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Determination of the Rate and Reasons of Blood Sample Rejection in the Pre-Analytical Phase in Ruhengeri, Rwanda: A Single Center Study

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ABSTRACT

Background and objectives: All three phases of laboratory testing are equally important for improving total quality management, but the pre-analytical phase is the most error-prone. This study aimed to determine the rate and reasons for blood sample rejection in the pre-analytical phase of laboratory testing in a referral hospital in Ruhengeri, Rwanda.

Methods: This study was a cross-sectional and retrospective study in which 222 samples with nonconformities were discovered from 19,775 clinical samples. Various data related to the rejected samples were recorded along with nonconformities.

Results: The rate of blood sample rejection was 1.045% and 1.165% for the cross-sectional and retrospective approaches, respectively. The overall blood sample rejection rate was 1.105%. The most frequent error in the cross-sectional aspect was mislabeling (38.3%), while clotting (46.4%) was the most common cause of sample rejection in the retrospective aspect.

Conclusion: Based on the results of our study, the rate of blood sample rejection is high in the study area. Thus, there should be a laboratory policy for error record keeping as well as a settlement in “laboratory sentinel events” covering the total testing process.

Keywords: Pre-Analytical Phase, Blood, Rwanda.

INTRODUCTION

Laboratory diagnostics is a fast-growing field, which substantially contributes to clinical decision-making by supporting the prevention, diagnosis, and therapeutic monitoring of most if not all, human disorders (1). Quality and safety in diagnostic testing are, however, essential for providing high-quality and safe healthcare, with no other discipline having such a prominent position in the patient safety solution than laboratory medicine. The whole process of testing a patient's blood from ordering, testing to reporting, and ultimately reaching the treating doctor can be divided into three broad steps (2).

Those steps are pre-analytical, analytical, and post-analytical phases. The pre-analytical phase comprises test selection, patient identification, sample collection, sample handling, sorting, pipetting, and centrifugation. Negligence in any of these steps can lead to erroneous results attributed to the pre-analytical phase (3).

In the total analytical process of clinical specimens, there are many possible pre-analytical sources of errors. Although every single biological fluid and tissue may be a representative sample for generating useful diagnostic and prognostic information, blood specimens are most widely used due to the simplicity of collection and the stability over time (4). Blood samples are associated with more pre-analytical errors than other clinical samples (5). Pre-analytical errors can occur both before and after receiving specimens in the laboratory. They have previously been shown to comprise a significant proportion (68.2%) of errors in laboratory processes (6).

The laboratory has no direct control of the pre-analytical phase. Factors that can affect errors in this phase include sample type, sampling time, sample handling, patient preparation, and the nutritional status of the patient (7).

The most common technical errors are unlabeled samples, clotted samples (EDTA and sodium citrate), diluted samples, incorrect medical record numbers, hemolyzed samples, inappropriate quantities, insufficient samples, and incorrect tubes. Biological errors are divided into uncontrollable factors such as age, gender, menopausal status, and disease state. Controllable factors such as circadian rhythm, menstrual cycle, food intake, and exercise can be minimized by standardizing the timing and conditions under which samples are taken (8).

Although all three phases are equally important for improving laboratory standards, the pre-analytical phase is the most error-prone. Lippi and colleagues reported that the total error rate in laboratory medicine is 0.1% to 3.0% (2).

Analytical errors account for less than 10% of all diagnostic mistakes, whereas pre-analytical errors account for 46-68.2% of all diagnostic mistakes. Moreover, pre-analytical errors constitute 18.5-47% of laboratory errors. Missing patient identification, inappropriate containers, and missing samples are the most commonly encountered pre-analytical errors (9).

The International Organization for Standardization (ISO 15189:2012 document) claims that necessary improvements and potential sources of nonconformities, either technical or concerning the quality management system, shall be systematically identified and corrected (3). The above standard deals with quality system requirements (i.e. quality indicators implementation) to be applied to the field of laboratory medicine, with a strong focus on patient safety. Nevertheless, compliance with these guidelines is poor, especially at the sampling site where nurses or junior doctors operate in the absence of laboratory personnel (2). Furthermore, there is heterogeneity in the criteria for sample rejection from one laboratory to another. Given the research gap in the documentation, root cause analysis, and preventive strategies for laboratory errors in Rwanda (10, 11), this study aimed to evaluate the challenges in the pre-analytical phase and to establish the rate of blood sample nonconformity in a referral hospital in Rwanda.

MATERIALS AND METHODS

This research was conducted at the Ruhengeri Referral Hospital (RRH) in the Muhoza sector, Musanze district, Northern Province of Rwanda. The hospital admits approximately 3,400 patients a year and has 12 wards. This study had two approaches: a retrospective study in which patients' data from 1st June 2020 to 31st December 2020 were retrieved, and a cross-sectional study in which rejected samples from 1st January 2021 to 31st January 2021 were recorded. For both approaches, samples from all hospital wards were included

as long as they were to be tested in the hematology or clinical biochemistry services of the laboratory department. Overall, 188 out of 16,499 patients' blood samples were recorded with nonconformity from June to December 2020, and 34 out of 3,276 blood samples were rejected before analysis during January 2021. Out of 19,775 blood samples, 222 blood samples were associated with rejection issues and were considered as sample size. Exclusion criteria were as follows: insufficient samples, clotted samples, mislabeled samples, inappropriate tubes, hemolyzed samples, and samples without ID as well as wrong/mismatched ID.

The analysis of data was performed using IBM SPSS software (version 20.0). The data were described using descriptive statistics including frequency distributions and percentages. A *p*-value of less than 0.05 was considered statistically significant.

RESULTS

Of 222 samples, 100 samples (45.05%) were collected from male patients, and 122 samples (54.95) were collected from female patients. The mean age of patients was 33.41 ±21.39 years. There was no significant association between the age or sex of the patients and sample rejection ($p>0.05$).

Table 1 shows the age-wise distribution of blood samples with pre-analytical nonconformities.

Table 2 represents the frequency of nonconformities that occurred for both cross-sectional and retrospective approaches. The most identified errors in the cross-sectional aspect were related to mislabeling (38.3%), while clotting of blood samples was the most frequent error (53.7%) in the retrospective aspect (Table 2). The overall rejection rate was calculated as 1.12% (1.03% for the cross-sectional aspect and 1.13% for the retrospective aspect).

Table 1- Age-wise distribution of blood samples with pre-analytical nonconformities

Cross-sectional study			Retrospective study		Total (%)
Age group (years)	Female N (%)	Male N (%)	Female N (%)	Male N (%)	N (%)
0-19	3 (8.82)	9 (26.47)	16 (8.51)	19 (10.11)	47 (21.17)
20-39	5 (14.72)	6 (17.65)	61 (32.45)	27 914.36)	99(44.59)
40-59	4 (11.76)	4 (11.76)	18 (9.57)	17 (9.04)	43 (19.37)
60-79	3 (8.82)	0 (0)	12 (6.38)	18 (9.57)	33 (14.87)
Total	15 (44.12)	19 (55.88)	107 (56.91)	81 (43.09)	222(100)

N= Number of participants

Table 2- Frequency of errors for rejection of blood samples

Errors	Cross-sectional aspect N (%)	Retrospective aspect N (%)	Total N (%)
Insufficient sample	1 (2.9%)	29 (15.4%)	30 (13.5%)
Clotted sample	2 (5.9%)	101 (53.7%)	103 (46.4%)
Mislabeling	13 (38.3%)	10 (5.3%)	23 (10.4%)
Inappropriate tube	8 (23.6%)	18 (9.6%)	26 (11.7%)
Hemolyzed sample	1 (2.9%)	10 (5.3%)	11 (4.9%)
Sample without ID	6 (17.6%)	14 (7.4%)	20(9.0%)
Wrong/Mismatch ID	3 (8.8%)	6 (3.6%)	9 (4.1%)
Total	34 (100%)	188 (100%)	222 (100%)

N= Number of participants

DISCUSSION

Improving the quality of medical diagnosis is essential for providing safe healthcare. Among clinical disciplines, laboratory medicine plays a vital role in patient safety (1). Conventionally, laboratory practice can be divided into the pre-analytical, analytical, and post-analytical phases. As mentioned earlier, the majority of nonconformities are related to sample collection and its transportation, which occur in the pre-analytical phase. Identification and documentation of problems are key steps for improving the quality of laboratory medicine. We conducted a retrospective and a cross-sectional study to identify the rate of sample rejections at the RRH laboratory. We calculated an overall blood sample rejection rate of 1.12%. Magwai et al. (2021) reported a rejection rate of 1.4% and 1.2% in 2016 and April 2018–March 2019, respectively (12).

Our results are in agreement with studies that have been carried out in other developing countries. In a study conducted in India, Chawla et al. (2010) reported a pre-analytical error rate of 1.52% (14), which is similar to the rate observed in our study. Approximately 1.48% of the samples were rejected in the research by Alavi et al. (2020) in Pakistan (2).

Most errors occurring in the pre-analytical phase are due to in vitro hemolysis, incorrect patient identification, clotted specimens, and insufficient sample volume. Hemolysis has specimen rejection (15). This phenomenon occurs due to excessive shaking, delayed separation of blood cells, inadequate clotting, low transportation temperature, and excessive centrifugation speed. Therefore, correct organization and management of both personnel and nonconformities (errors) of blood samples, as well as analytical procedures are important. The rejection of clinical chemistry specimens delays the availability of results, which may impact patient management (13). Our findings indicated that the most frequent error in both cross-sectional and retrospective approaches was blood clotting (46.4%). Clots are easily detectable by visual inspection; however, micro-clots are sometimes difficult to detect. The presence of clots might be due to negligence during sample collection and handling, which increases blood to anticoagulant ratio and leads to improper mixing of the blood after mixing with the anticoagulant. Moreover, improper mixing of the blood sample and overfilling of the EDTA could contribute to sample clotting (1).

The results indicated that the most serious error before blood sample collection was patient misidentification. It is essential to ensure that blood samples are collected from the right patients. Blood samples should never be taken before the identity of the patient is confirmed. It is important to follow established guidelines for sample collection in all circumstances to ensure the standardization of blood collection (17). Standardized blood collection is a prerequisite for comparing the patients' results both with reference values and with their own earlier and subsequent results. Given the importance of patient safety, it is necessary to reduce nonconformities in the pre-analytical phase. Atay et al. (2014) performed a study on clinical biochemistry laboratory rejection rates due to various types of pre-analytical errors and revealed that the total rejection rate of samples was 0.69%. In the same study, 29% of all rejections were due to hemolysis, while 14% of the rejections were due to clotting (13). Similar to our study, plasma–citrated samples had the highest rate of rejection (1.47%), while the lowest rejection rate was related to whole blood-EDTA samples (0.38%).

CONCLUSION

Although all three phases of laboratory testing are equally important for improving total quality management and should be targeted individually for improving standards of laboratory practice, the pre-analytical phase is the most-error testing phase. Based on the results of our study, the rate of blood sample rejection is high in the RRH. Sample clotting, followed by insufficient samples, inappropriate tubes, mislabeling, unidentified samples, wrong or mismatched samples, and hemolyzed samples are the most common reasons for sample rejection in the study area.

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DECLARATIONS

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Ethics approvals and consent to participate

This study was granted ethical clearance from the INES Ruhengeri Research Committee. All personal information of the patients remained confidential, and laboratory coding was used to identify blood samples rather than patients' names.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this article.

REFERENCES

1. Saurav PM, Mukherjee B, Das AK. *Pre-analytical errors in the clinical laboratory and how to minimize them.* Int J Bioassays. 2013; 2(3):551-553. [Google Scholar]

2. Alavi N, Khan SH, Saadia A, Naeem T. *Challenges in Preanalytical Phase of Laboratory Medicine: Rate of Blood Sample Nonconformity in a Tertiary Care Hospital.* EJIFCC. 2020 20;31(1):21-27. [PubMed] [Google Scholar]

3. Lima-Oliveira G, Volanski W, Lippi G, Picheth G, Guidi GC. *Pre-analytical phase management: a review of the procedures from patient preparation to laboratory analysis.* Scand J Clin Lab Invest. 2017 ;77(3):153-163. [DOI:10.1080/00365513.2017.1295317] [PubMed] [Google Scholar]

4. Giavarina D, Lippi G. *Blood venous sample collection: Recommendations overview and a checklist to improve quality*. Clin Biochem. 2017 ;50(10-11):568-573. [View at Publisher] [DOI:10.1016/j.clinbiochem.2017.02.021] [PubMed] [Google Scholar]

5. Da Rin G. *Pre-analytical workstations: a tool for reducing laboratory errors.* Clin Chim Acta. 2009 ;404(1):68-74. [View at Publisher] [DOI:10.1016/j.cca.2009.03.024] [PubMed] [Google Scholar]

6. West J, Atherton J, Costelloe SJ, Pourmahram G, Stretton A, Cornes M. *Preanalytical errors in medical laboratories: a review of the available methodologies of data collection and analysis*. Ann Clin Biochem. 2017 ;54(1):14-19. [DOI:10.1177/0004563216669384] [PubMed] [Google Scholar]

7. Plebani M. *Errors in clinical laboratories or errors in laboratory medicine?* Clin Chem Lab Med. 2006;44(6):750-9. [DOI:10.1515/CCLM.2006.123] [PubMed] [Google Scholar]

8. Lombardi G, Lanteri P, Colombini A, Banfi G. *Blood biochemical markers of bone turnover: pre-analytical and technical aspects of sample collection and handling*. Clin Chem Lab Med. 2012 3;50(5):771-89. [DOI:10.1515/cclm-2011-0614] [PubMed] [Google Scholar]

9. Almatrafi AA. *Preanalytical Errors: A Major Issue in Medical Laboratory.* Acta Scientific Medical Science. 2019; 3(2):93-95. [Google Scholar]

10. Marin AG, Rivas-Ruiz F, Del Mar Pérez-Hidalgo M, Molina-Mendoza P. *Pre-analytical errors management in the clinical laboratory: a five-year study*. Biochemia medica. 2014; 24(2):248-257. doi: 10.11613/BM.2014.027. [DOI:10.11613/BM.2014.027] [PubMed] [Google Scholar]

11. Rusanganwa V, Gahutu JB, Nzabahimana I, Ngendakabaniga JMV, Hurtig AK, Evander M. *Clinical referral laboratories in Rwanda: the status of quality improvement after 7 years of the SLMTA program.* American Journal of Clinical Pathology. 2018; 150(3):240-245. [View at Publisher] [DOI:10.1093/ajcp/aqy047] [PubMed] [Google Scholar]

12. Magwai T, Warasally Z, Naidoo N, Gounden V. *Reducing sample rejection in Durban, South Africa*. Clinical Chemistry and Laboratory Medicine. 2021; 59(4):687-692. [View at Publisher] [DOI:10.1515/cclm-2020-0827] [PubMed] [Google Scholar]

13. Atay A, Demir L, Cuhadar S, Saglam G, Unal H, Aksun S, et al. *Clinical biochemistry laboratory rejection rates due to various types of preanalytical errors.* Biochemia medica. 2014; 24(3):376-382. [View at Publisher] [DOI:10.11613/BM.2014.040] [PubMed] [Google Scholar]

14. Chawla R, Goswami B, Tayal D, Mallika V. *Identification of the types of preanalytical errors in the clinical chemistry laboratory: 1-year study at GB Pant Hospital*. Laboratory Medicine. 2010; 41(2):89-92. [View at Publisher] [DOI:10.1309/LM9JXZBMLSVJT9RK] [Google Scholar]

15. Najat D. *Prevalence of pre-analytical errors in clinical chemistry diagnostic labs in Sulaimani city of Iraqi Kurdistan.* Plos One. 2017; 12(1):170-211. [View at Publisher] [DOI:10.1371/journal.pone.0170211] [PubMed] [Google Scholar]

16. Plebani M. *Quality indicators to detect pre-analytical errors in laboratory testing*. The Clinical Biochemist Reviews. 2012; 33(3):85-89. [View at Publisher] [PubMed] [Google Scholar]

17. Mazzocca AD, McCarthy MBR, Chowaniec DM, Cote MP, Romeo AA, Bradley JP, Beitzel K. *Platelet-rich plasma differs according to preparation method and human variability.* Journal of Bone and Joint Surgery. 2016; 94(4):308-316. [View at Publisher] [DOI:10.2106/JBJS.K.00430] [PubMed] [Google Scholar]

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