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Clinical Biochemistry

STUDY OF PRE ANALYTICAL ERRORS IN CLINICAL BIOCHEMISTRY LABORATORY IN A TERTIARY REFERRAL RURAL HOSPITAL

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ABSTRACT The pre-analytical phase holds significance in the realm of laboratory medicine, encompassing the duration from the clinician's test order until the sample is prepared for analysis. This phase is crucial, as it can contribute to up to 70% of errors throughout the entire diagnostic process. The key components essential for ensuring quality and reliability in laboratory diagnostics are comprised of (a) Quality Laboratory Process (QLPs), (b) Quality Control (QC), (c) Quality Assurance/Assessment (QA), (d) Quality Improvement (QI), and (e) Quality Policy (QP). These five components form the foundation for establishing and maintaining the standards necessary for accurate and reliable laboratory diagnostics. A prospective study was done for a period of 6 months from 1st June 2023 to 30th November 2023 in Clinical Biochemistry laboratory of Karuna medical college, Palakkad. All types of pre-analytical errors were recorded. In our study, total blood specimens received during June 2023 to November 2023 were 21141. Out of which 608 specimens were sorted with pre analytical errors. A meticulous implementation of effective quality control measures, comprehensive education for phlebotomists regarding potential errors, and the adoption of efficient collection systems are essential steps to enhance the overall quality management of the laboratory. These measures are instrumental in ensuring comprehensive total quality patient care.

KEYWORDS : Preanalytical Errors, Quality Control, Clinical Biochemistry

INTRODUCTION

The pre-analytical phase holds significance in laboratory medicine, encompassing the duration from the clinician's test order to the preparedness of the sample for analysis. This phase is pivotal, as it has the potential to contribute to as much as 70% of errors in the overall diagnostic process[1]. The establishment of quality and reliability in the laboratory hinges on five major components: (a) Quality Laboratory Process (QLPs), (b) Quality Control (QC), (c) Quality Assurance/ Assessment (QA), (d) Quality Improvement (QI), and (e) Quality Policy (QP)[2].

These essential components operate within a feedback loop and should be seamlessly integrated. Errors impacting any of the aforementioned key components can have repercussions on the entire quality management system of the laboratory. Research indicates that errors related to preanalytical variables contribute to more than one-third to 50% of all laboratory errors[3]. Understanding the nature and extent of preanalytical errors specific to each laboratory, along with their impact on Total Quality Management (TQM), is crucial for establishing tailored quality goals and implementing effective measures. These goals will vary among laboratories and play a pivotal role in enhancing overall quality and reliability in the diagnostic process[4]. Motivated by this, we have undertaken a study to assess the types, frequency, and magnitude of errors in our tertiary health care clinical biochemistry laboratory during the preanalytical testing process, aiming to gauge their overall impact on the laboratory's Total Quality Management system. Furthermore, we have endeavored to devise corrective measures to eliminate potential preanalytical errors in the future.

OBJECTIVES

1. Stratifying the preanalytical errors recorded during the preanalytical testing process.
2. Developing potential corrective measures to minimize these errors.

MATERIALS AND METHODS

A prospective study was done for a period of 6 months from 1st June 2023 to 30th November 2023 in Clinical laboratory of Karuna medical college, Vilayodi. All types of preanalytical errors were recorded systematically under the following categories:

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.

OBSERVATION AND RESULT

Table 1: Total number of samples and pre analytical errors per month

Month	Improper request	Improper labelling	Insufficient sample	Improper tube collection	Hemolysis	Sample not received	Errors	Total OPD
June-23	16 (0.51)	11(0.35)	32(1.02)	23 (0.74)	32 (1.02)	12 (0.38)	126 (4.03)	3124
Jul-23	14 (0.41)	13 (0.38)	35 (1.01)	21 (0.61)	12 (0.35)	11 (0.32)	106(3)	3450
Aug-23	15 (0.42)	12 (0.34)	30 (0.84)	20 (0.56)	33 (0.93)	10 (0.28)	120 (3.36)	3567
Sep-23	14 (0.38)	13 (0.35)	29 (0.79)	21 (0.57)	35 (0.95)	11 (0.30)	123 (3.34)	3678
Oct-23	12 (0.31)	12 (0.31)	31 (0.80)	22 (0.57)	33 (0.85)	10 (0.26)	120 (3.10)	3876
Nov-23	11 (0.32)	11 (0.32)	33 (0.96)	21 (0.61)	32 (0.93)	11 (0.32)	119 (3.45)	3446
							608 (2.88)	21141

DISCUSSION

In recent decades, there has been a notable shift in research focus towards preanalytical errors. While earlier studies concentrated on the analytical phase of diagnostic tests, numerous quality control programs were introduced in diagnostic labs to monitor errors during this phase. Surprisingly, post- and pre-analytical errors received little attention globally. Presently, there is a growing emphasis on recognizing the significance of the pre-analytical phase for achieving accurate laboratory results.Figure 1: The total testing process

A study conducted by an American pathologist program, involving 660 laboratories, revealed that preanalytical errors accounted for 4.8%[5]. The College of American Pathologists, with 120 labs under consideration, identified misidentification as a prevalent laboratory error[6].

Highlighting the prevalence of pre-analytical errors, a Danish study on laboratory errors indicated that a substantial 81% of lab errors occurred in the pre-analytical phase, while only 10% were analytical errors. The study also noted that 82.6% of errors were attributed to human factors, with technical errors contributing 4.3%.

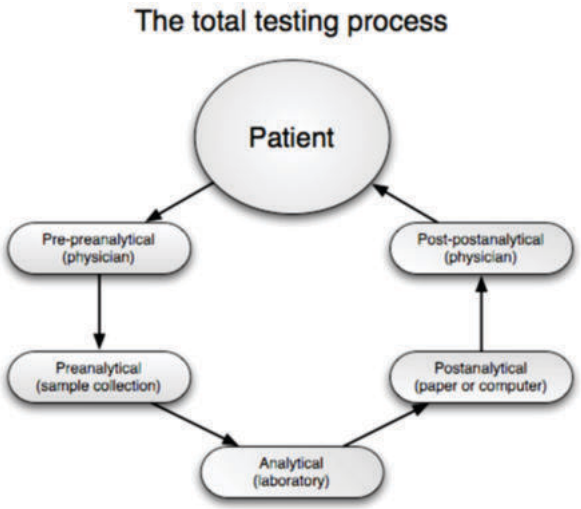

Figure 1: The total testing process

According to a study conducted by Jay and colleagues, the majority of hemolysed samples (>95%) could be attributed to in vitro processes resulting from incorrect sampling procedures or transportation[7]. In the current study, the hemolysis rate (2.2%) is comparable to a study by Salvagno GL et al in 2012, where they observed a 4% hemolysis rate in whole blood samples[8]. Hemolysis induces the release of intracellular contents into the plasma, leading to falsely elevated values of potassium and intracellular enzymes such as SGOT and LDH. Additionally, hemolysis contributes to a prolonged turnaround time (TAT) as fresh samples are required for processing the request.

Another factor contributing to the rejection of blood samples in our study was insufficient blood volume. Each analytical process necessitates a specific volume of serum/plasma for analysis. The primary reasons for this issue include phlebotomists' lack of awareness and challenges in sampling, particularly in pediatric patients.

Binita Goswami and colleagues gathered data from individuals with chronic, debilitating diseases and patients undergoing chemotherapy, where locating thin veins proved challenging. The primary cause of test rejection in samples collected in the OPD was insufficient sample volume, accounting for 0.37%[9].

In their study involving 67,438 routine venous blood specimens, Binita Goswami et al. identified preanalytical errors as the most prevalent, constituting 77.1%, followed by post-analytical errors at 15%, and analytical errors at 7.9%.

The discussion underscores that incorrect phlebotomy practices are the primary cause of preanalytical errors. Factors contributing to such practices include a lack of awareness or a potentially heavy workload. This is why phlebotomy has been identified as a distinct area for improvement among medical technicians[10].Figure 2: Errors within the total testing process

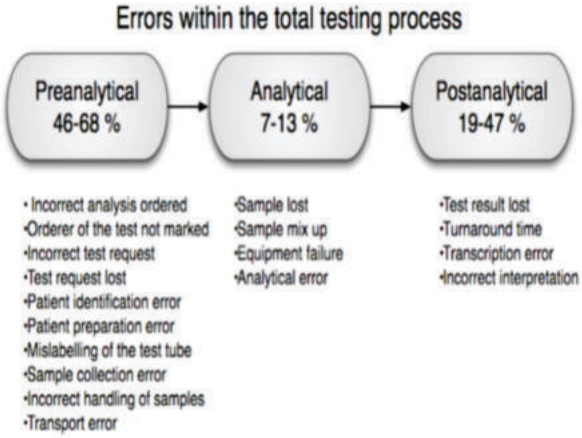

Figure 2: Errors within the total testing process

To address pre-analytical errors, the following corrective measures have been recommended by experts such as Lippi G, Sciacovellia L, and Jo Gile T[11]:

1. Skilled Staff: Employ skilled and sufficient staff to uphold collection standards, ensuring an additional level of expertise.

2. Phlebotomists: Utilize trained personnel with proper knowledge of phlebotomy.

3. Regular Educational Competency Assessments: Encourage ongoing assessments to provide both new and experienced staff with opportunities to recognize and manage errors.

4. Vacutainers: Ensure lab personnel have proper knowledge of the evacuated tube system, including sample volume and the use of anticoagulants.

5. Transport: Guide laboratory personnel on the importance of promptly transporting specimens to the laboratory after collection to prevent errors related to delays.

6. Advanced Technology: Emphasize the utility of barcode scanner systems for individual sample recognition.

CONCLUSION

In the contemporary landscape, significant advancements in laboratory automation, sample collection, transport, and report dispatch have immensely enhanced laboratory performance. Despite these strides, there is still a considerable journey ahead before achieving 100% accuracy and precision.

While pre-analytical errors are not entirely avoidable, they can be minimized or eliminated through enhancements in laboratory testing. Advocating for quality control and systemic monitoring will contribute to improved test reliability, enabling physicians to optimize clinical management for patient care.

Laboratory experts should institute ongoing internal programs that extend beyond the detection of analytical errors, encompassing overall quality management and improvement within laboratories. A comprehensive program tailored for laboratory personnel, including orientation programs on total quality management, is essential for achieving superior laboratory testing, monitoring, reporting, and performance in terms of accuracy and precision. Ultimately, these efforts will provide physicians with valuable insights for more effective patient care.

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Conflict of Interest
None.

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