ORIGINAL RESEARCH

Types and Frequency of Errors occurring in Medical Laboratories Root Cause Analysis

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ABSTRACT

Aim: To evaluate and identify pre-analytical, analytical and post analytical laboratory errors occurring in Pathology and Biochemistry Laboratories of a tertiary care teaching hospital. **Study Design:**An observational study was conducted on 287165 blood samples received in Central Laboratory for various laboratory investigations. Out of the 287165 samples, 200407 were OPD samples and 86758 were IPD samples. The study was conducted for a period of 06 months from August 2022 to January 2023. **Methodology:** All requisition forms, specimens, entered reports and certified reports were scrutinized, and any error identified was recorded according to the type of error. Root cause analysis was then performed for each error. Data was then analyzed for frequency distribution and Chi Square test applied for categorical variables. Strategies were then developed to prevent errors in different phases in various sections. **Results:** All data collected was compiled on Microsoft Excel worksheets. Statistical evaluation was done using simple percentage distribution. Data was analyzed using (SPSS) 23. Chi-square test was applied to compare categorical data. P<0.05 will be considered statistically significant. It was observed that error was detected in 0.46 % of samples of which 0.2 % were OPD Samples and 0.01 % were IPD samples. In 0.47 % cases pre-analytical errors, in 0.02 % analytical errors and 0.01 % post-analytical errors were observed. **Conclusion:** Errors in pathology and biochemistry investigations are the biggest limitation to laboratory services with impact on healthcare management and its cost. Majority of reasons involved behind these errors is within the scope of laboratory and thus can be reduced to a great extent

Keywords: Laboratory error, Pre-analytical errors, Analytical errors, Post analytical errors.

INTRODUCTION

Medical laboratories play a pivotal role in health care system and the decision making of clinical doctors about their patients. Error in any laboratory starts from the moment any investigation is ordered till it is interpreted and clinical judgement is made[1]. Any error in laboratory reporting can have a tremendous effect on patients safety[2]. Therefore it is important to know the types of errors occurring in laboratories in order to formulate strategies to prevent these.

Such errors can be categorized into 3 stages-pre analytical, analytical and post-analytical. Pre-analytical errors constitutes majority (46-68%) of laboratory error followed by post analytical errors (19-47%) [3]. Analytical errors account for least percentage (13-32%)[4].

Pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from problems in patient preparation, sample collection, transportation and preparation for analysis & storage[5].

Not processing a specimen properly prior to analysis of substances interfering with assay performance can affect test results in the analytical phase. Establishing and verifying test accuracy are the areas where errors can occur in the Analytical phase of laboratory testing.[1]

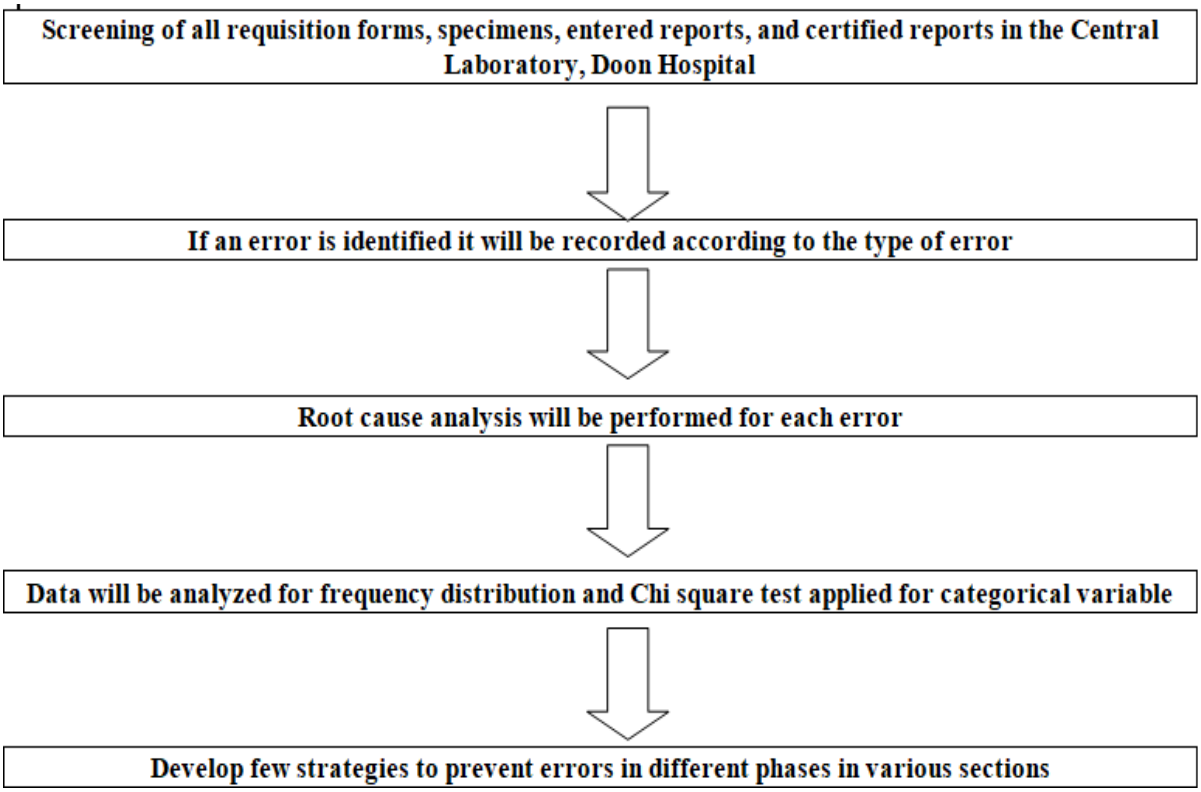
In the post analytical phase of the testing process, results are released to the clinicians who interpret them and make diagnostic & therapeutic decisions accordingly. Such things as inappropriate use of laboratory test results, critical result reporting and transmission of correct results are area of potential error[1].

METHODOLOGY

An observational study was conducted on 287165 blood samples received in Central Laboratory for various laboratory investigations. Out of the 287165 samples, 200407 were OPD samples and 86758 were IPD samples. The study was conducted for a period of 06 months from January 2023 to August 2023.

All requisition forms, specimens, entered reports and certified reports were scrutinized, and any error identified was recorded according to the type of error. Root cause analysis was then performed for each error. Data was then analyzed for frequency distribution and Chi Square test applied for categorical variables. Strategies were then developed to prevent errors in different phases in various sections.

STUDY FLOW CHART



RESULTS

All data collected was compiled on Microsoft Excel worksheets. Statistical evaluation was done using simple percentage distribution. Data was analyzed using (SPSS) 23. Chi-square test was applied to compare categorical data. $P<0.05$ will be considered statistically significant.It was observed that error was detected in 0.46 % of samples of which 0.2 % were OPD Samples and 0.01 % were IPD samples. In 0.47 % cases pre-analytical errors, in 0.02 % analytical errors and 0.01 % post-analytical errors were observed. The results are shown in Table (i) & (ii) and depicted graphically in Fig (i) and (ii).

Table (i): Shows the distribution of samples:

Total Samples	OPD Sample	IPD Sample
287165	200407	86758
0.46%	0.02%	0.01%

Figure (i):Shows the distribution of samples:

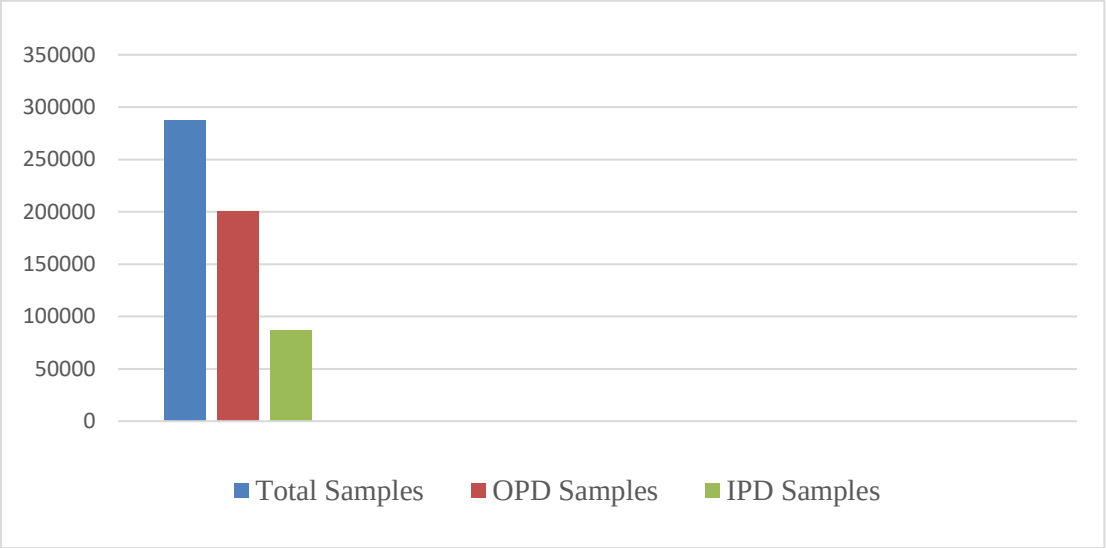


Table (ii): Shows the distribution of different types of errors:

Total Pre Analytic errors	Analytic errors	Post Analytic errors
1332	486	22
0.47%	0.02%	0.01%

Figure (ii): Shows the distribution of different types of errors:

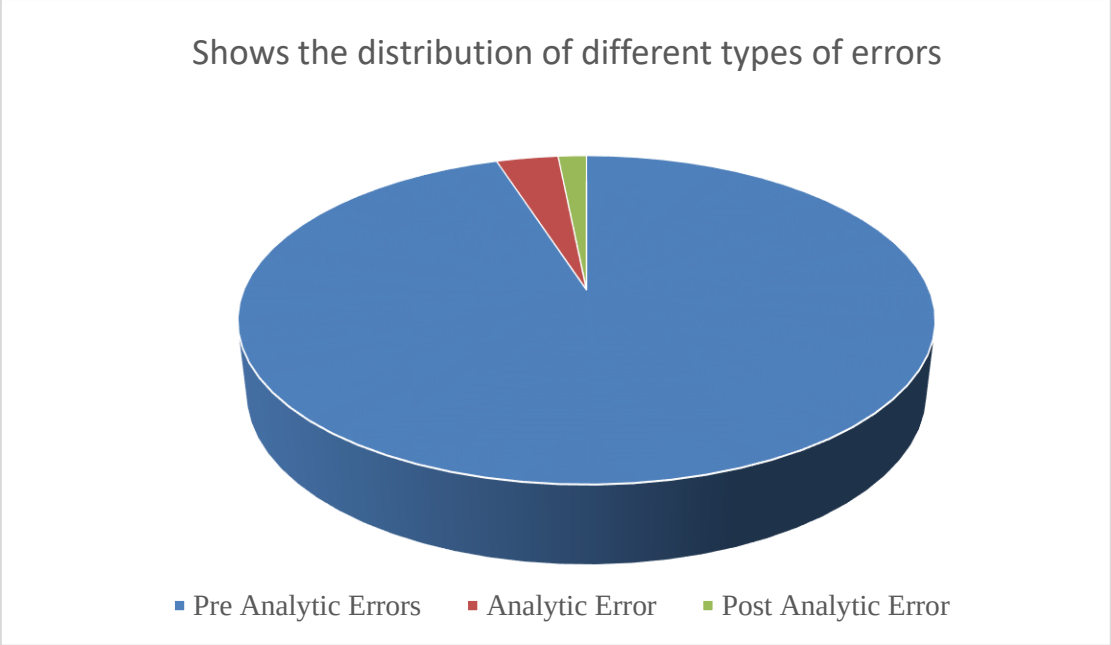
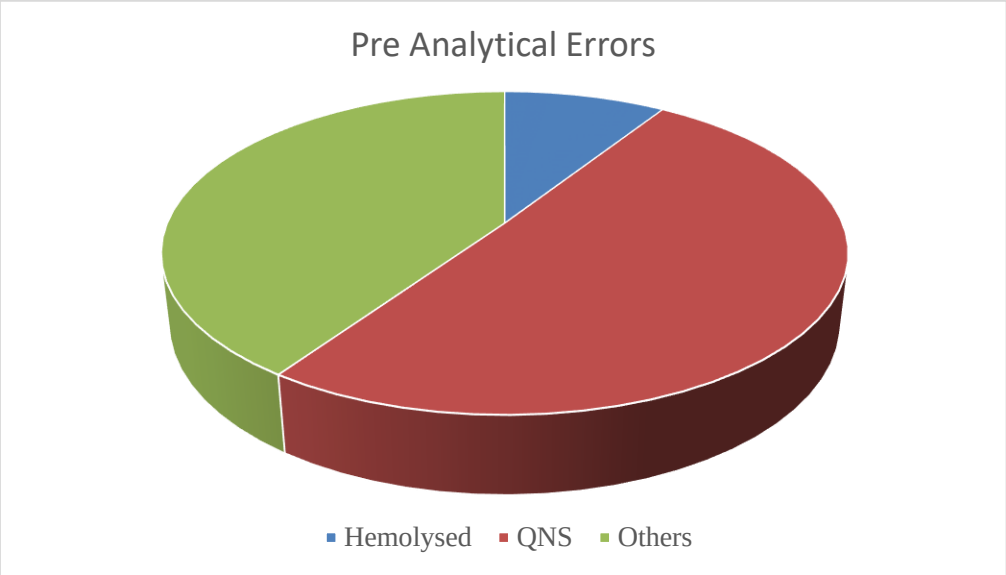


Table (iii): Shows the distribution of different types of Pre Analyticalerrors:

Hemolysed	QNS	Others
121	673	538
9.08%	50.52%	40.39%

Figure (iii): Shows the distribution of different types of Pre Analytical errors:



DISCUSSION

In the past decades a ten-fold reduction in the analytical error rate has been achieved[6], thanks to improvements in reliability and standardization of analytic techniques, reagents and instrumentation and advances in information technology, quality control & quality assurance methods.

Lippi and colleagues published that the total testing process error rates ranges widely from 0.1 % to 3.02 %[7]. In studies done by plebani and Cerraro,laboratory error rates declined over 10 years from 0.47 % in 1947 to 0.33 % in 2007[8-9].

A report by Bonini and colleagues found that pre-analytical errors predominated in the laboratory, ranging from 31.6 % to 75%.[10]

In 2008 and 2009, Chawla and colleagues performed a 1 year study in the Biochemistry laboratory on the frequency of pre-analytical errors observed in both in patients and out patients. For inpatients pre-analytical error rate was 1.2% and the variable with the highest frequency rating was insufficient volume for testing[11].

We can prevent pre-analytical errors by developing standard operating procedure for all tests, enhancing health care professional training, automation in labs, thus reducing manual errors and by monitoring quality indicators. Lastly there should be good communication among health care professionals.[12]

Morden robotic technologies can aid in reducing pre-analytical errors, Pre-analytical robotic workstations automate some of the steps and reduce the number of manual steps, Barcodes also simplifies specimen routing &tracking[13].

CONCLUSION

Errors in pathology and biochemistry investigations are the biggest limitation to laboratory services with impact on healthcare management and its cost. Majority of reasons involved behind these errors is within the scope of laboratory and thus can be reduced to a great extent by training of laboratory and hospital staff, participation in quality system and regular monitoring of equipment's.This can lead to remarkable changes in the culture of health care organizations, so medical errors can no longer be seen as inevitable, but as something that can be actively streamlined and prevented. Moreover, as labs are going for various accreditations, there is requirement of reducing errors in all phases of laboratory functioning.

BIBILIOGRAPHY

1. Hammerling JA. A review of medical errors in laboratory diagnostics and where we are today. Lab Med. 2012;43(2):41
2. Miligy DA. Laboratory errors and patient safety. Int J Health Care Qual Assur 2015;28:2-10.
3. Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. ClinChem Lab Med 2002; 48:691-698
4. Plebani M, Carraro P. Mistakes in stat laboratory: types and frequency. ClinChem Lab Med 1997; 43:1348-1351.
5. Lippi G, Chance JJ, Church S, Dazzi P, Fontana R, Giavarina D, et al. Pre-analytical quality improvement: from dream to reality. Clin Chem Lab Med 2011:49: 1113-26.
6. Plebani M. Errors in clinical laboratories or errors in laboratory medicine? Clin Chem Lab Med 2006:44: 750-9.
7. Lippi G, Plebani M, Šimundić AM. Quality in laboratory diagnostics: From theory to pracice, Biochem Med. 2010;20:126-130.
8. Plebani M, Carraro P. Mistakes in a stat laboratory: Types and frequency. CinChem. 1997;43: 1348-1351.
9. Carraro P, Plebani M. Errors in a stat laboratory: Types and frequencies 10 years later. Clin Clbem. 2007:53: 1338-1342.
10. Bonini P, Plebani M, Ceriotti F, et al. Errors in laboratory medicine. ClinChem. 2002;48:691 -698.

11. Chawla R, Goswami B, Taval D, ct al. Identification of the typcs ofpre-analytical errors in the clinical chemistry laboratory: I-year study at G.B.Pant Hospital. LabMedicine. 2010;41:89-92.
12. Bates DW, Gawande AA. Improving safery with information technology.N Engi J Med. 2003;348:2526-2534.
13. Da Rin G. Pre-analytical workstations: A tool for reducing laboratory errors, Clin Chim Acta. 2009; 404: 68-74.