Original Article

Exploring Preanalytical Errors in Hematology from the Ground Up in a Tertiary Care Center of North India

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Abstract

Background: Quality assurance in the hematology laboratory is essential for providing users with test results that are both precise and accurate. Despite significant advancements in hematology practices, pre-analytical errors continue to pose challenges for pathologists. This study aims to assess the types and frequency of pre-analytical errors occurring in the hematology laboratory.

Materials and Methods: This analytic study was conducted over a period of one year (August 2023–July 2024) in the Hematology Laboratory of Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh, India. The pre-analytical variables that hampered the results were classified as insufficient samples, clotted samples, inappropriate vials, labeling errors, hemolyzed samples, diluted samples, excessive samples, and delays in sample transfer.

Results: Samples received from OPD were 48,300 (66.6%), while samples from IPD were 24,228 (33.4%). Pediatric age group samples were 9,432 (13%), and 150 (1.6%) samples showed pre-analytical errors, while adult samples were 63,096 (87%), and only 752 (1.0%) samples showed errors. A total of 72,528 samples were received, and 902 (1.24%) samples showed pre-analytical errors. The most common error was insufficient samples (53.4%), followed by hemolyzed, clotted, excessive, and diluted samples, inappropriate vials, delays in transfer to the lab, and labeling errors.

Conclusion: Insufficient samples, followed by hemolyzed samples, represent the majority of pre-analytical issues. Errors due to insufficient and diluted samples are most frequently seen in pediatric patients. Following best practices in the laboratory, including the use of pediatric vials, can substantially decrease these pre-analytical errors. Addressing these issues can be effectively managed through regular staff education and training.

Keywords:

Pre-analytical errors, hematology, tertiary care center, IPD, OPD, pediatric sample errors

Introduction

Quality assurance in haematology laboratories is essential for delivering reliable test results to users. Variability in test outcomes could arise from pre-analytical, analytical, and post-analytical factors. Technological advancements and automation have significantly improved the analytical phase of sample processing, hence providing robust quality control practices. Post-analytical

errors, such as typographical mistakes, can be minimized with the use of laboratory interface systems and hospital information systems. However, pre-analytical errors continue to pose challenges for pathologists [1,2].

The pre-analytical phase is a critical component of laboratory medicine and encompasses all activities before the sample is processed in the laboratory [3,4]. This phase includes specimen collection, handling, processing, physiological variables, and endogenous factors. While some pre-analytical variables, such as specimen characteristics, can be controlled, understanding uncontrollable variables like patient characteristics, environmental factors, seasonal changes, and circadian rhythm is crucial for distinguishing their effects from disease-related changes affecting laboratory results [5,6].

According to the study conducted by Carraro et al. in 2007 and Hammerling in 2012, pre-analytical errors account for 61.9% of all errors. Common pre-analytical errors include ordering tests for the wrong patient, misidentifying patients, ordering incorrect tests, missing samples or test requests, incorrect or missing patient identification, contamination during sample collection, hemolysis, clotting, insufficient samples, inappropriate containers, improper labeling, incorrect blood-to-anticoagulant ratios, and improper transport and storage conditions [7,8]. These errors can lead to inconsistencies and incorrect reporting, which burden the laboratories [4].

Materials and Methods

This analytic study was conducted over a period of one year (August 2023–July 2024) in the Hematology Laboratory of Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh, India. All samples received during this period were included in the study. Ethical clearance was obtained from the institutional ethics committee. Before sampling, written consent was taken from the patients or their guardians.

Sample collection was done using vacutainers by trained technologists and nurses in the outpatient department (OPD) collection center and wards, respectively. A total of 72,528 samples from the OPD and inpatient department (IPD) were received. The pre-analytical errors that hampered the results were classified as: Insufficient samples, Clotted samples, Inappropriate vials, Labeling errors, Hemolyzed samples, Diluted samples, Delay in sample transfer to the lab, Excessive samples.

Results

Samples in the hematology laboratory were received from OPD and IPD. Samples received from OPD were 48,300 (66.6%), while samples received from IPD were 24,228 (33.4%). Paediatric age group samples were 9,432 (13%), while samples received from adult patients were 63,096 (87%).

Out of the total 72,528 samples received in the laboratory, preanalytical errors, as per the above-mentioned categories, were found in 902 (1.24%) samples. Out of 48,300 samples received from OPD, preanalytical errors were observed in 567 (1.2%) samples, slightly lower than IPD samples. Out of the 24,228 samples received from IPD, preanalytical errors were observed in 335 (1.4%) samples [Table 1] [Fig. 1].

Out of the 9,432 samples received from paediatric age group patients, 150 (1.6%) samples had preanalytical errors. However, only 752 (1.0%) samples from adult age group patients showed preanalytical errors [Table 2] [Fig. 2].

The most common error was insufficient samples, seen in 481 samples, comprising 53.4% of total preanalytical errors, followed by hemolysed samples (115 samples, 12.7%), clotted samples (76 samples, 8.4%), excessive samples (71 samples, 7.9%), diluted samples (61 samples, 6.8%), inappropriate vials (42 samples, 4.6%), delay in transfer to the lab (35 samples, 3.9%), and labelling

errors (21 samples, 2.3%) [Table 3] [Fig. 3].

Table 1: Distribution and frequency of preanalytical errors in IPD & OPD samples

Source of the samples	Number of samples	Preanalytical errors	Percentage
OPD	48,300	567	1.2%
IPD	24,228	335	1.4%
Total	**72,528**	**902**	**1.24%**

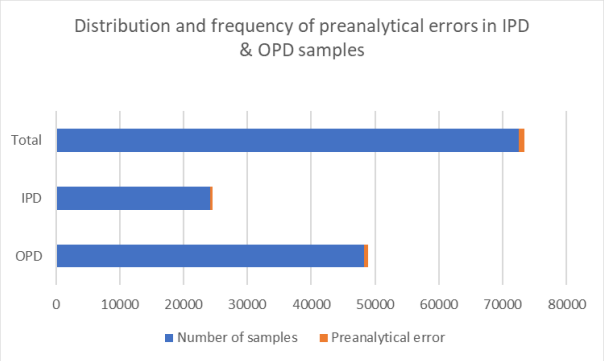

Figure 1: Distribution and frequency of preanalytical errors in IPD & OPD samples

Table 2: Distribution and frequency of preanalytical errors in samples according to age group

Age group	Number of samples	Preanalytical errors	Percentage
Paediatric	9,432	150	1.6%
Adults	63,096	752	1.0%
Total	**72,528**	**902**	**1.24%**

Table 3: Types and frequency of preanalytical errors

Preanalytical errors	Number of samples	Percentage
Insufficient sample	481	53.4%
Hemolysed sample	115	12.7%
Clotted sample	76	8.4%
Excessive sample	71	7.9%
Diluted sample	61	6.8%
Inappropriate vial	42	4.6%
Delay in sample transfer to lab	35	3.9%
Labelling error	21	2.3%
Total	**902**	**100%**

Discussion

This study aimed to evaluate the types of pre-analytical errors in our tertiary care setting. A laboratory error is generally defined as a defect occurring throughout the testing process—from ordering tests to reporting results—that impacts the quality of laboratory services. Both pre-analytical and post-analytical phases are crucial, as addressing pre-analytical issues can reduce errors in subsequent phases [9].

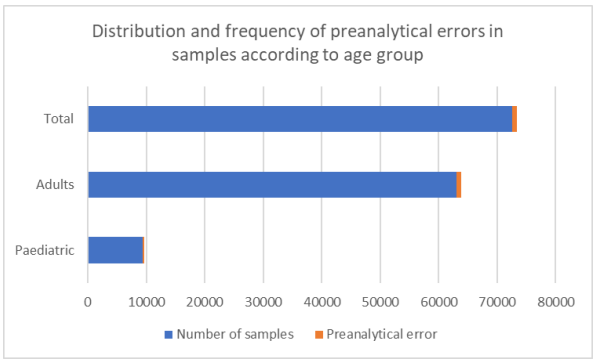

Figure 2: Distribution and frequency of preanalytical errors in samples according to age group

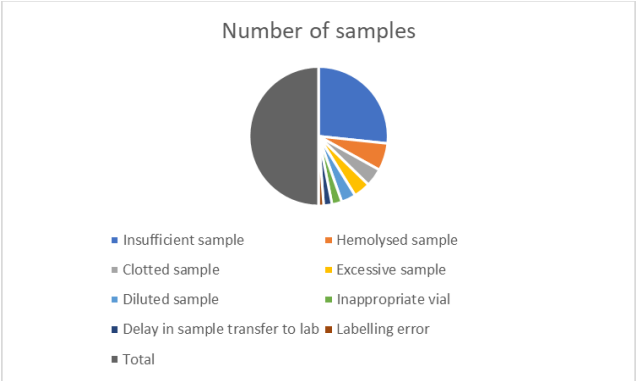

Figure 3: Types and frequency of preanalytical errors

Over a one-year analytical study, we analyzed the frequency and types of pre-analytical errors leading to sample rejection. Out of the total samples, 115 (0.16%) were rejected for testing. Out of these 115 rejected samples, 50 samples were recollected and accurately reported. Some of the measured parameters were WBC count, RBC count, hemoglobin, hematocrit, MCV, MCH, RDW, platelet count, MPV, etc. In our study, 902 (1.24%) pre-analytical errors were reported from the hematology lab of the pathology department, with similar proportions reported in other studies.

In our study, samples received from OPD were more frequent compared to IPD. However, pre-analytical errors were more common in IPD samples. Similar observations were seen in studies conducted by Upreti et al. (2013), Arul et al. (2018), Gaur et al. (2020), and Iqbal et al. (2023) [10,11,12,21]. This may be due to a varied workforce that includes inexperienced interns and nursing staff in the wards, indicating a need for better training and education for blood collection personnel. Another reason for more IPD sample errors could be the fact that dedicated phlebotomists are responsible for collection in OPD, while collection for IPD patients is an added responsibility for IPD staff and overburdened personnel. Implementing regular training for all staff can enhance knowledge of the pre-analytical phase, significantly minimizing pre-analytical errors in healthcare and nursing practices [4,20].

In our study, we received a higher number of samples from adults than from pediatric patients. However, we observed that pre-analytical errors were more prevalent in pediatric samples compared to those from adults. Our findings were corroborated by studies conducted by Upreti et al. (2013), Arul et al. (2018), and Iqbal et al. (2023) [10,12,21]. This may be due to the challenges

of obtaining an adequate amount of venous blood samples from newborns and young children, along with the increased likelihood of pre-analytical errors associated with capillary blood sample collection [13]. We recommend using pediatric vials for pediatric samples to minimize pre-analytical errors, leading to improved assessment and diagnosis of patients.

In our study, the most common issue was insufficient blood samples, accounting for 53.4% of all pre-analytical errors. Previous studies by Arul et al. (2018), Gaur et al. (2020), and Iqbal et al. (2023) also reported high rates of insufficient samples [10-12]. A similar study conducted by Lorque et al. in 2023 also observed insufficient sample volume to be the most common error [23]. This problem was notably prevalent in the pediatrics division, likely due to difficulties in obtaining an adequate amount of venous blood from newborns and young children, which increases the risk of pre-analytical errors [13]. Samples diluted with IV fluids were found only in inpatient department (IPD) patients, for clear reasons. Occasionally, nursing staff may not fully appreciate the importance of selecting veins that do not have IV lines in place. Low hematocrit, low MCV, and high MCHC are typical alterations associated with insufficient sample volume when processed on automated analyzers [14]. Narang et al. (2016) found clotted samples to be the most common cause of rejection, which is discordant with our study [17].

Hemolyzed samples were the second most common error, representing 12.7% of all pre-analytical errors. This finding is consistent with the results of Goswami et al. (2009) and Ercan et al. (2021), who found that extensive hemolysis can lead to incorrect CBC results [13,15]. Common causes of hemolysis include inadequate cleaning of the venipuncture site, improper use of syringes, vigorous mixing, and forcing blood into tubes [16].

Clotted samples were the third most frequent error, making up 8.4% of all pre-analytical errors. Narang et al. (2016) and other studies have similarly highlighted clotted samples as a significant cause of rejection [17]. Studies conducted by Arul et al. (2018), Gaur et al. (2020), and Iqbal et al. (2023) also reported a high proportion of specimens rejected because of clotting [10-12]. However, Alshaghdali et al. (2022) found clotted samples to be the most frequent error [22]. Blood clotting often results from an incorrect anticoagulant-to-blood ratio, improper mixing of samples, and delays in transferring blood to collection vials, leading to cell damage and unusable samples for assays requiring plasma or whole blood [16].

Excessive samples accounted for 7.9% of pre-analytical errors. Overfilling can lead to insufficient mixing, causing pseudo-polycythemia, pseudo-thrombocytopenia, and pseudo-leukopenia [13]. Additionally, overfilling and insufficient mixing could result in small clots that are not easily detected unless checked with wooden applicators.

Diluted samples, making up 6.8% of the pre-analytical errors, often occur when collected through intravenous catheters. To avoid dilution, blood samples should be drawn after turning off intravenous infusions and applying the tourniquet below the infusion site or from an alternate collection site with no IV line [18].

Other pre-analytical errors, including inappropriate vials, delays in sample transfer, and labeling mistakes, represented 4.6%, 3.9%, and 2.3%, respectively. Ideally, CBC specimens should be analyzed within six hours of collection, especially if cell morphology is crucial, to avoid sample deterioration, including artefactual cell morphology, increased MCV and MPV, hemolysis, and potential harm to patients [19].

Our study also found that pre-analytical errors, particularly sample insufficiency, were more frequent in inpatient samples compared to outpatient ones. This finding aligns with Arul et al.'s observation and may reflect the impact of a heterogeneous workforce, including inexperienced staff [19]. This highlights the need for improved training and standardization in sample collection procedures, such as Mitra, HemaPEN, Touch-Activated Phlebotomy Devices, and PIVO.

During the study period, corrective measures implemented to reduce pre-analytical errors included staff training, avoiding sample collection from IV line sites, and ensuring timely sample transfer to the laboratory. Additionally, interns and staff were trained on proper sample handling, such as filling the EDTA vial to the required level, labeling samples correctly, and using the appropriate vial for different laboratory tests.

Minimizing errors in laboratory practices is a key priority. ISO 15189:2007 underscores the significance of quality management (QM) systems, which should include both internal quality control and inter-laboratory comparisons, such as external quality assessment schemes. The quality manual must include sample collection, transportation, and handling, as well as reporting and communication with patients, healthcare providers, and referral labs, while overseeing the quality program. It is essential to document instrument performance, calibration procedures, and provide an overview of the analytical system [18]. Pre-analytical errors can be reduced by providing thorough training to staff and incorporating greater automation in the laboratory.

Conclusion

Pre-analytical errors remain a significant issue in laboratories, as many steps leading to these errors are beyond the lab's direct control. Despite advancements in the analytical phase, pre-analytical errors persist due to human intervention throughout the process. Improved coordination between labs and wards, ongoing education for laboratory staff, enhanced computerization, and regular competency checks are essential to address and mitigate these errors effectively.

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