OPEN ACCESS

Check for updates

Original Article

Pre-Analytical non-conformities in the clinical biology laboratory of the university clinics of Kinshasa, Democratic Republic Of Congo: A cross-sectional assessment of compliance with quality standards.

Muembia Kasomboyi Paulin, Muamba Kalombo Donat, Cyanga Ngandu Placide, Sita Luemba Louange, Ilunga N-Tita Gustave, Tshibuela Beya Dophie, Pambu Pholo Dahlia & Muwonga Masidi Jérémie

Department of Clinical Biology, University Hospital of Kinshasa, Kinshasa, Democratic Republic of the Congo.

DOI: https://doi.org/10.29052/IJEHSR.v14.i2.2026.77-83

ISSN (P): 2307-3748
ISSN (E): 2310 -3841

Citation:
Paulin MK, et al. Pre-Analytical non-conformities in the clinical biology laboratory of the university clinics of Kinshasa, Democratic Republic Of Congo: A cross-sectional assessment of compliance with quality standards. Int. j. endorsing health sci. res. 2026;14(2):77-83.

Corresponding Author Email:
mobetimuamba@gmail.com

Funding:
The authors received no external funding for this study.

Conflicts of Interests:
The authors have declared that no competing interests exist.

Data Sharing Statement:
The data that support the findings of this study are available on request from the corresponding author. The data is not publicly available due to privacy or ethical restrictions.

Received 22/12/2025
Accepted 19/03/2026
First Published 01/06/2026

Abstract

Background:
Laboratory test reliability depends on quality standards across the pre-analytical, analytical, and post-analytical phases. The pre-analytical phase is the most error-prone, covering procedures from test prescription and patient preparation to specimen collection, transport, and processing. This study evaluated pre-analytical non-conformities and compliance with laboratory quality requirements at the Clinical Biology Laboratory of the University Clinics of Kinshasa, Democratic Republic of the Congo.

Methodology:
A descriptive cross-sectional study was conducted from June to August 2025 at the Clinical Biology Laboratory of the University Clinics of Kinshasa. A total of 392 pre-analytical observations were assessed using a standardized form based on ISO 15189 requirements and World Health Organization recommendations. Compliance was evaluated across six domains: beneficiary information, prescriber identification, patient identification, specimen collection, specimen transportation, and biosafety. Data were analyzed using descriptive statistics, with proportions reported using 95% confidence intervals.

Results:
All beneficiary information requirements showed complete non-compliance, including patient information materials, laboratory operating procedures, and communication about laboratory services. High compliance was observed for prescriber qualification and date of request (95.4% each), patient sex documentation (97.4%), appropriate tube selection, and patient-specimen identification (100%). Major deficiencies were found in clinical information documentation (3.8%), patient preparation before collection (12.0%), specimen protection from light during transport (31.4%), and hand hygiene before and after glove use (0.8% and 15.6%, respectively). Appropriate transport equipment and temperature-controlled transportation were absent in all cases.

Conclusion:
The study identified substantial non-conformities throughout the pre-analytical phase, particularly in beneficiary information, documentation practices, specimen transportation, and biosafety procedures. These findings highlight the need for strengthened implementation of ISO 15189 quality management requirements, staff training, and continuous monitoring to improve laboratory performance and ensure the reliability of diagnostic results.

Keywords:
Pre-Analytical Phase, Non-Conformities, Laboratory Quality, ISO 15189, Biosafety, Clinical Biology Laboratory, Democratic Republic Of Congo.

Introduction

Medical biology laboratories play a central role in modern healthcare systems by providing essential information for disease diagnosis, therapeutic monitoring, prognosis assessment, and public health surveillance. Advances in laboratory medicine and the growing demand for diagnostic testing have further strengthened the importance of ensuring the accuracy, reliability, and timeliness of laboratory results. Consequently, laboratory quality management has become a fundamental requirement for patient safety and effective clinical decision-making [1].

The process of laboratory testing consists of three interdependent phases: the pre-analytical phase, the analytical phase, and the post-analytical phase. The reliability of laboratory results depends on the proper execution of each of these phases according to internationally recognized quality standards, particularly ISO 15189 requirements for medical laboratories [1,2]. Errors occurring at any stage may compromise the quality of results and potentially lead to inappropriate clinical decisions.

Among these three phases, the pre-analytical phase has consistently been identified as the most error-prone component of the laboratory testing process [3–5]. This phase includes all procedures performed before specimen analysis, beginning with test prescription and patient preparation and extending through specimen collection, labeling, transportation, storage, and preparation for analytical testing. It represents approximately 58% of the total laboratory process, with nearly 20% occurring outside the laboratory and 38% occurring within laboratory facilities. Studies have shown that between 60% and 85% of all laboratory errors originate during this phase [6].

Several investigations conducted worldwide have demonstrated the critical impact of pre-analytical non-conformities on laboratory quality. Wiwanitkit reported that approximately 85% of laboratory non-conformities originated during the pre-analytical phase, whereas only 4% and 11% occurred during the analytical and post-analytical phases, respectively [7,8]. Similarly, Kadour Djobo et al. identified significant deficiencies in the completion of laboratory request forms in Niger, particularly regarding documentation of specimen collection date, sampling time, and specimen type, resulting in widespread non-compliance with quality requirements [9].

Accurate completion of laboratory request forms constitutes a critical component of the pre-analytical phase. In Nepal, Gyawali et al. reported that 61.39% of laboratory request forms lacked information regarding the requesting department [10]. Such omissions may impede communication between clinicians and laboratory personnel, delay result reporting, and compromise the investigation of laboratory errors. Furthermore, inadequate patient identification and insufficient clinical information may adversely affect result interpretation and diagnostic accuracy [4,11].

The consequences of pre-analytical non-conformities extend beyond administrative deficiencies. Studies have demonstrated that errors occurring during specimen collection, handling, transportation, and preparation can alter specimen quality and invalidate analytical results [2,8]. Factors such as prolonged tourniquet application, inadequate patient preparation, inappropriate transport conditions, and insufficient biosafety practices have all been associated with compromised laboratory performance and increased risk of diagnostic error [8,9].

To address these challenges, international standards and national guidelines have established specific requirements for quality assurance during the pre-analytical phase. The ISO 15189 standard and the Guide to Good Execution of Medical Biology Analyses (GBEA) developed by the Ministry of Public Health of the Democratic Republic of Congo emphasize the responsibility of laboratory personnel to maintain quality throughout all stages of laboratory testing [6,11,12].

Despite the recognized importance of the pre-analytical phase, limited evidence is available regarding the extent of pre-analytical non-conformities in clinical laboratories within the Democratic Republic of Congo. Understanding the nature and frequency of these deficiencies is essential for implementing targeted quality improvement interventions and strengthening laboratory performance.

Therefore, the present study aimed to evaluate pre-analytical non-conformities and assess compliance with established quality standards at the Clinical Biology Laboratory of the University Clinics of Kinshasa. The findings are expected to provide evidence for improving laboratory quality management practices and enhancing the reliability of diagnostic services within the institution.

Methodology

Study Design

This study employed a descriptive cross-sectional design to evaluate pre-analytical non-conformities occurring within the Clinical Biology Laboratory of the University Clinics of Kinshasa (CUK), Democratic Republic of Congo. The study was conducted prospectively over a three-month period from June to August 2025. The objective was to assess compliance with internationally recognized quality standards governing the pre-analytical phase of laboratory testing, particularly those outlined in ISO 15189 and the Guide to Good Execution of Medical Biology Analyses (GBEA). The unit of analysis consisted of individual laboratory request forms, sample collection procedures, specimen transport activities, and biosafety practices observed during routine laboratory operations.

Ethics

The study protocol was reviewed and approved by the Ethics Committee of the School of Public Health, Kinshasa, under approval number ESP/CE/115/2024. Administrative authorization was obtained from the management of the University Clinics of Kinshasa before data collection commenced. The study involved observation of routine laboratory practices and assessment of laboratory documentation without interfering with patient care. All collected information was handled confidentially, and no personal identifiers were recorded in the study database.

Setting

The study was conducted at the Clinical Biology Laboratory of the University Clinics of Kinshasa (CUK), a tertiary-level teaching hospital that provides laboratory diagnostic services to both hospitalized and ambulatory patients. The laboratory performs a wide range of clinical analyses and serves multiple clinical departments within the institution. The pre-analytical phase evaluated in this study included activities related to test prescription, patient identification, sample collection, biosafety practices, specimen transport, and sample processing prior to analytical testing.

Participants

The study population consisted of all observations related to the pre-analytical phase of laboratory testing performed during the study

period. Eligible observations included biological test request forms, sample collection procedures, specimen transport processes, and biosafety practices observed within the Clinical Biology Laboratory. Inclusion criteria comprised all pre-analytical activities related to test prescription, patient identification, specimen collection, transportation, and handling performed during the study period. Analytical and post-analytical non-conformities were excluded from the study. A total of 392 observations were included in the final analysis.

Variables

The primary outcome variables were the presence or absence of pre-analytical non-conformities. Variables were categorized into five domains: beneficiary information, prescriber information, patient identification information, specimen collection practices, specimen transportation conditions, and biosafety measures. Each variable was classified as either compliant or non-compliant according to predefined criteria derived from ISO 15189 requirements and WHO recommendations concerning laboratory quality management. Compliance was defined as the presence, completeness, and correctness of required information or procedures according to established standards. Non-compliance was defined as the absence, inadequacy, incorrect execution, or omission of any required element. Missing documentation was considered a non-conformity in accordance with ISO 15189 quality requirements.

Data Sources / Measurement

Data were collected using a structured observation and assessment form specifically developed from ISO 15189 standards, WHO recommendations, and national guidelines governing laboratory quality assurance. Prior to data collection, all investigators received standardized training regarding study procedures, observation methods, definitions of non-conformities, and completion of the survey instrument. Systematic random sampling was employed. At the sample collection unit, every third eligible observation was selected for inclusion. Following the first selected observation, subsequent observations were selected at regular intervals (3, 6, 9, 12, etc.) throughout the study period. Each selected observation was assessed using the same standardized data collection instrument. Data collection involved direct observation of laboratory personnel from the initiation of specimen collection until specimen transfer to the analytical section. Information recorded included the source of the sample, completeness of laboratory request forms, compliance with patient identification procedures, adherence to sample collection protocols, transport conditions, biosafety measures, and preparation of primary specimens for analysis. All observations were documented immediately after completion of the procedure to minimize recording errors.

Bias

Several measures were implemented to reduce potential sources of bias. Selection bias was minimized through the use of systematic random sampling. Information bias was reduced by employing a standardized data collection instrument based on internationally recognized standards. Observer bias was minimized through investigator training and the use of predefined operational definitions for all study variables. To ensure consistency, all investigators followed identical observation procedures and recorded data using the same survey form. Nevertheless, because observations were conducted in a single institution, some degree of institutional bias may remain and should be considered when interpreting the findings.

Study Size

The minimum sample size was calculated using the standard formula for estimating a population proportion in descriptive studies: $n = Z^2P(1-P)/d^2$, where n represents the required sample size, Z is the standard normal deviate corresponding to a 95% confidence level (1.96), P is the estimated prevalence of the characteristic of interest (0.50 in the absence of prior local data), and d is the desired margin of error (0.05). The calculation yielded a minimum sample size of 384 observations. To ensure adequate statistical precision, a total of 392 observations were ultimately included in the study.

Quantitative Variables

Most study variables were categorical and were recorded as binary outcomes (compliant or non-compliant). Quantitative summaries were generated by calculating frequencies, percentages, and corresponding 95% confidence intervals. The prevalence of each type of pre-analytical non-conformity was estimated as the proportion of observations demonstrating non-compliance relative to the total number of observations assessed.

Statistical Methods

Data were entered into Microsoft Excel 2016 and subsequently analyzed using SPSS version 25. Descriptive statistical analyses were performed to summarize the frequency and distribution of pre-analytical non-conformities. Categorical variables were presented as frequencies and percentages. For each observed proportion, 95% confidence intervals (95% CI) were calculated to estimate the precision of the findings. Results were organized according to the principal components of the pre-analytical phase, including beneficiary information, prescriber information, patient identification, specimen collection practices, transportation conditions, and biosafety measures. Given the descriptive nature of the study, no multivariable analyses were performed. Statistical findings were interpreted in accordance with ISO 15189 quality management requirements and WHO recommendations for laboratory practice.

Results

Participants

A total of 392 observations of the pre-analytical phase were included in the study and analyzed. These observations comprised laboratory request forms, specimen collection procedures, transportation practices, and biosafety measures performed at the Clinical Biology Laboratory of the University Clinics of Kinshasa during the study period. All selected observations met the eligibility criteria and were included in the final analysis. No observations were excluded after data collection.

Descriptive data

The evaluation of pre-analytical practices covered multiple domains including information provided to beneficiaries, prescriber identification, patient identification, specimen collection procedures, specimen transportation, and biosafety measures. Assessment of beneficiary information revealed a complete absence of all evaluated informational elements. No documentation regarding laboratory services, patient preparation requirements, specimen transport instructions, turnaround times, confidentiality procedures, or complaint management mechanisms was available to beneficiaries, resulting in a non-compliance rate of 100% for all assessed variables (Table 1). Regarding prescriber identification, the highest compliance rates were observed for the prescriber's title or qualification and the date of request, each present in 95.4% of request forms. Similarly, prescriber signatures were available in 94.1% of forms. However,

important deficiencies were observed for prescriber contact information, including telephone numbers and email addresses, which were absent in all forms reviewed. The prescriber's full name and official stamp were also incompletely documented in a substantial proportion of requests (Table 2). Patient identification information demonstrated variable levels of compliance. Patient sex and age/date of birth were documented in 97.4% and 86.5% of request forms, respectively, while the patient's full name was available in 73.5% of forms. In contrast, information such as address, occupation, marital status, telephone number, and email address was absent from all request forms. Clinical information necessary for appropriate interpretation of laboratory findings was recorded in only 3.8% of requests (Table 3).

Outcome data

Evaluation of specimen collection practices demonstrated generally high compliance with several technical requirements of the pre-analytical phase. Complete compliance was observed for concordance between requested analyses and collection tubes, adherence to recommended sampling times, appropriate order of tube filling, tube homogenization procedures, tube identification, and agreement between patient identity on the specimen tube and the request form. Compliance rates exceeding 99% were also observed for maintenance of the blood-to-anticoagulant ratio and collection of sufficient specimen volume (Table 4). Nevertheless, notable deficiencies remained. Patient preparation prior to specimen collection was adequately performed in only 12.0% of observations, while compliance with the recommended tourniquet application time of less than one minute was observed in 83.2% of cases. Double identification of specimen tubes was not performed in any observation (Table 4). With respect to specimen transportation, transmission forms accompanied specimens in 95.7% of cases and transport timelines were respected in 89.8% of observations. However, no dedicated transport equipment or temperature-controlled transport procedures were available. Furthermore, only 31.4% of light-sensitive specimens were adequately protected from light exposure during transport (Table 5). Assessment of biosafety practices demonstrated high compliance with glove use (98.5%), biomedical waste segregation (91.3%), and availability of appropriate biomedical waste containers (100%). Conversely, hand hygiene practices were poorly implemented, with handwashing before glove use observed in only 0.8% of procedures and handwashing after glove removal observed in 15.6% of procedures. In addition, blood contamination of specimen tubes was noted in 75.5% of observations (Table 6).

Main results

The findings of this study reveal substantial deficiencies throughout the pre-analytical phase of laboratory testing at the Clinical Biology Laboratory of the University Clinics of Kinshasa. The most critical non-conformities were observed in beneficiary information, where all evaluated informational requirements were absent (Table 1). Similarly, major deficiencies were identified in the documentation of prescriber and patient information, particularly regarding communication details and relevant clinical information necessary for appropriate interpretation of laboratory results (Tables 2 and 3). Although specimen collection procedures demonstrated high compliance with several technical aspects, significant weaknesses persisted in patient preparation and specimen identification practices (Table 4). Transportation processes were compromised by the absence of appropriate transport equipment and temperature control measures, potentially affecting specimen integrity before analysis (Table 5). Biosafety assessment revealed a concerning pattern characterized by poor adherence to hand hygiene recommendations despite widespread glove use (Table 6). The high frequency of blood-contaminated tubes further suggests deficiencies in infection prevention and specimen handling practices. The study demonstrates that non-conformities were present across all components of the pre-analytical process, with the greatest deficiencies affecting patient information systems, documentation practices, transport conditions, and biosafety measures. These findings indicate substantial opportunities for quality improvement and reinforce the need for strengthened implementation of ISO 15189 and laboratory quality management standards within the institution.

Table 1: Compliance of Pre-Analytical Information Available to Beneficiaries at the Clinical Biology Laboratory (n = 392).

Variables	Non-Compliant n (%)	Compliant n (%)
Informational document available to beneficiaries	392 (100.0)	0 (0.0)
Laboratory working hours displayed	392 (100.0)	0 (0.0)
List of laboratory tests available	392 (100.0)	0 (0.0)
Sample-specific requirements available	392 (100.0)	0 (0.0)
Patient preparation instructions available	392 (100.0)	0 (0.0)
Patient transport instructions available	392 (100.0)	0 (0.0)
Clinical advice regarding test ordering and interpretation available	392 (100.0)	0 (0.0)
Consent requirements for invasive procedures available	392 (100.0)	0 (0.0)
Turnaround time information available	392 (100.0)	0 (0.0)
Privacy and confidentiality information available	392 (100.0)	0 (0.0)
Information on factors affecting test results available	392 (100.0)	0 (0.0)
Complaint procedures available	392 (100.0)	0 (0.0)
Other relevant beneficiary information available	392 (100.0)	0 (0.0)

Table 2: Compliance of Prescriber Identification Information on Laboratory Request Forms (n = 392).

Variables	Non-Compliant n (%)	Compliant n (%)	95% CI
Full name	167 (42.6)	225 (57.4)	52.5–62.2
Title/Qualification	18 (4.6)	374 (95.4)	92.9–97.1
Contact number	392 (100.0)	0 (0.0)	0.0–1.0

E-mail address	392 (100.0)	0 (0.0)	0.0–1.0
Service address	87 (22.2)	305 (77.8)	73.4–81.6
Signature	23 (5.9)	369 (94.1)	91.3–96.1
Official stamp	302 (77.0)	90 (23.0)	19.1–27.4
Date of request	18 (4.6)	374 (95.4)	92.9–97.1
Legible information	392 (100.0)	0 (0.0)	0.0–1.0

Table 3: Compliance of Patient Identification Information on Laboratory Request Forms (n = 392).

Variables	Non-Compliant n (%)	Compliant n (%)	95% CI
Full name	103 (26.3)	288 (73.5)	68.9–77.6
Date of birth/Age	53 (13.5)	339 (86.5)	82.8–89.4
Sex	10 (2.6)	382 (97.4)	95.3–98.6
Address	392 (100.0)	0 (0.0)	0.0–1.0
Occupation	392 (100.0)	0 (0.0)	0.0–1.0
Marital status	392 (100.0)	0 (0.0)	0.0–1.0
Contact number	392 (100.0)	0 (0.0)	0.0–1.0
E-mail address	392 (100.0)	0 (0.0)	0.0–1.0
Clinical information	377 (96.2)	15 (3.8)	2.3–6.2
Legible information	392 (100.0)	0 (0.0)	0.0–1.0

Table 4: Compliance of Sample Collection Procedures During the Pre-Analytical Phase (n = 392).

Variables	Non-Compliant n (%)	Compliant n (%)	95% CI
Sampling equipment prepared	33 (8.4)	359 (91.6)	88.4–93.9
Patient preparation adequate	345 (88.0)	47 (12.0)	9.2–15.6
Appropriate tube used	0 (0.0)	392 (100.0)	99.0–100.0
Appropriate sampling time	0 (0.0)	392 (100.0)	99.0–100.0
Tourniquet application <1 minute	66 (16.8)	326 (83.2)	79.2–86.6
Correct order of tube filling	0 (0.0)	392 (100.0)	99.0–100.0
Proper tube homogenization	0 (0.0)	392 (100.0)	99.0–100.0
Correct tube identification	0 (0.0)	392 (100.0)	99.0–100.0
Double tube identification	392 (100.0)	0 (0.0)	0.0–1.0
Identity match between tube and request form	0 (0.0)	392 (100.0)	99.0–100.0
Blood/anticoagulant ratio respected	1 (0.3)	391 (99.7)	98.6–99.9
Adequate sample volume	1 (0.3)	391 (99.7)	98.6–99.9
Clotted sample absent	392 (100.0)	0 (0.0)	0.0–1.0
Hemolyzed sample absent	392 (100.0)	0 (0.0)	0.0–1.0

Table 5: Compliance of Specimen Transportation Conditions During the Pre-Analytical Phase (n = 392).

Variables	Non-Compliant n (%)	Compliant n (%)	95% CI
Compliance with transport deadline	40 (10.2)	352 (89.8)	86.4–92.4
Appropriate transport equipment available	392 (100.0)	0 (0.0)	0.0–1.0
Appropriate transport temperature maintained	392 (100.0)	0 (0.0)	0.0–1.0
Samples protected from light	269 (68.6)	123 (31.4)	27.0–36.2
Sample transmission form available	17 (4.3)	375 (95.7)	93.3–97.3

Table 6: Compliance with Biosafety and Biomedical Waste Management Practices During the Pre-Analytical Phase (n = 392).

Variables	Non-Compliant n (%)	Compliant n (%)	95% CI
Hand washing before glove use	389 (99.2)	3 (0.8)	0.3–2.2
Appropriate glove use	6 (1.5)	386 (98.5)	96.7–99.3
Blood-free specimen tubes	296 (75.5)	96 (24.5)	20.5–29.0
Hand washing after glove removal	331 (84.4)	61 (15.6)	12.3–19.5
Proper biomedical waste segregation	34 (8.7)	358 (91.3)	88.1–93.7
Availability of biomedical waste containers	0 (0.0)	392 (100.0)	99.0–100.0

Discussion

The present study evaluated compliance with pre-analytical quality requirements at the Clinical Biology Laboratory of the University Clinics of Kinshasa and identified substantial non-conformities across several components of the pre-analytical process. Although high compliance was observed for certain technical aspects of specimen collection, important deficiencies were identified in beneficiary information, documentation practices, specimen transportation, and biosafety measures. Given that the pre-analytical phase accounts for the majority of laboratory errors, these findings have important implications for the reliability of laboratory results and patient safety.

One of the most striking findings of this study was the complete absence of beneficiary information, with all evaluated parameters demonstrating a non-compliance rate of 100%. Information concerning laboratory services, patient preparation requirements, specimen transport conditions, turnaround times, confidentiality procedures, and complaint mechanisms was unavailable. These findings suggest the absence of a structured communication system between the laboratory and its users. Similar deficiencies have been reported in resource-limited settings where laboratory quality management systems remain underdeveloped [12,13]. Providing adequate information to patients and healthcare providers is an important requirement of ISO 15189 because it contributes to proper patient preparation, improves specimen quality, and enhances user satisfaction. The absence of such information may increase the risk of inappropriate sample collection, delays in diagnosis, and reduced confidence in laboratory services [1,11].

The evaluation of prescriber identification revealed satisfactory compliance regarding professional qualification, request date, and signature. However, critical deficiencies were observed concerning the documentation of contact information and official stamps. The absence of telephone numbers and email addresses in all request forms may hinder effective communication between laboratory personnel and clinicians when clarification of test requests or urgent reporting of critical results is required.

Our findings are consistent with those reported by BELDJILALI et al. and Aroubouna et al., who also identified deficiencies in prescriber identification and documentation practices [2,13]. Inadequate completion of request forms may compromise traceability and reduce the laboratory's ability to investigate non-conformities, thereby negatively affecting quality assurance activities.

Accurate patient identification is fundamental to laboratory quality and patient safety. In the present study, compliance was high for patient sex and age documentation but considerably lower for clinical information. Furthermore, several important variables, including address, occupation, marital status, and contact details, were absent from all request forms.

The very low availability of clinical information (3.8%) is particularly concerning because appropriate interpretation of laboratory results often requires knowledge of the patient's clinical condition. Similar observations have been reported in studies conducted in Mali, Nigeria, Ghana, and Tunisia, where incomplete request forms represented a major source of pre-analytical errors [14–18]. The absence of relevant clinical information may result in delayed interpretation, unnecessary repeat testing, and difficulties in identifying potential analytical interferences. Strengthening collaboration between clinicians and laboratory professionals could improve the quality and completeness of laboratory requests.

The study demonstrated excellent compliance with several technical aspects of specimen collection, including correct tube selection, adherence to the recommended order of draw, proper specimen identification, and maintenance of appropriate blood-to-anticoagulant ratios. These findings indicate that laboratory personnel generally possess adequate technical competence regarding specimen collection procedures.

However, compliance with patient preparation requirements was low, and approximately one-sixth of observations failed to comply with the recommended tourniquet application time. Similar findings have been reported by Aroubouna et al. and Bachir Ali, who highlighted prolonged tourniquet application as a common source of pre-analytical error [2,14].

Prolonged venous stasis caused by excessive tourniquet application may alter the concentration of several biochemical parameters, potentially affecting the validity of laboratory results [19]. Consequently, continuous professional training and periodic competency assessments remain essential to ensure adherence to recommended sampling procedures.

Specimen transportation represents a critical but often neglected component of the pre-analytical phase. In the present study, satisfactory compliance was observed regarding transport timelines and the availability of transmission forms. Nevertheless, no appropriate transport equipment or temperature-controlled transportation systems were identified, and protection of light-sensitive samples was inadequate.

These findings suggest weaknesses in specimen preservation during transportation, which may affect the stability of analytes and compromise result accuracy. Similar transportation-related deficiencies have been reported in previous studies conducted in Mali and other African settings [2,14,18]. Improving transport infrastructure, implementing temperature monitoring systems, and developing standardized transport protocols could substantially enhance specimen quality and laboratory performance.

Although glove use and biomedical waste management demonstrated high compliance, major deficiencies were observed regarding hand hygiene practices. Handwashing before glove use and after glove removal was rarely performed, and a substantial proportion of specimen tubes were contaminated with blood. These findings raise concerns regarding occupational safety and infection prevention practices. Proper hand hygiene remains one of the most effective measures for preventing healthcare-associated infections and protecting both healthcare workers and patients. Similar shortcomings have been documented in previous studies evaluating laboratory biosafety practices in low-resource environments [2,14]. Strengthening infection prevention and control training, implementing routine supervision, and promoting a culture of safety may improve compliance with biosafety standards and reduce the risk of laboratory-acquired infections.

The findings of this study highlight the need for a comprehensive quality improvement strategy within the Clinical Biology Laboratory of the University Clinics of Kinshasa. Priority areas should include standardization of laboratory request forms, strengthening clinician–laboratory communication, improving patient information systems, enhancing specimen transportation procedures, and reinforcing biosafety practices. Regular internal audits, staff training, and implementation of ISO 15189 quality management requirements may

contribute substantially to reducing pre-analytical errors and improving the reliability of laboratory services [1,11].

Limitations

Several limitations should be considered when interpreting the findings. First, the study was conducted in a single tertiary-care laboratory, which may limit the generalizability of the results to other healthcare facilities within the Democratic Republic of Congo. Second, the cross-sectional design provides a snapshot of practices during the study period and does not permit assessment of temporal variations or causal relationships. Third, some observations may have been influenced by the Hawthorne effect, whereby laboratory personnel modify their behavior because they are aware of being observed. Finally, the study focused exclusively on the pre-analytical phase and did not evaluate how the identified non-conformities influenced analytical performance, post-analytical processes, or patient outcomes.

Conclusion

The present study revealed significant deficiencies in the pre-analytical phase of laboratory testing at the Clinical Biology Laboratory of the University Clinics of Kinshasa. Major non-conformities were identified in beneficiary information, completion of laboratory request forms, documentation of clinical information, specimen transportation practices, and biosafety measures. Although several technical aspects of specimen collection demonstrated satisfactory compliance, weaknesses in communication, documentation, transport infrastructure, and infection prevention practices remain important challenges. Given the critical role of the pre-analytical phase in ensuring the reliability of laboratory results, these deficiencies may adversely affect diagnostic accuracy, laboratory efficiency, and patient safety. Strengthening quality management systems through implementation of ISO 15189 requirements, continuous professional training, regular quality audits, and standardized operating procedures is essential to reduce pre-analytical errors and improve laboratory performance.

Acknowledgement

The authors would like to express their sincere gratitude to all the staff members of the Clinical Biology Department of the University Clinics of Kinshasa for their cooperation, support, and active participation during the conduct of this study. Their assistance in facilitating data collection and providing access to laboratory activities was invaluable to the successful completion of this research. The authors also acknowledge the administrative authorities of the University Clinics of Kinshasa for granting permission to conduct this study.

References

1. Ruchet I. Pre-analytical laboratory: how to avoid the pitfalls. Medical Tribune. 2008. Available from: http://www.medical-tribune.ch
2. Aroubouna AABM. Pre-analytical non-conformities in the biomedical analysis laboratory of the Hospital of Mali [specialization thesis]. Bamako: University of Sciences, Techniques and Technologies of Bamako; 2020.
3. Ateba GN, et al. Evaluation of pre-analytical practices in biomedical laboratories in Yaoundé. Health Sci. 2014;1:1.
4. Nutt L, Zemlin AE, Erasmus RT. Incomplete laboratory request forms: the extent and impact on critical results at a tertiary hospital in South Africa. Ann Clin Biochem. 2008;45(5):463-466.
5. Maurellet-Evrard S, Daunizeau A, et al. Recommendations for the evaluation and monitoring of quality management in medical biology laboratories. Ann Biol Clin (Paris). 2013;(Special Issue 1):147-176.
6. Democratic Republic of Congo Ministry of Public Health, Directorate of Laboratories. Guide to the proper execution of medical biology analyses. Kinshasa: Ministry of Public Health; 2012.
7. Linsuke S, Nabazungu G, Ilombe G, Ahuka S, Muyembe JJ, Lutumba P. Laboratoires médicaux et qualité des soins: la partie la plus négligée au niveau des hôpitaux ruraux de la République Démocratique du Congo. Pan Afr Med J. 2020;35:22. doi:10.11604/pamj.2020.35.22.18755.
8. Wiwanitkit V. Types and frequency of preanalytical mistakes in the first Thai ISO 9002:1994 certified clinical laboratory: a 6-month monitoring. BMC Clin Pathol. 2001;1:5. doi:10.1186/1472-6890-1-5.
9. Djobo K, Yacouba A, Alhousseini D, Soumana BM, Chaibou S, Boutchi M, et al. Analyse multicentrique de la qualité rédactionnelle des bulletins d'analyses biologiques au Niger. Pan Afr Med J. 2022;43:59. doi:10.11604/pamj.2022.43.59.36896.
10. Gyawali P, et al. Incomplete laboratory requisition forms: an evaluation of documentation practices. JNAMLS. 2016.
11. Petti CA, Polage CR, Quinn TC, et al. Laboratory medicine in Africa: a barrier to effective health care. Clin Infect Dis. 2006;42(3):377-382.
12. Nkengasong JN, Yao K, Onyebujoh P. Laboratory medicine in low-income and middle-income countries: progress and challenges. Lancet. 2018;391(10133):1873-1875.
13. Beldjilali S, Betaouaf H. Management of non-conformities in the pre-analytical phase in immunohematology at the Tlemcen University Hospital [thesis]. Tlemcen: University of Tlemcen; 2018.
14. Bachir A. Non-conformities of the pre-analytical phase in the biology and pathology laboratory of the Hospital of Mali [doctoral thesis]. Bamako: Hospital of Mali; 2023.
15. Schauer R, Kamerling JP. Chemistry, biochemistry and biology of sialic acids. New Compr Biochem. 1997;29:243-402.
16. Olayemi E, Asiamah-Broni R. Evaluation of request forms submitted to the haematology laboratory in a Ghanaian tertiary hospital. Pan Afr Med J. 2011;8:33.
17. Oladeinde BH, Omoregie R, Osakue EO, Onifade AA. Evaluation of laboratory request forms for incomplete data at a rural tertiary hospital in Nigeria. N Z J Med Lab Sci. 2012;66(2):39-41.
18. Elargoubi A, Mastouri M, Najjar MF. Management of the pre-analytical phase: practical experience in the microbiology laboratory of Fattouma Bourguiba Hospital, Monastir. Ann Biol Clin (Paris). 2014;72(5):615-623. doi:10.1684/abc.2014.0992.
19. Drosdowsky S. Factors to be taken into account for blood sampling for the purpose of establishing reference values. 1980.
20. Schauer R, Kamerling JP. Chemistry, biochemistry and biology of sialic acids. New Compr Biochem. 1997;29:243-402.