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A STUDY OF PRE-ANALYTICAL VARIABLES IN A CLINICAL BIOCHEMISTRY LABORATORY OF A TERTIARY CARE CENTRE OF ASSAM

Biochemistry

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ABSTRACT

Objectives: Pre-analytical errors decisively influence the total error and consequently the diagnostic accuracy. The following were the objectives for the study:

1. To detect the percentage of pre-analytical errors in clinical biochemistry laboratory
2. To categorize these pre-analytical errors
3. To formulate corrective measures to be taken to avoid such errors

Design and methods: Study period was for 3 months with documenting the frequency and type of pre-analytical errors occurring in the venous samples.

Result: Average pre-analytical errors were 44.7% per day. Improper request, incorrect timing of sample, wrong tube collection and in-vitro hemolysis of samples amounted to the major proportion of errors.

Conclusion: Pre-analytical errors occurring in each laboratory have to be checked. Such errors are not inevitable and can be avoided with a diligent application of quality control, continuing education and effective collection systems to ensure total quality patient care.

KEYWORDS

Errors, Pre-analytical, Quality

1. Introduction

Laboratory diagnostics, a pivotal part of clinical decision making, is no safer than other areas of healthcare. In general when we speak of errors in the laboratory, we commonly refer to the analytical errors.

Pre-analytical errors decisively influence the total error and consequently the diagnostic accuracy [7]. Hence, pre-analytical phase accounts for an important phase of laboratory medicine and total laboratory quality.

Remarkable advances in instrument technology, automation and computer science have greatly simplified many aspects of laboratory diagnostics and analytical errors are no longer the main factor influencing the reliability and clinical utilization of laboratory diagnostics. In recent decades, evidences have demonstrated that quality in clinical laboratories cannot be assured by merely focusing on purely analytical aspects. Therefore, additional sources of variation like pre-analytical errors should become the focus for further quality improvements. Pre-analytical phase is much more vulnerable to uncertainties and accidents, which can substantially influence patient care [10].

It has been noticed that as much as 93% of errors encountered within the entire diagnostic process is largely due to lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage. Those errors relating to extra-analytical phases are harder to control. This highlights the importance of good laboratory practice and compliance with the new accreditation standards. It is necessary to adopt the suitable strategies for error prevention, including process redesign, the use of extra analytical specifications and improved communication among other clinical departments [4].

2. Materials and methods

A prospective study was done for a period of 3 months from 1st March 2018 to 30th May 2018 in clinical biochemistry laboratory of Jorhat Medical College and Hospital, Jorhat, Assam. We monitored the frequency and type of pre-analytical errors by screening all the inpatient venous blood samples received from the wards collected by the nurses/interns before the analytical phase was undertaken.

The objectives of the study were as follows:

1. To detect the percent of pre-analytical errors in clinical biochemistry laboratory
2. To categorize these pre-analytical errors
3. To formulate corrective measures to be taken to avoid such errors

All types of pre-analytical errors were documented by technical assistants and later verified by laboratory in-charge for final decision making.

'Pre-analytical variables' were recorded systematically under the following categories:

1. Improper request
2. Incorrect identification/Improper labelling
3. Timing of sample
4. Insufficient volume
5. In-vitro hemolysis
6. Wrong tube collection
7. Specimen handling & transport

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

3.Observation & results

Total number of samples received in 3 months was 11,883, of which 5334 showed variations. Table 1 shows total pre-analytical errors & their percentage distribution for a period of 3 months.

TABLE 1

Total pre-analytical errors & their percentage distribution				
MONTH	MARCH	APRIL	MAY	OVERALL
Total pre-analytical errors/day	71	55	51	177
Average venous samples/day	139	126	131	396
Percentage of pre-analytical errors	51.1 %	43.7 %	38.9 %	44.7 %

Pre-analytical errors happening at various levels of sampling namely at the level of patient identification, sample collection and sample transport have been shown in Table 2

TABLE 2

Distribution of pre-analytical errors at various levels of sample collection.				
MONTH	MARCH (%)	APRIL (%)	MAY (%)	OVERALL (%)
Errors occurring at the level of patient identification				
Improper request	20(28.2)	15(27.3)	16(31.4)	51(28.8)

Incorrect identification/ improper labelling	2(2.8)	2(3.6)	1(2.0)	5(2.8)
Errors occurring at the level of sample collection				
Improper timing of sample	15(21.1)	10(18.2)	12(23.5)	37(20.9)
Insufficient sample	5(7.0)	4(7.3)	4(7.8)	13(7.3)
Improper tube collection	11(15.5)	8(14.5)	8(15.7)	27(15.3)
Errors occurring during sample transport				
Delay in specimen handling & transport	3(4.2)	4(7.3)	3(5.9)	10(5.6)
In-vitro hemolysis	15(21.1)	12(21.8)	7(13.7)	34(19.2)
Total pre-analytical errors	71(100)	55(100)	51(100)	177(100)

4.Discussion

In a 3 month study of pre-analytical variations, it was observed that errors amounted to an average of 44.7% per day. Our figures are close to J Kalra report on pre-analytical variations (46–68.2%).

Among different categories, improper request, timing of sample, improper tube collection and in-vitro hemolysis of samples amounted to the major proportion among variations. A study done in Denmark by Pal Bela Szecsi and Lars Ødum for over one year period, found that pre-analytical errors amounted to as high as 81%. They have concluded that each clinical laboratory should record errors in a structured manner. [9].

Similarly, Binita Goswami and her associates suggest pre-analytical errors were common, with a frequency of 77.1% [1]. Their observations are much higher than the observations in the present study.

However, in the present study, errors like improper labelling of samples, insufficient sample volume and delay in specimen reaching the laboratory were in a small proportion. Lippi and his fellow members in their study reported insufficient specimen quality and quantity accounting for over 60% of pre-analytical errors [5] and 1% patient misidentification errors [7].

A literature survey study published in 2002 by Bonini & his co-workers clearly suggests there is a large heterogeneity in laboratory errors and they recommend for the implementation of a more rigorous methodology for error detection and classification, and the adoption of proper technologies for error reduction. Elimination of pre-analytical errors can be done by taking certain proactive steps and is must for good laboratory practice.

Lippi & Guidi emphasized to develop a reliable approach to overcome this problem entails prediction of accidental events, an increase in and diversification of defences and a decrease in vulnerability to overcome such pre-analytical variations [3].

From our study, to overcome such errors, the following corrective measures have been formulated:

I. Phlebotomy staffing: Adequate staffing to maintain collection standards [6], which give an extra edge of expertise.
II. Phlebotomy education: Phlebotomists should have completed a standard academic course in phlebotomy and undergo thorough on-the-job training under supervision.
III. Continuing education: Phlebotomists should participate in regular educational competency assessments, both written and observational, which give them an opportunity to recognize and overcome errors [6].
IV. Vacutainers: Use of evacuated tube system will overcome errors pertaining to sample volume and use of anti-coagulants [8].
V. Prompt transport: Education given to transport personnel to transport the specimens promptly to the laboratory soon after collection avoiding errors related to delay.
VI. Technology: Incorporation of barcode scanners for patient identification will recognize them individually [2].

5. Conclusion

Pre-analytical phase is a more vulnerable area to uncertainties and accidents, the errors accounted to a large extent can determine the outcome of patient care. The frequency and type of errors occurring in every laboratory must be documented and corrective measures should be designed accordingly to overcome such errors completely. Continuing such practice by laboratories will help in ensuring quality and patient care.

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