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ORIGINAL RESEARCH

Evaluation of Pre Analytical Errors in Clinical Biochemistry Laboratory and How to Minimize Them

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ABSTRACT

OBJECTIVE: to the study Evaluation of pre analytical errors in clinical biochemistry laboratory and how to minimize them

MATERIALS AND METHOD: A prospective study was done in the Clinical central laboratory symbiosis medical college for women & symbiosis university hospital research center, symbiosis international Deemed university pune, biochemical tests including blood glucose, renal function tests, liver function tests, lipid profile, phosphorus, uric acid, calcium, urine microprotein, other body fluids electrolytes, and blood gases were performed using the ERBA XL 340 and Trivitron Dirui Autoanalyzer. Serum samples were collected in plain vacutainer tubes having clot activator and gel separator. . Frequency of deficiencies in the request forms and different types of pre-analytical errors were recorded.

Results: the study period, the frequency of pre-analytical errors was about Sample hemolysis was the predominant error in sample collected from both indoor and outdoor patients.

Conclusion: pre-analytical errors requires continuous evaluation of source of errors, and By standardization and monitoring the steps involved in obtaining a sample, the pre-analytical errors will greatly reduce.

Keywords: Pre-analytical error, Process Capability Index, Lipemic Sample, Analytical, Post Analytical

INTRODUCTION

The pre analytical phase is an important component of laboratory medicine. Laboratory Medicine plays a vital role in modern day diagnosis and treatment. So it is pertinent that laboratory results which are generated are accurate as patient's health depends on it. The whole process of testing of a patient's blood from its ordering to its testing and then to its reporting and ultimately reaching the treating doctor can be divided into three broad steps The process of clinical laboratory testing comprises of 3 phases. Pre analytical, Analytical and Post analytical. The preanalytical phase includes a set of processes that take place from the time a laboratory request is made by a physician until the sample is ready for testing.[1] Errors can occur in any of these phases. In recent years, there is an increasing awareness of the importance of errors in laboratory practice and their possible negative impact on treatment outcomes. Advanced instrumentation and automation have simplified the work in the analytical phase but same is not true with regards to the pre-analytical phase.[2] Theoretically, the pre-analytical phase can be subdivided further into pre-pre-analytical phase and conventional phase. In the pre analytical phase, the clinician decides which test is to be ordered based on his knowledge and experience. The conventional phase involves series of processes starting with patient identification, selection of ideal tubes, proper transportation and storage, and preparation of samples.[3] Under the broad umbrella of the preanalytical phase specimen collection, handling and processing variables, physiological variables such as the effect of lifestyle, age, gender, pregnancy and menstruation and endogenous variables such as drugs and circulating antibodies can be included.[4] Some of the preanalytical variables such as specimen variables can be controlled, while acknowledge of uncontrollable variables need to be well understood in order to be able to separate their effects from disease related changes affecting laboratory results.[5] Most preanalytical errors result from system flaws and insufficient audit with operators involved in specimen collection handling responsibilities.[6] Preanalytical errors greatly interfere with the test analysis thus affects patient management protocols. Errors of this nature prove to be a burden for the laboratory and a serious issue for the hospital administration as sample rejection leads to loss of critical time and adds to the cost of patient care.[7,8] Errors at any of the phases can have a serious impact on the proper diagnosis and overall health of the patient. With automation of laboratory analysis laboratory errors have significantly

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decreased, especially those that occur during the analytical phase.70% of total errors within the entire diagnostic process occurs in pre-analytical phase.[1]

Though analytical errors have decreased but huge percentage of pre-analytical errors decisively influences the total error and consequently accuracy of test results. This study was conducted with the aim to enumerate the different errors taking place in the preanalytical phase and their frequency, so that steps can be taken to remove them and guarantee the accuracy of laboratory results generated.

MATERIALS AND METHOD

A prospective study was done in the Clinical central laboratory, symbiosis medical college for women & symbiosis university hospital research center, symbiosis international Deemed university pune.Clinical central laboratoryinternational Deemed university pune,tests including blood glucose, renal function tests, liver function tests, lipid profile, phosphorus, uric acid, calcium, urine microprotein, other body fluids electrolytes, and blood gases were performed using the ERBA XL 340 and Trivitron Dirui Autoanalyzer. Serum samples were collected in plain vacutainer tubes having clot activator and gel separator. Plasma was collected in vacutainer fluoride tubes for blood glucose estimation. Outdoor patient department were having computer generated paper with patient's detail and the test requested by the clinician. Indoor and outdoor samples were screened for the following pre-analytical errors: 1] Wrong number of sample, 2] Delay in sample transport, 3] Sample insufficient, 4] Sample hemolysed, 5] Clotted sample, 6] Sample collection in wrong container, 7] Sample contaminated, 8] Lipemic sample. parameters on laboratory request forms of indoor samples were screened for : (1) Patient Information: (a) Name (b) Age (c) Sex (d) Hospital number (e) Location (2) Clinical Information: (3) Sample Information: (a) Nature of the sample (b) Date and Time of collection. Clinical central laboratory symbiosis medical college for women & symbiosis university hospital research center, symbiosis international deemed university pune.

RESULTS

Table 1. The frequency of different pre-analytical errors in outdoor patients

No	Pre-analytical variables	Number (%)
1	Wrong numbering of sample	12(0.03%)
2	Delay in sample transport	15 (0.04%)
3	Sample insufficient	7 (0.02%)
4	Sample hemolysed	502 (1.3%)
5	Clotted sample	6(0.02%)
6	Wrong container	1 (0.002%)
7	Sample contaminated	3 (0.005%)
8	Lipemic sample	4(0.008%)

Table 2. The frequency of different pre-analytical errors in indoor patients

No	Pre-analytical variables	Number (%)
1	Wrong numbering of sample	19 (0.6%)
2	Delay in sample transport	15 (0.5%)
3	Sample insufficient	25 (0.8%)
4	Sample hemolysed	601 (20.3%)
5	Clotted sample	11 (0.3%)
6	Wrong container	11(0.4%)
7	Sample contaminated	9 (0.3%)
8	Lipemic sample	3(0.07%)

DISCUSSION

According to the Clinicians' decisions mainly rely on laboratory results; hence, laboratory errors must be kept to its minimum. With the advent of technologies, analytical errors have reduced and most errors are related to the pre-analytical phase.[9] In a retrospective study performed by Plebani et al., an Italian stat laboratory was assessed in 1996 and then in 2006. The study showed that about 65.09% of errors occurred in the pre-analytical phase, while about 23.2% and 11.68% of the errors occurred in the analytical and post-analytical phases, respectively.[10] A detail of the probable diagnosis or clinical information helps biochemists to correlate the critical results properly.[11] There is also huge controversy regarding reporting such results amongst laboratory specialists. Some laboratories manage hemolysed samples by reporting the results, but the final result is mathematically adjusted based on estimated degree of hemolysis.[12] Pre-analytical errors should never be considered as inevitable as they can easily be prevented with the right training and the use of proper quality control procedures in all phases of the collection and testing process. All employees should be required to take continuing education classes to ensure that not only are they familiar with current

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procedures, but that they become aware of any changes that can serve to reduce the risk of this type of error occurring.). This showed us where and how to take care of the lapses in the pre-analytical phase and ultimately improving the quality and performance of clinical laboratories as shown in other studies.[13,14] Serious conditions of hospitalized patients, heavy patient load, and variety of staff involved in the total testing processes may also increase the rate of error. Awareness should be raised amongst residents, interns, physicians, and nursing staff about the importance of providing all the required patient and sample information on the requisition form. Continuing education of phlebotomist, medical staff, and students on the correct blood collection procedure, sample volume, and proper mixing with anticoagulants should be encouraged. Samples should be received and numbered at collection center.[15-18] Pre-analytical errors damage an institution's reputation and impose a significant financial burden on the hospital and laboratory. Although it is not possible to eliminate all pre-analytical errors, compliance with best practices can significantly reduce their incidence.[19,20]

CONCLUSION

pre-analytical errors requires continuous evaluation of source of errors, By standardization and monitoring the steps involved in obtaining a sample, the pre-analytical errors will greatly reduce.In this regard, excellent two-way communication between clinicians and laboratory specialists is beneficial. The promotion of ideal phlebotomy practices and sample transport procedures is a pre-requisite for the efficacy of laboratory functioning.

REFERENCES

1. M Antonia LLopis, Virtudes Alvarez, Cecilia Martínez-Brú, Rubén Gómez, Núria Barba, Mercè Ibarz, Mariano Cortés, Montserrat Ventura and M. Jesús Alsina (2011).
2. Plebani M. Errors in clinical laboratories or errors in laboratory medicine? Clin Chem Lab Med .2006 Jun 1;44(6):750-9.
3. Sharma P. Preanalytical variables and laboratory performance. Indian Journal of Clinical Biochemistry. 2009 Apr;24(2):109.
4. Lippi G, Chance JJ, Church S, Dazzi P, Fontana R, et al. (2011) Pre-analytical quality improvement: from dream to reality. Clin Chem Lab Med 49: 1113-1126.
5. Plebani M (2010) The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 47: 101-110.
6. Singh NM, Sumarac Z. Quality indicators of the pre-analytical phase. J Med Biochem 2012; 31: 174-183.
7. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem. 1997;(8):4.
8. Karcher DS, Lehman CM. Clinical Consequences of Specimen Rejection: A College of American Pathologists Q-Probes Analysis of 78 Clinical Laboratories. Arch Pathol Lab Med. 2014 Aug;138(8):1003–8.
9. Dereen Najat; Prevalence of PreAnalytical Errors in Clinical Chemistry Diagnostic Labs in Sulaimani City of Iraqi Kurdistan. PLoS One. 2017; 12(1).
10. Plebani M. Errors in clinical laboratories or errors in laboratory medicine? Clin Chem Lab Med .2006 Jun 1;44(6):750-9.
11. Ezzelle J, Rodriguez-Chavez IR, Darden JM, Stirewalt M, Kunwar N, Hitchcock R, Walter T, D'souza MP. Guidelines on good clinical laboratory practice: bridging operations between research and clinical research laboratories. Journal of pharmaceutical and biomedical analysis. 2008 Jan 7;46(1):18-29.
12. Vermeer HJ, Steen G, Naus AJ, Goevaerts B, Agricola PT, Schoenmakers CH. Correction of patient results for Beckman Coulter LX-20 assays affected by interference due to hemoglobin, bilirubin or lipids: a practical approach. Clin Chem Lab Med. 2007;45(1):114-119.
13. Inal TC, GorurogluOzturk O, Kibar F, Cetiner S, Matyar S, Daglioglu G, et al. Lean six sigma methodologies improve clinical laboratory efficiency and reduce turnaround times. J Clin Lab Anal. 2018 Jan; 32(1):e22180.
14. Nevalainen D, Berte L, Kraft C, Leigh E, Picaso L, Morgan T. Evaluating Laboratory Performance on Quality Indicators With the Six Sigma Scale. Arch Pathol Lab Med. 2000;124:4.
15. Ezzelle J, Rodriguez-Chavez IR, Darden JM, Stirewalt M, Kunwar N, Hitchcock R, Walter T, D'souza MP. Guidelines on good clinical laboratory practice: bridging operations between research and clinical research laboratories. Journal of pharmaceutical and biomedical analysis. 2008 Jan 7;46(1):18-29.
16. . Nutt L, Zemlin AE, Erasmus RT. Incomplete laboratory request forms: the extent and impact on critical results at a tertiary hospital in South Africa. Annals of clinical biochemistry. 2008 Sep;45(5):463-6.
17. Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, et al. Haemolysis: an overview of the leading cause of unsuitable specimens in clinical laboratories. Clin Chem Lab Med. 2008;46(6):764-772.
18. . Jeffery J, Sharma A, Ayling RM. Detection of haemolysis and reporting of potassium results in samples from neonates. Annals of clinical biochemistry. 2009 May;46(3):222-5.
19. . Al-Ghaithi H, Pathare A, Al-Mamari S, Villacrucis R, Fawaz N, Alkindi S. Impact of Educational Activities in Reducing PreAnalytical Laboratory Errors: A quality initiative. Sultan Qaboos University Medical Journal. 2017 Aug;17(3):e309.
20. Chhillar N, Khurana S, Agarwal R, Singh NK; Effect of pre-analytical errors on Evaluation of Pre-Analytical Errors in Clinical … 8 quality of laboratory medicine at a neuropsychiatry institute in north India.Indian J Clin Biochem. 2011 Jan;26(1):46-9