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## **Study of pre-analytical errors in clinical biochemistry laboratory in Dhiraj General hospital, Piparia**

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**Abstract**---Introduction: Pre-analytical errors is the major source of mistakes in laboratory diagnostics. It includes from order of test by physician to sample is ready for analysis. Preanalytical errors are upto 70 % of errors of total diagnostic process. Objectives: 1. To evaluate the pre-analytical errors during pre-analytical testing process; 2. To formulate the possible corrective measures to be taken to minimise such errors. Materials and Methods: A prospective study was done for a period of 2 months from January 2022 to February 2022 in clinical biochemistry laboratory, central laboratory, Dhiraj general hospital, Piparia. All types of preanalytical errors were recorded. Total 15189 specimens were received during this period. Out of which 569 were sorted with pre analytical errors. Results: They were categorised as follows: Improper test request forms (n-91), Improper labelling (n-118), Insufficient sample (n-121), invalid samples (n-127), sample mix ups (n-18), Delay in sample transportation (n-32), Wrong timing for Collection (n-37), sample not received (SNR) (n-17), Sample from IV running area (n-08). Conclusion: The overall percentage of rejection found is 3.75 %. Hemolysis was the most common cause for sample rejection in clinical laboratory. Pre-analytical errors are not unavoidable and can be minimize by proper training of the staff and

checking competency thoroughly by conducting practical and theory assessment at frequent intervals.

**Keywords**---pre-analytical errors, clinical biochemistry laboratory, hemolysis.

## Introduction

Clinical Laboratory is the backbone to the hospital set up, as it contributes significantly in making the right diagnosis to the right patient at right time and hence the right treatment, which affects the duration of hospital stay, early treatment response and the well-being of the patient. [1] The majority of errors come from the pre-analytical phase, which is considered the basis for all laboratory works. Pre-preanalytical and true pre-analytic are two areas of the pre-analytical phase. Test selection, patient identification, sample collection, preparation and handling are part of the pre-pre-analytical process, while storing, pipetting and centrifugation sample are actual pre-analytical processes. [2] Currently, pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from problems in patient preparation, sample collection, transportation, and preparation for analysis and storage. [3]. Most errors affecting laboratory test results occur in the pre - analytical phase (46–68.2% of total errors) while a high error rate (18.5–47% of total errors) has also been found in the post-analytical phase. [4]. Figure: below shows the current stratification of errors in laboratory medicine and their distribution within the different phases of the testing processes

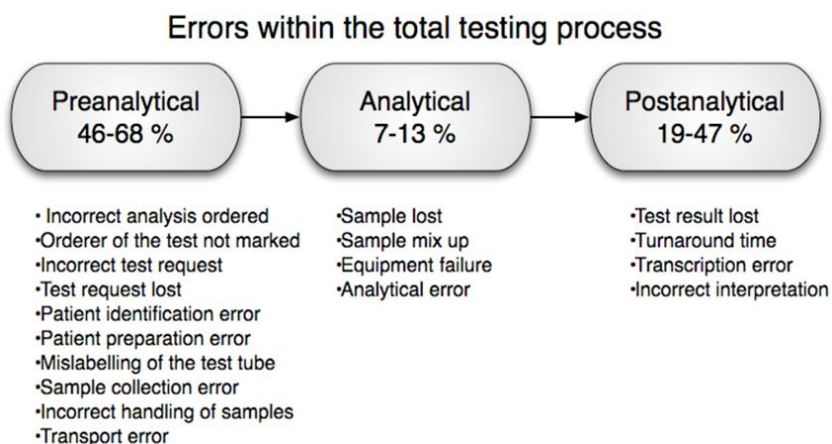


Figure 1. Shows the current stratification of errors in laboratory medicine and their distribution within the different phases of the testing processes. [4]

Accreditation programs according to EN ISO 15189:2012 require the laboratory to monitor and evaluate the preanalytical phase using quality indicators (QIs). Since the preanalytical phase step is mainly performed by the staff working outside the laboratory, it is difficult to manage and evaluate quality in this phase. In clinical laboratories, the laboratory staff, especially in the sample reception unit, have to be careful about the written policies for the sample reception and rejection

criteria. However, the human factor in the specimen collection and transport procedure are the root cause of these preanalytical phase errors. [5]

### **Objectives**

- To evaluate the pre-analytical errors during pre-analytical testing process;
- To formulate the possible corrective measures to be taken to minimise such errors.

### **Materials and Methods**

A prospective study was done for a period of 2 months from January 2022 to February 2022 in clinical biochemistry laboratory, central laboratory, Dhiraj General hospital, Piparia. All types of preanalytical errors were systematically recorded under following categories: Total 15189 specimens were received during this period. Out of which 569 were sorted with pre analytical errors.

- Improper test request forms
- Incorrect sample identification/ Improper labelling
- Insufficient sample (quantity of sample collected)
- Invalid samples (Haemolysed, lipemic or icteric samples)
- Sample mix ups
- Delay in sample transportation
- Wrong timing for Collection
- Sample not received (SNR)
- Sample from IV running area

Analysis of these errors was calculated as percentage.

### **Result**

A total of 15189 samples were analyzed in the clinical biochemistry laboratory for the period of 2 months, which included OPD & IPD samples, received from various clinical departments of our hospital. Out of 15,189 samples, pre-analytical errors were observed in 569 samples, which is approximately 3.75% of the total number of samples received. The distributions of different types of pre-analytical errors were calculated. Out of 15189 samples, 91 were Improper test request forms (0.60 %), 118 were Improper labelling (0.78 %), 121 were Insufficient sample (0.80 %), 127 were invalid samples (0.83 %), 18 were sample mix ups (0.12 %), 32 were delay in sample transportation (0.21 %), 37 were wrong timing for Collection (0.25 %), 17 were sample not received (SNR) (0.11 %), 08 were sample from IV running area (0.05 %), as mentioned in the table 1. All these samples were rejected for the testing and all these patients were advised for repeat fresh sample with proper test request form.

Table 1  
Shows the frequency and percentage of pre-analytical errors observed in month of  
January and February 2022

Sr. No	Pre analytical errors	JAN 22		FEB 22		Total no. of errors	Total no of percentage (%)
		Frequency	%	Frequency	%		
1	Improper test request forms	42	0.28	49	0.32	91	0.6
2	Incorrect sample identification	58	0.38	60	0.40	118	0.78
3	Insufficient sample	57	0.38	64	0.42	121	0.8
4	Invalid samples	61	0.40	66	0.43	127	0.83
5	Sample mix ups	10	0.07	8	0.05	18	0.12
6	Delay in sample transportation	15	0.10	17	0.11	32	0.21
7	Wrong timing for Collection	19	0.13	18	0.12	37	0.25
8	Sample not received	8	0.05	9	0.06	17	0.11
9	Sample from IV running area	3	0.02	5	0.03	08	0.05
TOTAL		273	1.81	296	1.94	569	3.75

### Discussion

A common assumption is that errors are most likely to occur in the analytical phase, the component of laboratory testing considered the most complex. Clinical laboratories invest considerable time and effort in maintaining quality control programs, participating in laboratory inspections, and complying with government regulations. In addition, significant advances in laboratory instrumentation and automation have improved the accuracy, reproducibility, and overall quality of the analytic phase. Contrary to popular belief, and perhaps as a consequence of the focus on technological improvements, it is actually the pre-analytic phase in which most errors occur. [6]

Errors can occur in any of the multiple steps involved in the pre-analytical phase it is imperative to catch the errors occurring during the pre-analytical phase itself. However, this is not always possible and occasionally these are detected in the analytical or post-analytical phases. Thus, although, analytical errors have reduced considerably, however a large proportion of pre-analytical errors occur and negatively impact the total error rate and subsequently reduce the accuracy of reported laboratory test results. [7] In the preanalytical phase, many professionals as physicians, specialists of laboratory medicine, nurses, laboratory technicians and phlebotomists are involved and is the hardest to regulate and monitor. [8]

In a study conducted by Namrata Bhutani et al concluded that haemolysis was the most common reason for sample rejection. (63.14% of total rejections).

Additionally, the second most common error was inadequate samples. [7]. Pre analytical errors were contributing significantly to laboratory errors (59.8%) as compared to analytical (30.84%) and post-analytical errors (9.35%). Hemolysed and clotted samples were the main causes of pre analytical errors (37.5% and 21.87% respectively). Calibration drifts were contributing mainly to analytical errors (39.39%). Transcription error (60%) was the main contributor to the post analytical error. [9]

Invalid samples include, haemolysed, lipemic and icteric samples. Hemolysed samples were most frequent preanalytical error in invalid samples in our study. Hemolysis leads to false high values of different parameters like potassium, SGOT and LDH. Also it increases the turnaround time. In our study, preanalytical errors which leads to rejection of blood samples were improper request forms, incorrect sample identification, insufficient samples and haemolysed samples. Insufficient sample volume is the main cause in paediatric patients and difficult to minimize. These preanalytical errors can minimize with proper training at various level. To overcome pre - analytical errors, the following corrective measures have been recommended [4]:

- Skilled staff: skilled and adequate staff to maintain collection standards, which give an extra verge of expertise.
- Phlebotomists: with proper knowledge pertaining to phlebotomy (trained personnel)
- Regular educational competency assessments should be encouraged to allow (new and old personal) an opportunity to recognize and manage errors.
- Vacutainers: Proper knowledge regarding use of evacuated tube system to the lab personal pertaining to sample volume and use of anti- coagulants.
- Transport: laboratory personnel guided regarding importance of transport the specimens promptly to the laboratory at the earliest after collection to avoid errors related to delay.
- Advanced Technology: Usefulness of barcode scanners system for individual sample recognition.

## **Conclusion**

Hemolysis, insufficient samples and incorrect sample identification were the most common causes of rejection in clinical biochemistry lab. Pre-analytical errors can adversely affect the treatment of patients and difficult to minimize or eliminate. However, it can be reduced by proper training of the staff and checking competency thoroughly by conduction of practical and the theory assessment of staff at frequent intervals.

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