Original Article

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Analysis of Preanalytical Errors in Clinical Biochemistry Laboratory of a Tertiary Care Hospital: A Retrospective Study

Biochemistry Section

DHANALAKSHMI BALASUNDARARAJ[1], M SENTHIL PRABHU[2], S THILAGARAJAN[3], KATHIRAVAN RAJENDRAN[4]

ABSTRACT

Introduction: Pre-analytical phase of laboratory testing is the most susceptible phase, as errors in this phase leads to more than 50% of erroneous results and often breaches the trust of the stakeholders on the quality of the laboratory results. Many pre-analytical errors occur during the pre-analytical phase, encompassing sample collection, labelling and transportation-factors often beyond the laboratory's direct control.

Aim: To determine the type and frequency of pre-analytical errors leading to sample rejection in clinical biochemistry laboratory.

Materials and Methods: Being a retrospective descriptive study, convenient sampling was used to analyse sample rejection due to pre-analytical errors in clinical biochemistry laboratory of a tertiary care teaching hospital- PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu, India for a period of six months from May 2023 to October 2023. All the cases/blood samples from Outpatient Department (OPD) and Inpatient Department (IPD), received and rejected during this period were included under study. The data collection and analysis was done over a period of five months using the sample rejection and resample description from Laboratory Information System (LIS). Using Statistical Package for the Social Sciences (SPSS) version 28.0, data were summarised using descriptive statistics such as numbers and percentages.

Results: During the six months period out of the total of 667454 samples, 1505 (0.23%) samples were rejected due to pre-analytical errors. The majority of the samples which were rejected were from IPD than OPD. Among the pre-analytical errors, haemolysis accounted for 806 (53.6%), clotted samples 256 (17%), delta check 217 (14.4%), insufficient sample 129 (8.6%), contamination 74 (4.9%), identification error 14 (0.9%), sample without request form 3 (0.2%) while missing samples, billing error, inappropriate tube, delay in transport and wrong test selection accounted for <3 (0.1%).

Conclusion: Haemolysis and clotted samples were the most common pre-analytical causes for sample rejection in the laboratory. The samples from IPD were rejected more often than OPD due to incorrect phlebotomy techniques. This accentuates the need for proper hands-on phlebotomy training sessions for novice nurses following their recruitment, as their competency will be instrumental in bringing down the errors in pre-analytical phase.

Keywords: Haemolysis, Patient care, Phlebotomy, Sample rejection

INTRODUCTION

In the contemporary healthcare landscape, clinical chemistry laboratories play an undisputed role in facilitating accurate diagnosis and treatment decisions. With the majority of medical interventions relying on laboratory results, the establishment of robust quality management systems within these facilities is imperative. Despite significant advancements in laboratory automation over the past decade, quality issues persist, highlighting the ongoing need for stringent quality assurance and improvement measures enforced by accreditation organisations.

The quality of laboratory results hinges on the detection and mitigation of errors across the pre-analytical, analytical and post-analytical phases of the testing process. Among these, pre-analytical errors loom large, contributing to over 50% of all errors [1] adversely affecting patient care through delays in diagnosis, sample rejection and inappropriate treatment. Notably, many pre-analytical errors occur before the pre-analytical phase, encompassing sample collection, labelling and transportation-factors often beyond the laboratory's direct control.

Efficient clinical laboratories are indispensable for delivering high-quality healthcare. Those that excel in standardisation and meticulous monitoring of each testing phase stand at the forefront of quality assurance. Studies by Abdollahi A et al., Rizk MM et al. and Aggarwal K et al., underscore the significance of the pre-analytical phase, where incomplete request forms, inadequate sample volumes, haemolysis and billing errors emerge as common culprits for sample rejection [2-4].

Amidst this backdrop, there exists a pressing need to delve deeper into the prevalence and impact of pre-analytical errors within clinical biochemistry laboratories of tertiary care hospitals. The present study intends to analyse and dissect the intricacies of pre-analytical errors, shedding light on their implications for patient care quality and healthcare efficiency. The novelty of the present study resides in its evaluation of the pre-analytical phase of laboratory testing a critical yet often overlooked area that contributes significantly to pre-analytical errors. By identifying key areas of improvement and enhancing healthcare personnel's awareness, this research endeavour strives to elevate the overall standard of laboratory practices, ultimately optimising patient outcomes and advancing the quality of healthcare delivery. Hence, the present study is done to determine the cause and frequency of sample rejection in clinical biochemistry laboratory due to pre-analytical errors.

MATERIALS AND METHODS

This is a retrospective descriptive study conducted in a National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited clinical biochemistry laboratory of PSG Hospitals which is a tertiary care teaching hospital in Coimbatore, South India. This was a period study where all the samples rejected due to pre-analytical errors was analysed for a period of six months from May 2023 to October 2023.

Ethical clearance was obtained from the Institutional Human Ethics Committee (PSG/IHEC/2023/Appr/Exp/406) prior to the commencement of the study.

The clinical biochemistry laboratory caters round the clock services for both outpatients and in patients of the hospital which has a capacity of 1500 beds. In order to maintain quality of the laboratory results, there is strict compliance with the processing of internal and external controls as per the requirements of the NABL for large medical laboratories [5]. The laboratory is equipped with high end automated analysers capable of performing various biochemical tests comprising of clinical chemistry, hormones, enzymes, blood gas and electrolytes, lipid profile, metabolites, immunological tests, tumour, inflammatory markers, vitamins. Given the availability of a wide array of tests the sample requirements also varies for each test and the details have been made available in the sample collection manual in the LIS. In the present study the sample rejection due to various pre-analytical errors [Table/Fig-1] were collected using LIS from the sample rejection and resample description.

Errors in pre-analytical phase

- Identification error
- Billing error
- Sample without Test Request Form (TRF)
- Missing samples
- Delay in transport
- Wrong order of draw
- Sample with i.v. fluid contamination

} Identified during Delta check

- Inappropriate sample container
- Inappropriate test selection
- Insufficient sample
- Clotted sample
- Haemolysis

[Table/Fig-1]: List of pre-analytical errors leading to sample rejection.

STATISTICAL ANALYSIS

Statistical analysis was performed with the SPSS version 28.0 and the data were presented using descriptive statistics such as number and percentage.

RESULTS

The clinical biochemistry laboratory received a total of 667454 samples during the six months period. During these months a total of 1505 samples were rejected due to pre-analytical errors which is about (0.23%) of the total number of samples received. When the rejection rates from OPD and IPD were compared, it was found that the majority of the samples which were rejected were from IPD [Table/Fig-2].

Month	OP samples received (N)	IP samples received (N)	OP rejected samples N (%)	IP rejected samples N (%)
May	55757	49671	20 (0.04)	248 (0.50)
June	56032	48575	14 (0.02)	193 (0.40)
July	55509	56292	33 (0.06)	257 (0.46)
August	58454	55670	16 (0.03)	208 (0.37)
September	62713	55924	14 (0.02)	213 (0.38)
October	55488	57369	11 (0.02)	278 (0.48)

[Table/Fig-2]: Sample rejection rate of OPD and IPD samples.

Out of the 1505 rejected samples, 268 (0.25 %) were rejected in May, 207 (0.20%) in June, 290 (0.26%) in July, 224 (0.20%) in August, 227 (0.19%) in September and 289 (0.26%) in October. Different types of pre-analytical errors like identification error, delta check, sample without Test Request Form (TRF), missing samples etc., contributed to the sample rejection but among them haemolysis (53.6%) was the most common cause. The second most common cause was clotted samples (17.0%) [Table/Fig-3].

Pre-analytical error	Frequency (n)	Percentage (%)
Identification error	14	0.9
Delta check	217	14.4
Sample without Test Request Form (TRF)	3	0.2
Missing samples	1	0.1
Billing error	1	0.1
Inappropriate sample container	2	0.1
Insufficient sample	129	8.6
Clotted sample	256	17.0
Haemolysis	806	53.6
Contamination	74	4.9
Delay in transport	1	0.1
Inappropriate test selection	1	0.1

[Table/Fig-3]: Sample rejection rates due to pre-analytical errors for six months period.

DISCUSSION

Pre-analytical phase of laboratory testing is the most vulnerable phase, as errors in this phase leads to erroneous results and often breaches the trust of the stakeholders on the quality of the laboratory results. In the study, the most common pre-analytical error observed was haemolysis (53.6%) similar to the findings of Aggarwal K et al., [4]. Even though many inherited or acquired haemolytic anaemias can contribute to haemolysis, most of the times it is due to improper sample collection technique [6]. The following are some of the in-vitro causes for haemolysis: collection of blood before the evaporation of alcohol used for disinfection, prolonged tourniquet application, incorrect needle size and forceful transfer of blood from syringe when closed blood collection system [7] is not followed, vigorous mixing of samples instead of gentle inversions, incorrect ratio of sample and additive due to incorrect filling of tubes [8]. Haemolysis causes wrong laboratory results by resulting in elevation of analytes found in the Red Blood Cell (RBC) like potassium, lactate dehydrogenase, aspartate aminotransferase or decrease in analytes like cardiac troponin due to the proteases in RBC or by causing interference in spectrophotometric readings [9]. Contrary to the findings of Kamal F et al., clotted samples (17%) were the second most common cause of rejection which is observed when the recommended inversion technique for mixing the blood sample with anticoagulant (e.g., Heparin tube) is not followed or the tube is kept in horizontal position after blood sample collection [10,11].

The reason for sample rejection varies between institutions based on the institution policy. Likewise in the institution there are instances where resample is requested when there is a doubt in the value (14.4%) during delta check wherein the current value is verified with the previous one to detect issues related to sample integrity [12]. Even though the sample was rejected after analysis in the post-analytical phase the source of the problem was in the pre-analytical phase. This is because, the cause for lack of correlation of the value with the clinical diagnosis or with previous value had been found to be due to sample contamination with intravenous (i.v.) fluids or identification error or wrong order of draw [13], as in ionised calcium wherein blood sample was collected in serum tubes after the Ethylenediamine Tetraacetic Acid (EDTA) tubes leading to its underestimation due to EDTA complexing with ionised calcium [7,14]. This emphasises the need for proper education of the healthcare personnel involved in sample collection, about the order of draw for sample tubes and its significance to prevent contamination with additives.

Single centred studies by Jacobsz LA et al., and Bhutani N and Bhutani N, have found that insufficient sample volume contributed to 22% of sample rejections [15,16]. Contrarily, in the present study sample rejection due to insufficient samples was 8.6%. This was observed mainly in samples collected from paediatric and neonatal age groups due to the difficult venous access [17]. The other reasons leading to inadequate samples could be lack of proper knowledge and training of the phlebotomist with respect to the sample requirements of a test. In addition, drawing blood from patients who are debilitated due to chronic diseases like cancer

becomes challenging due to difficult venous access as a result of multiple venipunctures. In such scenarios the physicians and the phlebotomists should be well informed about the minimum volume requirement for a test so that they can prioritise the tubes during sample collection. In the current study, sample contamination accounted for 4.9% of pre-analytical errors contrary to the findings of Cao L et al., wherein specimen contamination representing 35.1% was the most common cause for sample rejection [18]. The frequently observed reason was i.v. fluid contamination because of the lack of knowledge that blood should not be drawn from an arm wherein i.v. infusion was being administered. Apart from this transfer of blood from one tube to other also contributed to sample contamination.

During the data collection process it was found that identification error accounted for 0.9% of the sample rejection which seemed to be under reported. On investigation it was found that many a time the resample was obtained without documentation by the laboratory personnel due to requests from the nursing staff or phlebotomists fearing penalty. This underscores the need for educating the laboratory personnel, phlebotomists and the nursing staff who are the phlebotomists in the IPD that proper documentation, aids in implementing preventive measures to decrease errors effectively and it is not for imposing penalties. The Joint Commission, in the United States of America in its National Patient Safety Goals has mandated the use of at least two identifiers excluding a patient's room number or physical location while providing services, treatment or care to the patient [19].

Apart from the abovementioned errors, missing samples, billing error, inappropriate sample container, delay in transport and inappropriate test selection accounted for 0.1% of sample rejection whereas sample without TRF was 0.2%. The observance of such a low rate in delay in transport could be attributed to the presence of a pneumatic system for sample transport in the hospital. The incidence of missing samples was rare and it was observed when the nursing staff sent the sample to a wrong destination instead of the laboratory by entering a different code in the pneumatic system. Similarly problems with inappropriate vacutainer or inappropriate test selection were remote and were observed when sample was collected by trainee.

Overall while considering OPD and IPD, the rejection rate in IPD was nearly 7 to 24 times more than OPD across the six months. This is probably due to recruitment of novice nurses at frequent intervals in IPD when compared to the phlebotomists at OPD collection centers who are fairly constant. Blood collection is one of the common nursing procedures and the expertise of novice nurses in phlebotomy is not remarkable. This emphasises the importance of assessing the knowledge of pre-analytical errors in newly recruited nurses so that training sessions can be conducted to enhance their competency.

The issues identified in the study shed light on the trends and areas for targeted intervention. This will aid in refining procedures related to sample collection, labelling and transportation thereby improving the quality of laboratory results and ultimately patient care.

Limitation(s)

Haemolytic samples were assessed subjectively through visual inspection, rather than the preferred automated spectrophotometric methods for quantitative evaluation of the threshold.

CONCLUSION(S)

Haemolysis and clotted samples were the most common pre-analytical causes for sample rejection in the laboratory. Both these are preventable errors still they are contributing for the majority of the rejection rate, pointing towards the need for appropriate education and training to facilitate accurate and prompt laboratory results. The samples from IPD were rejected more often than OPD due to incorrect phlebotomy techniques. This underscores the necessity of comprehensive hands-on phlebotomy training sessions for novice nurses following their recruitment, as their competency will be instrumental in bringing down the errors in pre-analytical phase. Longitudinal studies may be undertaken to assess the effectiveness of training programs on reducing pre-analytical errors over time.

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PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Biochemistry, PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu, India.
2. Assistant Professor, Department of General Surgery, PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu, India.
3. Assistant Professor, Department of Radiology, PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu, India.
4. Assistant Professor, Department of Community Medicine, PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Kathiravan Rajendran,
Assistant Professor, Department of Community Medicine, PSG IMSR, Off, Avinashi Road, Peelamedu, Coimbatore-641004, Tamil Nadu, India.
E-mail: maopusdei@gmail.com

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