

The influence of Pre-analytical Variable in the Biochemistry Laboratory

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ABSTRACT

Background and objective: The use of autoanalysers in the Clinical Laboratories has reduced the analytical errors but the pre analytical errors have a greater impact on the total error and diagnostic accuracy of the Clinical Biochemistry Laboratory reports. Hence this study was designed to evaluate the percentage of pre analytical error in the biochemistry laboratory of the regional diagnostic centre at Sriram Chandra Bhanja Medical College and Hospital (SCB MCH) and to develop preventive and corrective measures for the above errors.

Material and methods: The study was conducted during June 2019 to August 2019 a period of 3 months. The study was undertaken to access the sampling errors in a biochemistry laboratory of a tertiary care hospital. It was a prospective study. All the pre analytical errors were categorized and documented.

Observations: In the three months of study period, it was observed at 27.4% of pre analytical errors occur per day. The various categories were –Improper test request forms, incorrect blood collection tube, incorrect sample collection timing and hemolysis of the sample. The majority of pre analytical errors occurred in the indoor collection samples.

Discussion and conclusion: The pre analytical errors influence the diagnostic accuracy and affect critical value of the test results. Hence each laboratory should avoid such events by stringent quality control measures, awareness among sample collection personnel in order to provide quality patient care.

Key words: Pre-analytic phase, pre-analytic errors.

INTRODUCTION

In the present day health care, laboratory results play an important role in clinical decisions and affect patient treatment. The use of auto-analyzers has reduced the analytic errors. Hence, pre

analytical variables affect the diagnostic accuracy of the test results [1]. The pre analytical phase is an important component of laboratory medicine [2-5].

The introduction of automation instrument technology and computerization has simplified the analytical phase of the laboratories. The analytical errors have reduced to minimal and do not affect the test results. The reliability and clinical application of laboratory diagnostics has increased. Recently the focus in the quest for error free quality reporting has evidenced the role of pre analytical variables in the accuracy of laboratory reports. Hence, the pre analytical phase should be evaluated for the errors to improve the quality of lab results. The pre analytical phase is very liable to precariousness and affects patient care substantially. It has been observed that 67% errors encountered in laboratory diagnostic processes is due to use of unstandardized processes such as incomplete T.R.F. (Test request form), Improper patient preparation, incorrect blood collection tube, improper storage and transport. In order to comply to accreditation standards and achieve good clinical practice, it is necessary to adopt suitable methods to avoid errors in the pre analytical and extra-analytical phase.

Hence this study aims to evaluate the percentage of pre analytical errors in the biochemical section of RDC (Regional Diagnostics Centre) and to develop preventive and corrective measures for the above errors.

MATERIAL AND METHODS

The study was conducted in the biochemical section of the Regional Diagnostics Centre (RDC) of SCB Medical College and Hospital for a period of 3 months from June 2019 to August 2019. The pre analytical errors were categorized and the frequency was noted. The various categories of pre analytical errors were as follows:

1. Incomplete TRF
2. Use of incorrect blood collection tube
3. Improper labeling on the sample
4. Illegible handwriting
5. Not mentioning the date and time of collection

OBSERVATION

We encountered the various categories of Pre analytical errors, and calculated the percentage of each error (Table1).

Table1 showing the frequency of various categories of Pre analytical errors

Sl.No.	Category	Percentage
1	Incomplete TRF	14%
2	Use of incorrect blood collection tube	6%
3	Improper labeling on the sample	12%
4	Illegible handwriting	15%
5	Not mentioning the date and time of collection	14%
Total (Percentage)		61%

DISCUSSION

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.^[6] Pre analytical errors are largely due to human errors, and they are preventable as they involve mostly human handling in comparison to analytic and post analytic phase.^[7,8]

The pre-analytical errors include two types of variables. Patient related such as age, sex, positional effects, exercise, stress and menstruation. Sample related variables such as hemolysis, sample collection technique, transport and storage.

Patient identification process is the first important step, and any deviation from

patient identification procedure can lead to gross errors. Now days, two identifiers of patient-name and unique identification number, sometimes a wristband and occasionally attendant in case of comatose patient are used for identification. The use of unlabelled or incorrectly labeled tube for sample collection is prone to error. The vials should contain the patient name, unique ID, age, sex, date of collection and time of collection.

It is mandatory to follow the order of draw as it can lead to wrong test result due to contamination with additive from previous blood collection tube. Proper venipuncture technique, maintaining aseptic conditions, allowing drying of antiseptic before skin prick, avoidance of prolonged application of tourniquet, repeated clenching of fist and vigorous shaking of tubes can reduce error rate. There are studies which demonstrated lower incidence of pre-analytical error when laboratory personnel collect blood samples in comparison to nursing or other personnel.^[9]

Specimen should be transported in proper manner after collection to maintain its quality. Timely separation of plasma / serum with 24 hr of collection, protection of sunlight and appropriate storage and transport of specimens at recommended temperature are measures that improve laboratory results.

All those persons involved in this entire process from collection of sample to release of report should understand the impetus of pre-analytical phase and its impact on examination results. These include the patient, the clinician (ordering the test), nursing staff, phlebotomist, ward boy (sample collection and transport), medical technician (processing) and laboratory doctor (authentication and release of the reports).

Total elimination of medical error is not possible especially in analytical phase. But to minimize laboratory errors and to prevent the errors we should follow good laboratory practices. We need multidisciplinary approach involving all

stakeholders engaged in patient care process. Effective communication between all health care providers is the key element in reduction of human errors.

College of American Pathologists for laboratory inspection and accreditation address specimen related pre-analytical variable.^[9] The National Committee for Clinical Laboratory Standard in the USA update their guidelines on various aspects of pre-analytical variables.^[10] Each laboratory should have a quality manual addressing pre-analytical variables and device measures to recognize and control these crucial components of laboratory quality. Issue such as minimum sample volume needed for test, patient preparation, posture, duration of tourniquet application time, time of blood collection, processing guidelines, transport and storage conditions should be delineated.^[11]

Ultimately, it is the quality manual that acts as a standard reference book in troubleshooting erroneous results.

CONCLUSION

Pre-analytical phase is an important component of total laboratory quality. Standardization of pre-analytical phase is critical component on laboratory results. In health care system we need to pay attention to system factors involved in these errors and design an intelligent system approach to control and eliminate many of these errors. Strategies to recognize pre-analytical errors will help in improving the quality of the laboratory, which is finally within our hands.

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Conflict of interest:

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REFERENCES

1. Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Mattiuzzi C, Plebani M. Causes, consequences, detection, and prevention of

identification errors in laboratory diagnostics. *Clin Chem Lab Med.* 2009; 47(2):143-53.

2. Narayanan S. The preanalytic phase. An important component of laboratory medicine. *Am J Clin Pathol.* 2000 Mar; 113(3): 429-52.
3. Walter G, Guder, Sheshadri Narayanan, Hermann Wisser, Bernd Zawta Diagnostic Samples: From the Patient to the Laboratory: The Impact of Preanalytical Variables on the Quality of Laboratory Results, 4th, Updated Edition, September 2009 Wiley-Blackwell
4. Young DS. Effects of preanalytical variables on clinical laboratory tests. Washington, DC:AACC Press, 2nd ed, 1997.
5. Guder WG. Preanalytical factors and their influence on analytical quality specifications. *Scand J Clin Lab Invest.* 1999 Nov;59(7):545-9.
6. Lippi G, Chance JJ, Church S, Dazzi P, Fontana R, Giavarina D, Grankvist K, Huisman W, Kouri T, Palicka V, Plebani M, Puro V, Salvagno GL, Sandberg S, Sikaris K, Watson I, Stankovic AK, Simundic AM. Preanalytical quality improvement: from dream to reality. *Clin Chem Lab Med.* 2011 Jul;49(7):1113-26.
7. Kalra J. Medical errors: impact on clinical laboratories and other critical areas. *Clin Biochem.* 2004 Dec;37(12):1052-62.
8. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. *Clin Chem.* 2007 Jul;53(7):1338-42.
9. Szecsi PB, Ødum L. Error tracking in a clinical biochemistry laboratory. *Clin Chem Lab Med.* 2009;47(10):1253-7.
10. Sciacovelli L, Plebani M. The IFCC Working Group on laboratory errors and patient safety. *Clin Chim Acta.* 2009 Jun; 404(1):79-85.
11. Goswami B, Singh B, Chawla R, Mallika V. Evaluation of errors in a clinical laboratory: a one-year experience. *Clin Chem Lab Med.* 2010;48(1):63-6.

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