



## Original Research Article

## Study of pre analytical errors in clinical biochemistry laboratory in rural area of Punjab

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## ABSTRACT

**Introduction:** The pre analytical phase is an important component of laboratory medicine. It includes the time from the order of test by the clinician until the sample is ready for analysis – it can account up to 70% of errors during the total diagnostic process.

The major 5 key components for the establishment of quality and reliability in the laboratory diagnostics include (a) Quality laboratory process (QLPs), (b) Quality control(QC), (c) Quality Assurance/Assessment (QA), (d) Quality Improvement (QI) and (e) Quality policy(QP).

**Objectives:** 1. To stratify the pre-analytical errors documented 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 6 months from 1st august 2019 to 31<sup>st</sup> Jan 2020 in Clinical Biochemistry laboratory of PGIMER satellite centre, Sangrur. All types of pre-analytical errors were Recorded.

In our study, total blood specimens received during Aug 2019 to Jan 2020 were 2980. Out of which 284 specimens were sorted with pre analytical errors.

**Results:** These 284 specimens were categorised as follows:

Improper request form (n= 24); improper labelling (n=39); improper tube collection (n=51); insufficient sample n=48; in-vitro haemolysis (n=66), sample not received(SNR) (n=56).

**Conclusion:** Pre-analytical errors are not inevitable and can be avoided with a diligent application of proper quality control, proper education of phlebotomist about the errors and effective collection systems to improve the total quality management of laboratory so as to ensure total quality patient care.

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## 1. Introduction

The pre analytical phase is an important component of laboratory medicine. It includes the time from the order of test by the clinician until the sample is ready for analysis – it can account up to 70% of errors during the total diagnostic process.<sup>1</sup>

The major 5 key components for the establishment of quality and reliability in the laboratory include (a) Quality laboratory process (QLPs), (b) Quality control(QC), (c) Quality Assurance/Assessment (QA), (d) Quality Improvement (QI) and (e) Quality policy(QP).<sup>2</sup>

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## 2. Objectives

1. To stratify the pre-analytical errors documented during pre analytical testing process.
2. To formulate the possible corrective measures to be taken to minimise such errors.

## 3. Materials and Methods

A prospective study was done for a period of 6 months from 1st august 2019 to 31<sup>st</sup> Jan 2020 in Clinical laboratory of PGIMER satellite centre, Sangrur. All types of pre-analytical errors were recorded systematically under the following categories:

## The total testing process

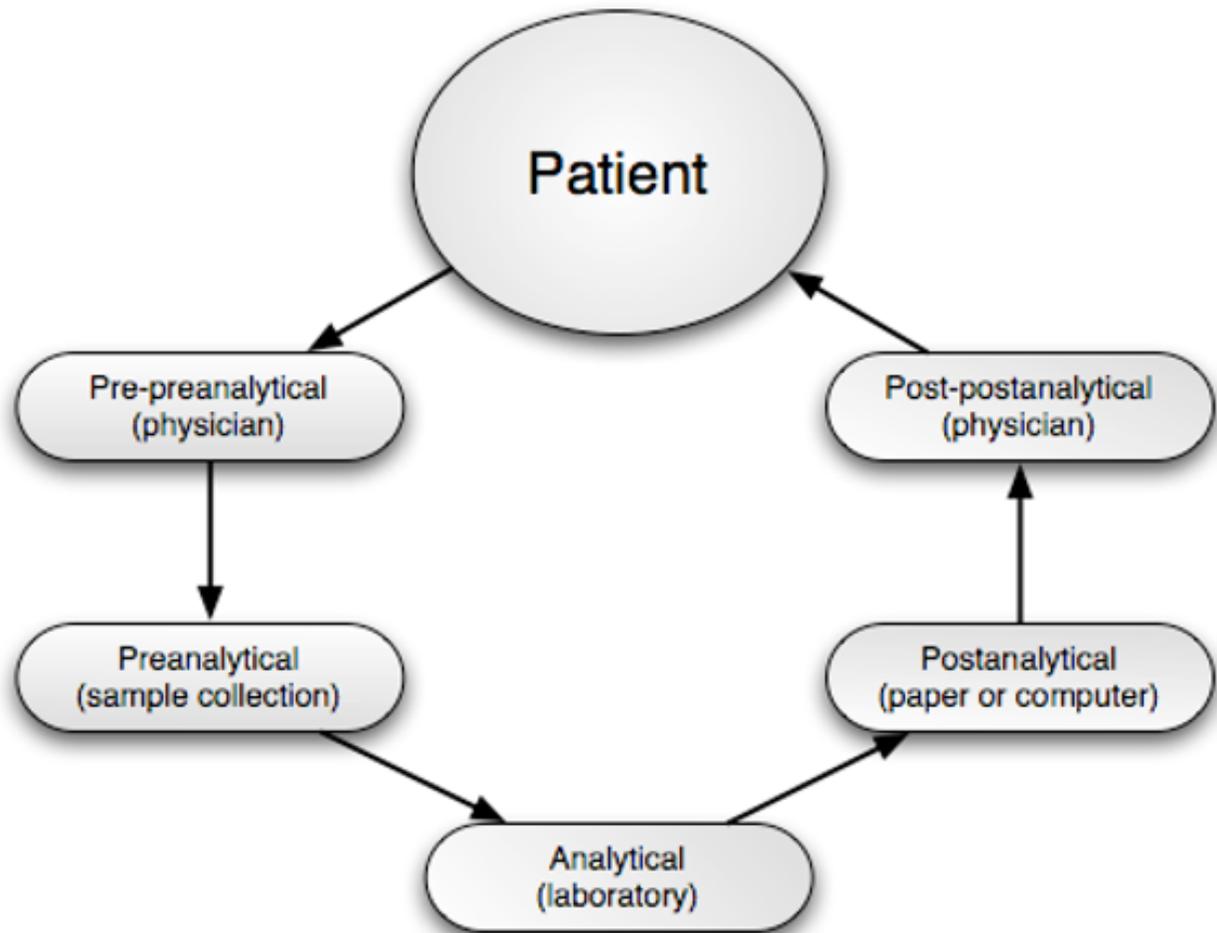


Fig. 1:

1. Improper request forms (sample requisition).
2. Incorrect identification/Improper labelling.
3. Insufficient volume (quantity of sample collected).
4. In-vitro haemolysis.
5. Improper tube (usage for sample collection).
6. Specimen handling.

The analysis of such errors was done by calculating the percentage and of each category.

#### 4. Observation & Result

Types of pre analytical errors: Table 1.

#### 5. Discussion

Pre-analytical errors have been the focus of research in past decades. Previous studies have focused on the analytical

phase of diagnostic tests, and many quality control programs were initiated at diagnostic labs to monitor analytical phase errors.

However, post- and pre-analytical errors were neglected worldwide, and currently many studies are focusing on the importance of the pre-analytical phase to obtain accurate lab results.

An American pathologist program conducted a study enrolling 660 laboratories and showed that preanalytical errors were 4.8%.<sup>3</sup>

The College of American Pathologists, including 120 labs, concluded that misidentification is a common laboratory error.<sup>4</sup>

A Danish study on laboratory errors showed that 81% of lab errors were pre-analytical, while only 10% of lab errors were analytical. Moreover, 82.6% human errors and 4.3% technical errors were observed

## Errors within the total testing process

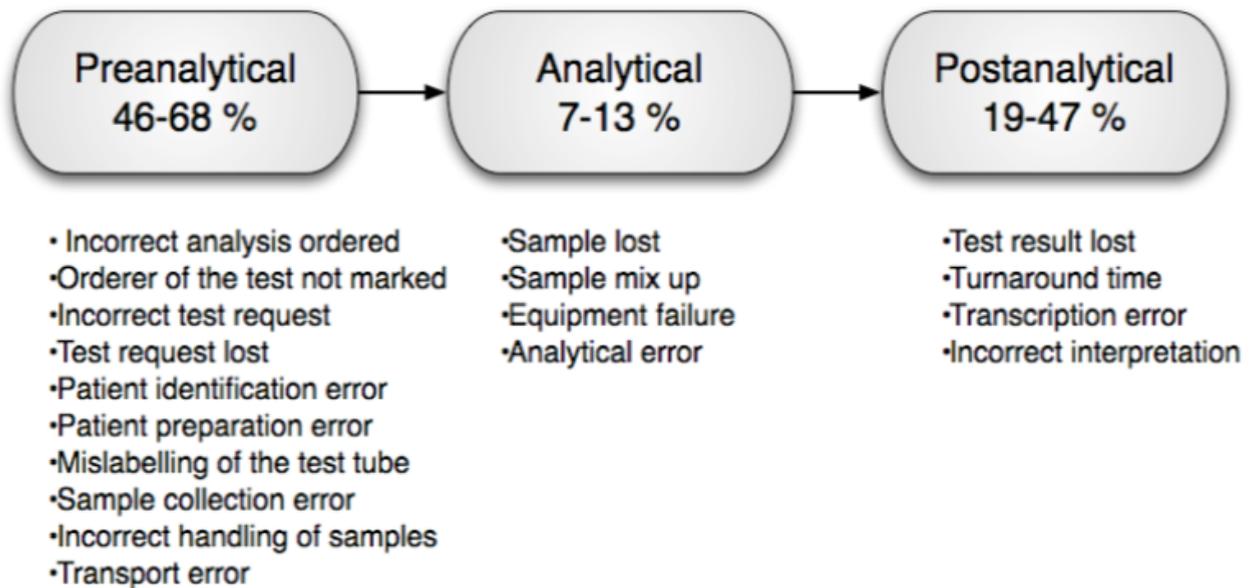


Fig. 2:

Table 1: Pre analytical errors

Month	Improper request	Improper labelling	Insufficient sample	Improper tube collection	Hemolysis	Sample not received	Errors	Total OPD
August	5 (1.02)	7( 1.42)	7(1.42 )	7(1.42 )	13( 2.65)	10(2.04 )	49(10 )	490
Sept	5 (0.92 )	6( 1.11)	8(1.48 )	8( 1.48)	12(2.22 )	9( 1.66)	48( 8.88)	540
Oct	4 (0.71 )	8(1.42)	10(1.78)	12(2.14)	8(1.42)	10(1.78)	52(9.28)	560
Nov	3(0.6 )	7(1.4)	12 (2.4)	10(2)	10(2)	8(1.6)	50(10)	499
Dec	4( 0.83)	5 (1.04)	5(1.04)	6(1.25)	14(2.91)	11(2.29)	45(9.37)	480
Jan	3(0.72 )	6 (1.45)	6 (1.45)	8( 1.94)	9 (2.18)	8 (1.94)	40(9.73)	411
Total	24(0.8 )	39 (1.3)	48(1.6)	51(1.71)	66(2.2)	56 (1.87)	284(9.53)	2980

There has been varied information on the error rate within the whole lab testing procedure (0.1% to 9.3%).

Plebani and Carraro observed in their paper that the great majority of errors result from problems in the preanalytical or post-analytical phases.<sup>5</sup>

In a study by Jay and colleagues, the majority of hemolyzed samples (>95%) could be attributed to in vitro processes resulting from incorrect sampling procedure or transportation.<sup>6</sup>

The rate of hemolysis in the present study (2.2%) comparable with study conducted by Salvagno GL et al 2012 where they observed 4% in whole blood sample.<sup>7</sup>

Hemolysis leads to the extravasation of intracellular contents into the plasma, leading to false high values of potassium and intracellular enzymes such as SGOT and LDH. It also leads to a prolonged turnaround time (TAT) due to the need for fresh samples for processing the request.

Another factor leading to rejection of blood samples in our study was insufficient blood volume. Every analytical process requires a fixed volume of serum/plasma for analysis. The main reasons behind this anomaly are ignorance of the phlebotomists, difficult sampling as in pediatric patients, patients with chronic, debilitating diseases, and patients on chemotherapy whose thin veins are difficult to localize. Insufficient sample volume constituted the most frequent cause of test rejection in the samples collected in the OPD (0.37%).

Binita Goswami et al. collected data for 67438 routine venous blood specimens and found 77.1% pre analytical errors followed by post analytical 15% and analytical 7.9%, respectively.<sup>8</sup>

It is clear from the above discussion that incorrect phlebotomy practices are the main reason behind preanalytical errors. The reason for incorrect phlebotomy practice includes lack of awareness or possibly a heavy

workload. This is the reason phlebotomy has been considered a separate area of improvement for medical technician.<sup>9</sup>

To overcome pre - analytical errors, the following corrective measures have been recommended: (Lippi G et al, Sciacovellia L et al, Jo Gile T).

1. Skilled staff: skilled and adequate staff to maintain collection standards, which give an extra verge of expertise.<sup>10</sup>
2. Phlebotomists: with proper knowledge pertaining to phlebotomy (trained personnel)
3. Regular educational competency assessments should be encouraged to allow (new and old personal) an opportunity to recognize and manage errors.
4. Vacutainers: Proper knowledge regarding use of evacuated tube system to the lab personal pertaining to sample volume and use of anti- coagulants.<sup>11</sup>
5. 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.
6. Advanced Technology: Usefulness of barcode scanners system for individual sample recognition.

## 6. Conclusion

Now a day, pre-eminent advances in laboratory automation, sample collection, transport, and report dispatch leads to an utmost improvement in laboratories performance. But still there is long path to pace before we achieve 100% accuracy and precision.

Pre-analytical errors are not unavoidable, but we can minimize or eliminate it by improving laboratory testing. Promoting quality control and systemic monitoring, will help to improve test reliability and thus enable physicians to have optimal clinical management for patient care.

Laboratory experts should implement continuous internal programs not only for detection of analytical errors but for overall quality management & improvement in laboratories. Proper exhaustive program should be silhouette for laboratory personnel like orientation program regarding total quality management to attain better laboratory testing, monitoring, reporting and performance in terms of accuracy, precision and will eventually assists physicians to have favourable insights in patients care.

## 7. Source of Funding

None.

## 8. Conflict of Interest

None.

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