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Analysis of Preanalytical Errors in Biochemistry Laboratory of a Tertiary Care Hospital

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ABSTRACT

Introduction

Pre-analytical phase of laboratory testing is the most susceptible phase, with errors in this phase amounting to more than 50% of error results.

Preanalytical phase involves all the steps taken before a sample is received by the laboratory, ranging from order of a test, patient preparation, sample collection, transportation, accession, and specimen preparation.

Many pre-analytical errors occur during this phase, including sample collection, labelling and transportation factors often beyond the laboratory's direct control.

Aim

To determine and analyse pre-analytical errors leading to sample rejection in clinical biochemistry laboratory

Material And Methods

It is a retrospective descriptive study, sampling was used to analyse sample rejection due to pre-analytical errors in clinical biochemistry laboratory of Rama Medical College, Hospital & Research Centre, Kanpur for a period of four months from June 2024 to September 2024. All the blood samples from Outpatient Department (OPD) and Inpatient Department (IPD), received and rejected during this period were included under this study. The data collection and analysis was done over a period of six months using the sample rejection and resample description from Laboratory Information System (LIS). Using (SPSS) version 28.0, data were summarised using descriptive statistics such as numbers and percentages.

Results

During the four months out of the total of 5460 samples, 1255 (23%) samples were rejected due to pre-analytical errors. The majority of the samples which were rejected were from IPD rather than OPD. Among the pre-analytical errors, haemolysis accounted for 673 (53.6%),clotted samples 150 (12%), delta check 181 (14.4%), insufficient sample 108 (8.6%),contamination 61 (4.9%), identification error 12 (0.9%), sample without request form

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3 (0.2%) while missing samples, billing error, inappropriate tube, delay in transport and wrong test selection accounted for <2 (0.1%)

Conclusion

Haemolysis and clotted samples were the most common causes for sample rejection in the preanalytical phase in laboratory. The samples from IPD were rejected more often than OPD due to incorrect phlebotomy techniques. Staff should be trained for proper hands-on phlebotomy techniques following their recruitment, as their competency
will be beneficial in bringing down the errors in the pre-analytical phase.

Keywords: Biochemistry Laboratory, Pre-analytical error, Sample rejection

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INTRODUCTION

In the healthcare sector, clinical biochemistry laboratories play a major role in facilitating to the point diagnosis and treatment decisions. Having significant advancements in laboratory automation over the time, quality issues persist, demanding need for stringent quality assurance and improvement measures laid down by accreditation organisations.

The quality of these results lies in the detection and correction of errors across the pre-analytical, analytical and postanalytical phases of the testing process. Among these, pre analytical errors contribute to over 50% of all errors [1] adversely affecting patient care through delays in diagnosis, sample rejection and inappropriate treatment.

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. Various Studies show the significance of the preanalytical phase, where incomplete request forms, inadequate sample volumes, haemolysis and billing errors emerge as common culprits for sample rejection [2-4].

Pre-analytical Errors

1. Patient details: There should be proper details such as name, gender, age, IPD/OPD registration, including patient's posture, exercise, diet, present/past medical history, pregnancy.[5]
2. Insufficient sample: An insufficient sample cannot be enough for processing all the tests prescribed by the consultant clinician.
3. Faulty technique of sample collection: e.g., taking venous blood sample for running ABG test.[6]

ISSN:0975 -3583,0976-2833 VOL 15, ISSUE 12, 2024

4. Lack of storage facilities for the samples meant to be stored overnight. Or samples getting exposed to heat and light can affect the values of analytes such as photo-degradation of bilirubin by light exposure.
5.Use of sample specific vacutainer : e. g., sodium citrate vacutainer used for plasma glucose estimation instead of sodium fluoride vacutainer.
6. Robust shaking of the sample can make samples hemolyzed which can't be processed for tests such as enzymes, serum electrolytes.
7.Patient preparation: Certain tests require precautions to be followed by the patient. Like the state of fasting for tests like fasting blood glucose, lipid profile, thyroid profile. There are also specific timing requirements for tests such as drug levels and hormones. This needs to be taken care of to ensure that a reliable result is generated as an error at this phase makes the following steps of analysis and interpretation of sample irrelevant, even if performed correctly.
8.Wrong labelling of the containers: Patient identification errors can amount to 25% of all preanalytical errors [7]. It can lead to patients being diagnosed and treated for the wrong condition based on a sample from different patients.
9.Transportation: Sample should be transported in specified time to ensure timely analysis and interpretations.

Steps to minimise pre-analytical errors

1.Checking the test requisition form, name of patient on vacutainer and the requested tests.
2. Use of Barcodes: generated by LIS can be assessed by one or more bar code readers placed in key positions.
3.Proper history taking of the patient:Such as asking the patient regarding food intake, alcohol intake, any drug usage, smoking, etc.
4. Proper instructions to the patients: For the collection of the sample, confirming the use of the right anticoagulant and sufficient amount of the sample.
5. Record maintenance: Time of sample receiving along with the time report was ready and dispatched.

MATERIALS AND METHODS

This is a retrospective descriptive study conducted in the clinical biochemistry laboratory of Rama Medical College, Hospital & Research centre, Kanpur. Study was conducted for a period of four months from June 2024 to September 2024. Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study.

ISSN:0975 -3583,0976-2833 VOL 15, ISSUE 12, 2024

Errors in pre-analytical phase
• Identification error • Hemolysis • Billing error • Sample with i.v. fluid contamination • Sample without Test Request Form • Missing samples • Inappropriate test selection • Delay in transport • Wrong order of draw • Inappropriate sample container • Insufficient sample • Clotted samples

Table 1: List of pre-analytical errors leading to sample rejection.

RESULTS

Total of 5460 samples were received during the four month period. Out of total, 1255 samples were rejected due to pre-analytical errors which is about (23%) of the total number of samples received.

In comparison, it was found that the majority of the samples which were rejected, IPD samples were more than OPD samples.

MONTH	OPD SAMPLE RECEIVED (N)	IPD SAMPLE RECEIVED (N)	OPD REJECTED SAMPLE (%)	IPD REJECTED SAMPLE (%)
JUNE	730	610	48 (0.87)	276 (5.05)
JULY	806	652	35 (0.64)	281 (5.14)
AUGUST	792	602	50 (0.91)	248 (4.54)
SEPTEMBER	686	578	21 (0.38)	296 (5.42)

Table 2: Sample rejection rate of OPD and IPD samples.

Out of a total 1255 rejected samples, 324 (5.93%) were rejected in June, 316 (5.78%) were rejected in July, 298 (5.45%) were rejected in August, 317 (5.80%) were rejected in September. Different pre-analytical errors like identification error,
samples without Test Request Form (TRF), delta check, etc., contributed to the sample rejection but among them haemolysis (53.6%) was the most common followed by clotted samples (17.0%)

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Pre-analytical error	Frequency (N)	Percentage (%)
Identification error	12	0.9
Delta check	178	14.18
Sample without Test Request Form (TRF)	3	0.2
Missing samples	1	0.07
Billing error	1	0.07
Inappropriate tube	2	0.15
Insufficient sample	107	8.6
Clotted sample	219	17
Haemolysis	670	53.38
Contamination	60	4.9
Delay in transport	1	0.07
Inappropriate test selection	1	0.07

Table 3: Sample rejection rate due to Pre-analytical error for period of four months

DISCUSSION

Pre-analytical phase of laboratory testing is the most susceptible phase, as errors in this phase lead to a high percentage of errors which may breach the trust of the patients on the quality of the laboratory results. In the study, the most common pre-analytical error observed was haemolysis (53.38%) [4] . Although there are many inherited or acquired causes of haemolytic anaemia, most of the time it is due to improper sample collection technique [6].Some of the in-vitro causes for haemolysis are: collection of blood before the evaporation of spirit used for disinfection, prolonged application of tourniquet, wrong needle size and forceful transfer of blood from syringe [7], vigorous mixing of samples, incorrect ratio of sample and additive due to incorrect filling of tubes [8]. Haemolysis causes incorrect

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laboratory results by resulting in elevation of analytes found in the RBCs like potassium, lactate dehydrogenase(LDH), aspartate aminotransferase or decrease in analytes like cardiac troponin due to the proteases in RBC[9]. Clotted samples (17%) were the second most common cause of rejection as the recommended inversion technique for mixing the blood sample with anticoagulant is not followed or keeping the tube in horizontal position after sample collection [10,11].

The reason for sample rejection varies based on the institution policy. In some cases,resample is requested when the value is doubtful (14.4%) during delta check where the current value is verified with the previous one [12]. Even though the sample was rejected after analysis in the post-analytical phase the source of the error 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 was found to be due to sample contamination or identification error or wrong order of draw [13]. 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.

Insufficient sample volume contributed to an 8.6% rejection rate. This was observed mainly in samples collected from paediatric and geriatric age groups due to the difficult venous access [14].In addition, drawing blood from patients of chronic diseases like cancer becomes challenging due to difficult venous access as a result of multiple venipunctures in the past. In such scenarios the consultant and the phlebotomists should be well informed about the minimum volume requirement for a test so as to prioritise the tubes during sample collection.

In the current study, sample contamination accounted for 4.9% of pre-analytical errors. The frequently observed reason was i.v. fluid contamination. Apart from this transfer of blood from one tube to another also contributed to sample contamination.

During the data collection process it was found that identification error accounted for 0.9% of the sample rejection was presumed to be misreported due to requests from the nursing staff or phlebotomists fearing penalty. This calls for the need of educating the laboratory personnel, phlebotomists and the nursing staff to do proper documentation regarding the sample collection.

Apart from the above-mentioned errors, missing samples, billing error, inappropriate sample container, delay in transport and inappropriate test selection accounted for 0.47% of sample rejection whereas sample without request forms was 0.2%. The incidence of missing samples was rare and negligible. Similarly problems with inappropriate tubes or incorrect test selection were remote. Overall while considering OPD and IPD, the rejection rate in IPD was nearly 8-9 times more than OPD across the four months, which might be due to recruitment of new staff at frequent intervals in IPD when compared to the phlebotomists at OPD collection centers. Blood collection is one of the common nursing procedures and the expertise of the new staff in the collection centre is not up to the mark. The issues identified in the study shed light on the trends and areas for targeted intervention. This will help in refining procedures related to sample collection, labelling and transportation thereby improving the quality of laboratory results and ultimately patient care.

ISSN:0975 -3583,0976-2833 VOL 15, ISSUE 12, 2024

CONCLUSION(S)

Haemolysis and clotted samples were the most common preanalytical causes for sample rejection. Both are preventable errors still they contribute for the majority of the rejection rate, pointing towards the need for appropriate education and training to facilitate accurate and prompt results. The samples from IPD were rejected more often than OPD due to incorrect phlebotomy techniques. This reflects the necessity of comprehensive hands-on training sessions for new staff following their recruitment, as their competency will be instrumental in bringing down the errors.

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