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A Prospective Observational Study On Preanalytical Errors In A Tertiary Care Centre Based Clinical Chemistry Laboratory, Theni, Tamil Nadu, India.

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ABSTRACT

Clinical Laboratory Testing process is essential for appropriate diagnosis , management and follow up of Patients. It is pertinent that Laboratory results generated need to be accurate since management of the patient depends on investigation reports. The present study was carried out to identify the Preanalytical errors occurring in our laboratory and to device measures to avoid these errors in future. The Prospective study was conducted in Clinical Chemistry Laboratory – Govt. Theni Medical College for a period of 5 months from August 2021 to December 2021. Incomplete sample requisition forms, wrong Identification / mislabelling of samples, Insufficient volume, Invitro haemolysis, inappropriate container, mishandled specimens were recorded. The sample requisition forms of In patient and samples were screened. The analysis of each error was done by calculating the percentage of each type of error.The request forms were screened for Name, Age, Sex , Ward ,Clinical Diagnosis and History .In this study 87% of request forms were incomplete.27.11% of samples were hemolysed. The highest reason for sample rejection is insufficient volume of sample for analysis. 65.1% of samples were inadequate for analysis. The processes in Preanalytical phase is manually done and are more prone to errors. Awareness regarding Preanalytical error among doctors and staff nurses is essential to prevent Preanalytical error.

Keywords: Preanalytical errors, clinical, diagnosis, device measures.

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INTRODUCTION

Laboratory medicine has a major role in diagnosis and treatment of Patients.Accuracy of investigation results is of utmost importance, because treatment depends on the investigation results. The entire Clinical Laboratory process can be divided into three phases – Preanalytical, Analytical and Post analytical. Preanalytical Phase - the important component of Laboratory testing includesprocesses from ordering of test by the treating physician till the sample analysis. About 70 % of Laboratory error occur in this phase [1, 2]. The various steps in this phase includes ordering of tests by the physician, filling up of request forms , sample collection and labelling , sample transportation , receiving the sample in a laboratory and finally sample preparation for analysis [3, 4]. Error can occur in any of these steps and need to be monitored. Analytical errors have decreased to a great extent but the Preanalytical errors the major contributor of Laboratory error need to be curtailed and they are avoidable. Hence the present study was carried out to identify the Preanalytical error occurring in our laboratory and to device measures to avoid these errors in future.

MATERIALS AND METHODS

The Prospective study was conducted in Clinical Chemistry Laboratory – Govt. Theni Medical College for a period of 5 months from August 2021 to December 2021.The Preanalytical errors recorded were

- Incomplete sample requisition forms.
- Wrong Identification / mislabelling of samples
- Insufficient volume
- Invitro hemolysis
- Inappropriate container
- Mishandled specimens.

The sample requisition forms of In Patients were screened for Name, Age, Sex, In Patient number, Location – ward, Clinical history and Probable diagnosis. Improper centrifugation of samples was also recorded by looking for fibrin strands in sample and inadequate centrifugation. The analysis of each error was done by calculating the percentage of each type of error.

RESULTS

The total no of samples received in 5 months were 62,640. In Patient samples – 46,346 and Outpatient samples – 16,294. Requisition forms were provided for Inpatients alone.6022 Inpatient request forms contained all the necessary details. Remaining 40,324 requests forms were incomplete.

Table 1: Errors in Laboratory request form

S.No	Category	Number of error	Percentage of error
1	Name	04	0.01%
2	Age	320	0.8%
3	Gender	280	0.7%
4	Ward	8382	20.8%
5	In Patient number	36482	90.5%
6	Clinical details	20453	50.7%

The highest error rate was with entering the In Patient number.

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Table 2: Percentage of Preanalytical errors in Patient samples.

S.No	Category	Number of errors	Percentage of error
1	Sample collected in inappropriate container	67	2.21%
2	Delay in sample transport	22	0.7%
3	Sample not received	04	0.13%
4	Hemolysed sample	820	27.11%
5	Insufficient volume	1968	65.06%
6	Contamination from infusion route	42	1.4%
7	Contamination with EDTA sample	102	3.4%

The highest error rate was with inadequate sample for analysis. The second highest error rate was with invitro haemolysis of sample.

DISCUSSION

Laboratory Automation had decreased errors to a great extent. Analytical errors have been curtailed in most of the Diagnostic laboratories by participating in Quality control Programmes.Most of the errors occur in Preanalytical Phase. The term Preanalytical error was coined by Statland and Winkel in 1977. The term Preanalytical phase was coined by Statland and Winkel in 1977 [5]. Quality assurance guidelines for Preanalytical phase have been issued by Clinical Laboratory Standard Institute and the World Health Organization. In 2015, an opinion paper on Harmonization of Preanalytical phase was published by European Federation for Clinical Chemistry and Laboratory Medicine (EFLM)Working Group for Preanalytical Phase (WG-PRE) [6]. Accreditation programs according to EN ISO 15189:2012 requires the laboratory to be monitored and evaluated for Preanalytical phase using Quality indicators [7]. Since the Preanalytical phase step is mainly performed by the staff working outside the laboratory, it is difficult to manage and evaluate quality during this phase [8]. The Preanalytical error mostly occurs outside the Laboratory facilities and the root cause is human error [9].

In this study 87% of request forms were incomplete and 13% of request forms were complete. This may be due to lack of awareness regarding importance of Patient identification information The Age and Sex of the patient was not mentioned in 0.7% and 0.8 % of request forms. Age and Sex is essential for comparing with the proper reference range. Patient location was not mentioned in 20.8 % of request forms. Patient location would help us in proper dispatch of results and to communicate the critical results if any. Clinical diagnosis and History was not mentioned in 50.7% of request forms. A brief clinical note will help Biochemist to interpret the results and to do reflex testing. Nutt et al, reported that Clinical diagnosis was not mentioned in 19.1% , mentioned in 80.9%, the remaining 37.3 % were in abbreviated forms. Sometimes the sample reaches the Laboratory very late, in our study 0.7% of the samples reached after 5 hours from sample collection. The National Committee for Clinical Laboratory Standards(NCCLS) H5-A3 in 1994 had recommend that, a maximum of 2 hours can be allowed for transport of blood samples in the temperature range of 10-22^{o}C [1]. In samples with time lapse between collection and reception ,due to delayed separation of cells from Serum or Plasma- Glucose level will be reduced, hemolysis may occur and Potassium levels will increase and the sample become unsuitable for analysis. The Spanish Society of Clinical Chemistry (SECQ) Quality Assessment Program for the Preanalytical phase found that the most common Preanalytical error was “sample not received”, followed by “hemolysed samples” [10]. In our study 0.13% of the samples were missed and 27.11% of samples were hemolysed. In Inpatient sample hemolysis occurs during transportation by Patient attenders. The highest reason for sample rejection in our study is insufficient volume of sample for analysis. Most of these samples were received from Pediatric wards. About 65.1% of samples were inadequate for analysis. This may be due to difficulty in blood sample collection in pediatric patients. Lippi etal reported inadequate sample Volume accounting for about 60% of pre-analytical errors [11]. Carroroetal showed that patient identification is the second commonest error [4]. Atay et al. reported that the rejection rates for hemolysis, clotted specimen, and insufficient volume were 8%, 24%, and 34%, respectively whereas the fill volume error had the highest rate [9].

The processes in Preanalytical phase is manually done and are more prone to errors. Awareness regarding Preanalytical error among doctors and staff nurses is essential to prevent this. Continuous Training of Phlebotomist and medical staff for proper collection technique, identification of appropriate

tubes, mixing the tubes with additive need to done. Satellite Sample collection centers may reduce delay in transport and missing of samples.

The limitation of this study is that Phlebotomy procedure was not observed. Samples from OP Department were not included.

CONCLUSION

Continuous education and Training regarding Preanalytical process and reinforcement will help us in reducing the Preanalytical error. Inadequate volume the common error in our study could be eliminated by proper phlebotomy technique and knowledge of sample requirement for various tests and co-operation from Patients. Co-operation from other medical departments is required in providing correct information regarding the patient and the sample, for appropriate tests processing and result interpretation.

REFERENCES

[1] M Antonia LLopis, Virtudes Alvarez, Cecilia Martínez-Brú, Rubén Gómez, Núria Barba, MercèIbarz, Mariano Cortés, Montserrat Ventura and M. Jesús Alsina. (2011). Quality Assurance in the Preanalytical Phase, Applications and Experiences of Quality Control, Prof. OgnyanIvanov (Ed.), ISBN: 978-953- 307-236-4, InTech, DOI: 10.5772/15854.
[2] Plebani M, Carraro P. Clin Chem 1997;43:1348-1351. 10.1093/clinchem/43.8.1348
[3] Plebani M. Clin Biochem Rev 2012;33:85-8.
[4] Carraro P, Plebani M. Clin Chem 2007;53:1338-42. 10.1373/clinchem.2007.088344
[5] Statland BE, Winkel P. CRC Crit Rev Clin Lab Sci 1977;8:105-44. 10.3109/10408367709151694
[6] Lippi G, Banfi G, Church S, et al. Clin Chem Lab Med 2015;53:357-70. 10.1515/cclm-2014-1051
[7] Simundic AM, Church S, Cornes MP, et al. Clin Chem Lab Med 2015;53:1321-31. 10.1515/cclm-2014-1053
[8] Plebani M, Sciacovelli L, Aita A, Chiozza ML. Biochem Med 2014; 15:105-13. /10.11613 /BM.2014.012
[9] Atay A, Demir L, Cuhadar S, et al. Biochem Med 2014;124:376-82. 10.11613/BM.2014.040
[10] Alsina MJ, Alvarez V, Barba N, Bullich S, Cortes M, Escoda I, et al. Int J Bioassays 2014:3.
[11] Lippi G, Bassi A, Brocco G, Montagnana M, Salvagno GL, Guidi GC. Clin Chem 2006; 52:1442-3.