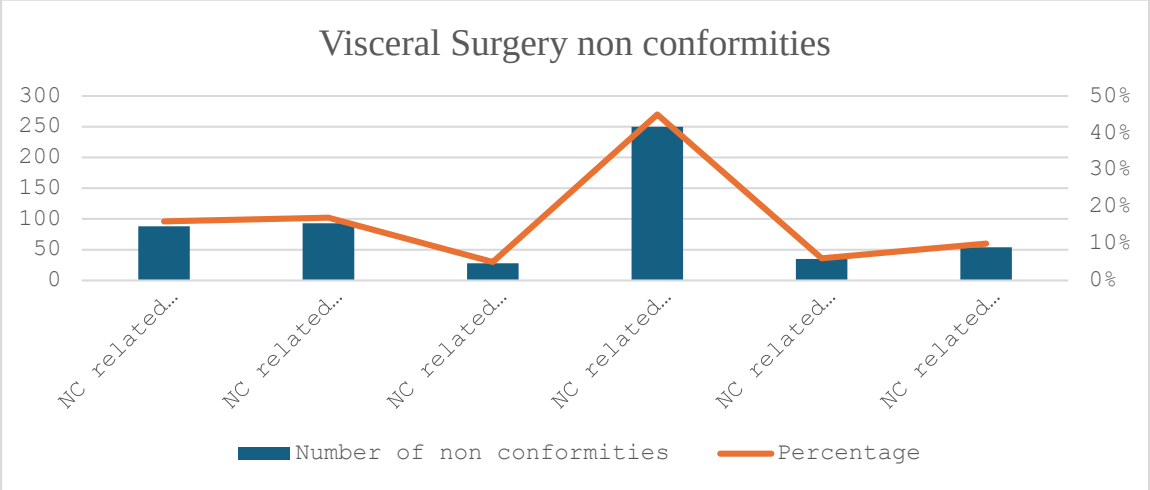


**Figure 4. Global representation of preanalytical NC collected within the Visceral Surgery Department**

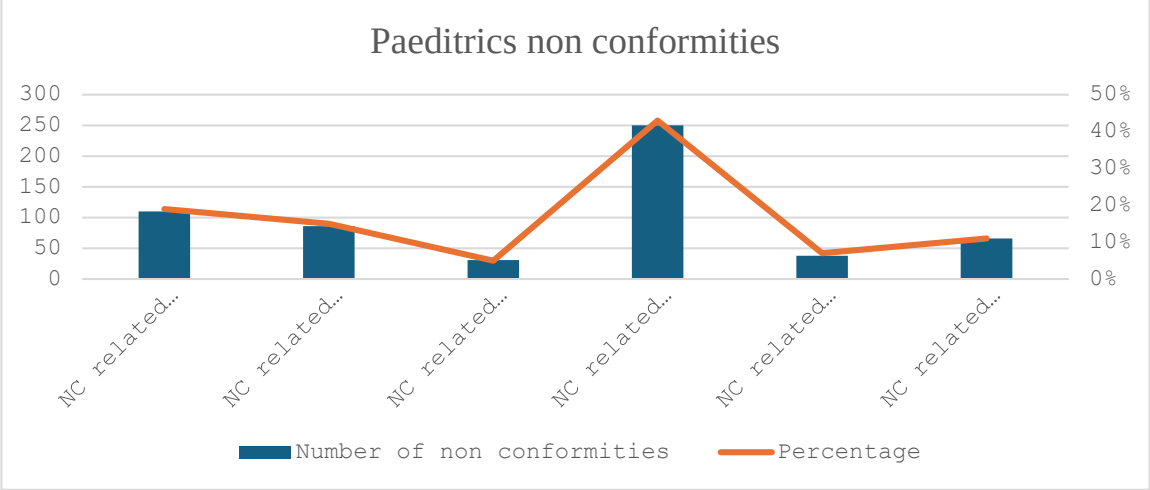


**Figure 5. Global representation of preanalytical NC collected within the Paediatrics Department**

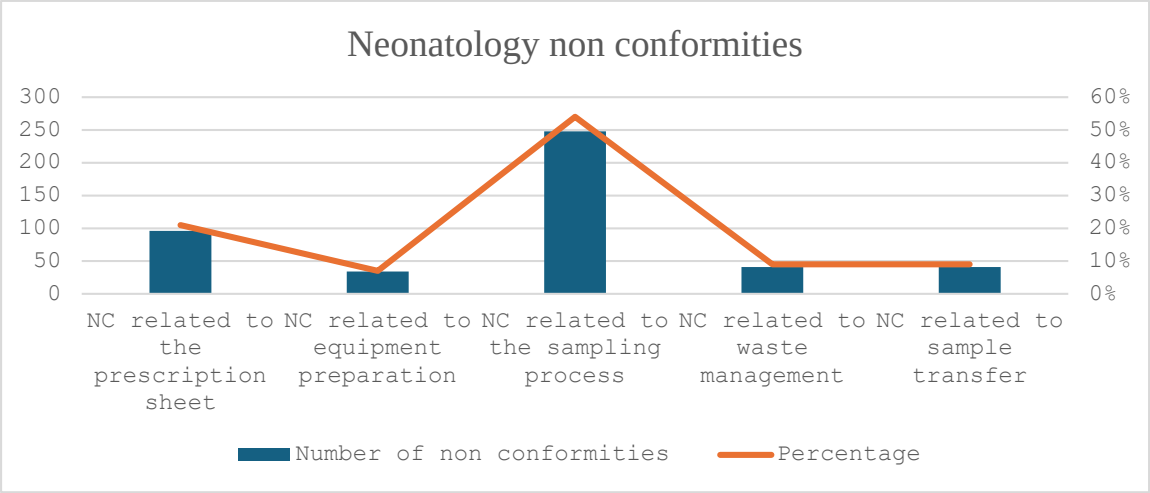


**Figure 6. Global representation of preanalytical NC collected within the Neonatology Department**

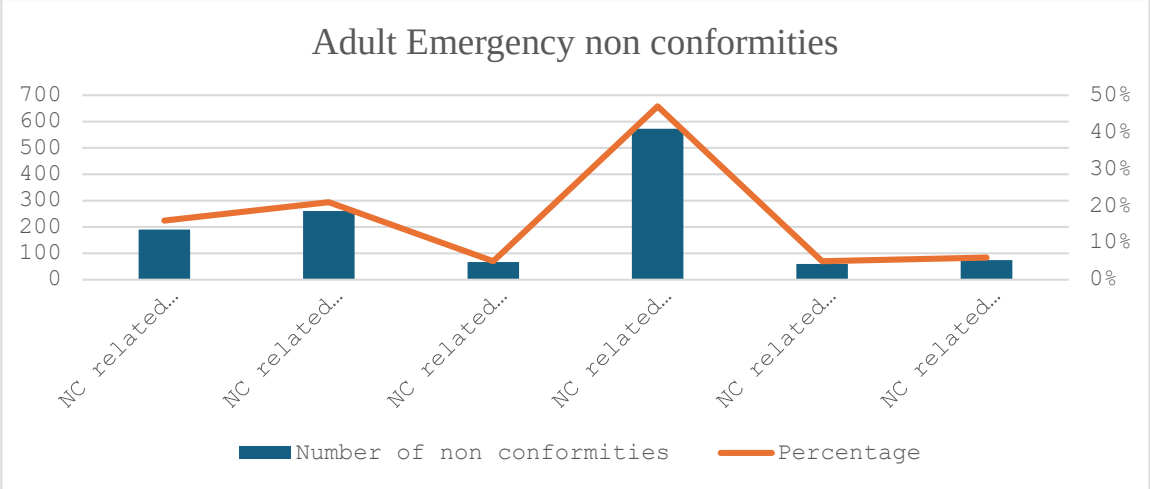


**Figure 7. Global representation of preanalytical NC collected within the Adult Emergency Department.**

**Table 1. Overall results of nonconformities at the evaluated services level**

| | | Central Laboratory | Adult Emergencies | Nephrology | Internal Medicine | Visceral Surgery | Pediatrics | Neonatology | Total |
|---|---|---|---|---|---|---|---|---|---|
| **Prescription Sheet** | Identification of patients | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| | Prescription verification | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| | Identification / Prescriber's Stamp and Signature | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| | Sampler's Identification | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| | Sampling Time | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| | Clinical Information | 0% | 84% | 28% | 40% | 51% | 82% | 53% | 51% |
| **Patient Preparation** | Patient Information | 19% | 93% | 64% | 82% | 74% | 31% | _ | 68% |
| | Patient Consent | 0% | 0% | 0% | 0% | 0% | 0% | _ | 0% |
| | Resting Period Before Conducting the Sampling | 61% | 100% | 69% | 55% | 77% | 87% | _ | 75% |
| | Identity Verification | 0% | 0% | 67% | 57% | 46% | 41% | _ | 36% |
| | Fasting Duration Verification | 58% | 99% | 41% | 55% | 37% | 38% | _ | 59% |
| | Medication Intake Verification | 61% | 99% | 36% | 41% | 31% | 23% | _ | 52% |
| **Material Prep** | Preparation of Equipment | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| | Expiry Date Check on the Tube | 100% | 100% | 85% | 87% | 80% | 79% | 89% | 89% |
| **Sampling Procedure** | Hand Washing/Gloving | 29% | 94% | 41% | 28% | 74% | 28% | 45% | 50% |
| | Choice of Venipuncture Site and Order | 0% | 13% | 21% | 13% | 20% | 13% | 21% | 15% |
| | Use of Tourniquet | 0% | 90% | 69% | 87% | 69% | 77% | 82% | 73% |
| | Tourniquet Placement Distance | 0% | 9% | 13% | 11% | 77% | 5% | _ | 17% |
| | Site Disinfection | 0% | 96% | 33% | 0% | 9% | 10% | 0% | 25% |
| | Drying Time | 0% | 96% | 33% | 0% | 9% | 10% | 34% | 29% |
| | Puncture Device | 0% | 100% | 100% | 71% | 37% | 100% | 100% | 77% |
| | Order of Collection | 10% | 69% | 74% | 70% | 71% | 46% | 45% | 59% |
| | Correlation between Biological Tests and Recommended Tube Types | 0% | 0% | 5% | 4% | 3% | 3% | 0% | 2% |
| | Tube Fill Level | 0% | 0% | 3% | 37% | 20% | 18% | 18% | 16% |
| | Tourniquet Application Duration | 10% | 81% | 77% | 99% | 74% | 85% | 74% | 77% |
| | Sampling Duration | 0% | 15% | 10% | 21% | 3% | 13% | 18% | 13% |
| | Tube Identification | 0% | 0% | 69% | 90% | 54% | 62% | 16% | 45% |
| | Homogenization | 71% | 94% | 79% | 82% | 94% | 72% | 100% | 85% |
| | Tube Placement | 0% | 100% | 100% | 100% | 100% | 100% | 100% | 91% |
| **Waste** | Container Availability | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| | Needle Disposal | 68% | 78% | 90% | 89% | 97% | 90% | 95% | 86% |
| | Hygiene and Safety Conditions | 3% | 12% | 21% | 13% | 3% | 8% | 13% | 11% |
| **Transfer** | Packaging | 0% | 79% | 72% | 55% | 66% | 82% | 47% | 60% |
| | Transport of Samples | 0% | 9% | 0% | 35% | 20% | 8% | 16% | 15% |
| | Transport Temperature | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| | Turnaround Time to Laboratory | 0% | 22% | 67% | 72% | 69% | 79% | 45% | 52% |

The work practices within the central laboratory diverge notably from those in various other hospital departments, particularly in the execution of the sampling process. While a shared commitment to precision and patient care underpins both settings, unique factors characterize the methodologies employed.

The hospital departments outside the central laboratory exhibit a more diverse spectrum of work practices. Due to the dynamic nature of patient care, sampling procedures may vary based on clinical urgency, patient condition, and the department's primary focus. In these settings, the emphasis often lies in swift response and immediate patient needs. This can lead to variations in sample collection techniques and processes, impacting the preanalytical phase.

Finally, we have noticed that the central laboratory relies on venipuncture for

sampling, ensuring accuracy and consistency. In contrast, hospital departments use syringes, introducing variability that could affect result quality. Different methods impact the outcome reliability.

## DISCUSSION

Nonconformities related to prescription forms:

Note that at the University Medical Centre, the prescription of biological tests is connected. The physician must complete all fields for validation. Yet, crucial fields for interpreting and validating results were absent, including sampler identity and sampling time in all requests (100%). These observations were documented and shared with relevant departments, along with the service provider, as part of ongoing improvement and maintenance of the hospital information system. The advantage of the connected prescription is the ability to reprint the examination request at any time. Indeed, it ensures accurate prescription of medical biology tests, excellent traceability throughout the process, and formalizes the relationship between the laboratory and clinicians [5]. This significant issue cannot be ignored. It could lead to result errors and wasted reagents. Context matters for precise test interpretation, improving reliability and speed. Verification against potential factors enhances result quality [6].

Nonconformities related to patient preparation:

Patient information is a recognized right, reshaping the patient-physician relationship. Clear, honest, and tailored details enable informed consent for medical care [7]. No sampling is performed without the patient's free and informed consent. With elderly individuals, affirmative responses are common, making it vital for the sampler to actively confirm the patient's identity. Using an active question such as "What is your name?" instead of a passive one like "Are you Mr X?" prevents identity confusion. As per EFLM-COLABIOCLI [8] a 15-minute rest before sampling is advised. Body position changes, such as lying down to standing, impact parameter concentrations. Our study's contradiction may stem from sampler shortage and insufficient awareness among personnel about the necessity of rest and its impact on tests. Except for blood glucose, samplers often overlook the importance of fasting. Yet, many parameters, not just glucose, can change post-meal and with meal-to-sampling interval. Parameters such as Triglycerides; Cholesterol; Lactate dehydrogenase; Low-density lipoprotein; Phosphorus and Apo lipoproteins need a 12-hour fast. High-fat diets causing milky serum/plasma can disrupt analysis too.

Nonconformities related to equipment preparation:

Vacuum blood collection tubes that have exceeded their expiration date may have reduced vacuum, which can lead to drawing a blood volume lower than expected and result in an incorrect blood-to-additive ratio. Additionally, tubes with expired expiration dates can exhibit chemical deterioration of the additive [9]. All samplers had previously prepared the necessary equipment for the collection.

Nonconformities related to the collection procedure:

As per the World Health Organization (WHO), healthcare workers should use a mix of 2% Chlorhexidine gluconate and 70% isopropyl alcohol. This should be applied over the entire skin for 30 seconds. Alternatively, they can use 70% alcohol for 30 seconds followed by Povidone Iodine/Chlorhexidine. Hand sanitizers are

WHO's preferred method for routine hand antisepsis before and after sampling [10]. Gloves should be changed between patients, blood contact, and contaminated sites [10]. Selecting the right vein and insertion site is vital to quality, patient comfort, avoiding injuries, and achieving success in blood collection. Failed venipuncture can lead to severe injuries [9].

Gloves used as tourniquets do not notably affect collection quality, aligning with traditional tourniquet criteria. Placed about a hand's width (7.5 cm) above the site, it should halt venous but not arterial flow [9]. For under 1 minute, tourniquet impact is minor [3]. Beyond that, certain analytes concentrations rise due to fluid leakage and small molecules. Muscle contraction during tourniquet use also elevates potassium levels [8, 11].

The vacutainer system is currently recommended by all quality standards in clinical laboratory practice due to its numerous advantages, including direct tube filling, control of the blood quantity drawn based on the vacuum in the tube, prevention of hemolysis, and adherence to aseptic measures [12, 13].

As per World Health Organization (WHO) guidance, the order for filling collection tubes is citrate, serum, heparin, EDTA, and finally, sodium fluoride and potassium oxalate tubes [3]. Correct order prevents additive contamination between tubes [14]. Sample identification by the sampler at the patient's bedside prevents identity errors [14]. Inadequate mixing causes uneven anticoagulant distribution, forming clots. Overly vigorous shaking can cause hemolysis [15].

Nonconformities related to waste management:

During the study period, we observed that nearly 11% of prescription sheets and/or tubes were contaminated with blood: Nephrology (21%); Internal Medicine and Neonatology (13%); Adult Emergency (12%); Paediatrics (8%) and Central Laboratory and Visceral Surgery (3%). The disposal container was always available. 86% of the sample collectors recapped the needles before discarding: Visceral Surgery (97%); Neonatology (95%); Nephrology and Paediatrics (90%); Internal Medicine (89%); Adult Emergency (78%) and the Central Laboratory (68%). This contradicts the standard precautions of the blood exposure accident prevention organization in healthcare facilities (GERES) [16].

Our recommendations for corrective and preventive actions:

- Implement a systematic approach to record and classify nonconformities within the organization. Establish a centralized system for documentation, including date; time; location; personnel involved and detailed descriptions. Introduce a classification system to categorize nonconformities, enabling a clear understanding of their nature. This systematic recording and classification process provide a foundation for effective analysis and management, facilitating corrective and preventive actions to address issues promptly and contribute to continuous improvement.
- Train designated quality focal points to effectively communicate and instil awareness of the standard's requirements among staff. The training should encompass key elements of the standard; emphasize individual roles in compliance; equip focal points with strong communication skills; implement a feedback mechanism for ongoing support and clarification, fostering a culture of continuous improvement and

ensuring a cohesive, compliant work environment; establish a quality unit and appoint a quality manager whose role is to oversee the quality of the preanalytical phase of biological tests.

- Conduct systematic internal audits to evaluate ISO 15189 compliance. Trained auditors to assess procedures, documentation, and practices regularly, identifying areas for improvement. Implement corrective actions to ensure ongoing adherence, fostering a culture of quality within the medical laboratory operations.
- Ensure healthcare units are adequately supplied with the necessary collection and transportation materials to enhance patient care. This involves providing sufficient resources such as specimen collection kits, transportation containers, and related materials. By ensuring these supplies are readily available, healthcare units can streamline their processes, improve efficiency, and maintain high standards of patient care. This proactive approach contributes to the overall effectiveness and smooth functioning of healthcare services.

Establish a comprehensive manual for validated biological sample collections, approved by the laboratory's chief physician, and regularly update a list of available laboratory tests. This manual serves as a standardized guide for the collection of biological samples, ensuring accuracy and consistency in procedures. Simultaneously, maintaining an up-to-date list of laboratory tests enhances communication and accessibility for healthcare professionals. Regular updates to these resources ensure that the latest protocols and test offerings are readily available, promoting efficiency and adherence to quality standards within the laboratory setting.

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# تقييم شامل للمرحلة القبلية في الطب المختبري، وعلم الكلى، والتخصصات الطارئة، وجراحة الأعضاء الداخلية، وعلم الأطفال، والطب الداخلي، وأقسام مستشفيات حديثي الولادة: رؤى عميقة مستمدة من تحليل الممارسات في مركز جامعي طبي في المغرب

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**الملخص**

**الخلفية والأهداف :** دقة نتائج الفحص البيولوجي تعتمد على التدابير التحضيرية الدقيقة قبل القيام بالتحليل، المعروفة بالمرحلة القبلية للتحليل. تسهم هذه المرحلة بشكل كبير في معدلات الأخطاء (48–68%). قامت دراستنا بتقييم المرحلة القبلية للتحليل في سبعة أقسام مستشفى جامعة محمد السادس. كان الهدف من ذلك هو التعامل مع الأسباب الرئيسية لعدم الامتثال في المرحلة القبلية للتحليل

**منهجية الدراسة:** خلال هذا الاستقصاء، قمنا بمراقبة 331 عينة من مختلف الأقسام: المختبر المركزي، وعلم الكلى، والطب الداخلي، وجراحة الأعضاء الداخلية، والتخصصات الطارئة، وعلم الأطفال، وحديثي الولادة. قامت تقييماتنا بتحديد 4945 حالة من عدم الامتثال في المرحلة القبلية للتحليل. شملت هذه الحالات مشاكل في ورقة الوصفة الطبية (501)، تحضير المريض (848)، تحضير الأجهزة (295)، عملية الأخذ من العينة (1957)، إدارة النفايات (323)، ونقل العينة(422)

**النتائج:** أظهر تحليلنا وجود العديد من حالات عدم الامتثال في المرحلة القبلية للتحليل داخل أقسام المستشفى التي تم فحصها. ألقت هذه الاختلافات الضوء على المجالات الحرجة حيث كانت الإجراءات التصحيحية والوقائية ضرورية للالتزام بالمعايير المعتمدة في المواصفة القياسية الدولية

**الاستنتاجات:** تؤكد نتائج هذه الدراسة على أهمية قصوى للمرحلة القبل التحليلية في ضمان الحصول على نتائج فحص بيولوجي دقيقة. من خلال تنفيذ سلسلة من الإجراءات المستهدفة في الأقسام الطبية المعنية، تم التعامل مع عدم المطابقة المحددة. شملت هذه الإجراءات التعليم المستمر، وتوعية ودعم العاملين، والتدقيقات الدورية، وتوفير الموارد التقنية مثل الدلائل وكتالوجات العينات، واستخدام معدات مناسبة لجمع ونقل العينات. يظل التعلم المستمر أمرًا أساسيًا، مشمولًا تقنيات الأخذ من العينات الصحيحة، ومتطلبات التعبئة والنقل، وكذلك إجراءات تحديد وتصحيح عدم المطابقة في العينات البيولوجية

**الكلمات الدالة:** المرحلة القبل التحليلية، رعاية المريض، أقسام المستشفى، عدم المطابقة، إدارة الجودة.