ORIGINAL RESEARCH

Study of errors in Pre analytical, analytical and post analytical phases of testing cycle at Central Clinical Laboratory of a tertiary hospital

Apurva N. Kumthekar[1], Minal S. Sonune[2]

[1]Assistant Professor, Department Of Pathology, Government Medical College & Hospital, Alibag, Limaye wadi, beach road, Alibag, District Raigad, MS. 402209, INDIA.
[2]Senior Resident, Department Of General Surgery, HBT Medical College & Dr RN Cooper Municipal general hospital, Mumbai, MS. INDIA.

ABSTRACT

Background: Use of clinical laboratory test results in diagnostic decision making has become an integral part of clinical medicine. More than 70 % of the most important decisions of medical diagnosis are based on laboratory test results. Present study was aimed to study errors in pre-analytical, analytical and post analytical phases of testing cycle at central clinical laboratory of a tertiary hospital.

Material and Methods: Present study was single-center, descriptive, observational study, conducted in department of pathology & biochemistry, at Central Clinical Laboratory.

Results: From October 2014 to October 2016, a total of 1,88,819(59,229 from OPD and 1,29,590 from IPD) routine venous blood specimens were received in the Biochemistry Laboratory. Errors were detected in 17,607samples out of (9.32 %). Pre analytical, analytical, post analytical phases contributed to (5376 out of 17,607) 30.53%, (794 out of 17,607) 4.5% and (1196 out of 17,607) 6.79% of errors, respectively. Highest prevalence of errors seen in the 30.53% pre analytical phase. Pre analytical errors were detected in 5376 out of 17,607 samples (30.53%). Pre-analytical errors noted were incorrect requisition (48.54 %), clotted samples (16.9 %), samples not received (13.53 %), hemolysed samples (7.35 %), insufficient samples (7.02 %), incorrect label (5.38 %) & tube broken in centrifuged (1.24 %). Common analytical errors were non-conformity with QC (61.2 %), random error (11.2 %), calibration drift (13.97 %), systemic error (11.32 %) & errors as reported by clinician (2.26 %). Common post-analytical errors were Transcription Errors (61.87 %) & Prolonged Turn Around Time (38.13 %). All errors were common in IPD as compared to OPD & difference was statistically highly significant.

Conclusion: Since more than half of the laboratory errors occur during preanalytical phase, proper training and knowledge of the intervening factors that can influence laboratory results are essential to minimize laboratory errors.

Keywords: laboratory errors, preanalytical phase, laboratory results analytical stage

Corresponding Author: Dr. Apurva N. Kumthekar, Assistant Professor, Department Of Pathology, Government Medical College & Hospital, Alibag, Limaye wadi, beach road, Alibag, District Raigad, MS. 402209, INDIA.
Email ID: drapoorvakumthekar@gmail.com

INTRODUCTION

In spite of significant improvement in the total laboratory testing process due to automation, information and laboratory technology, standardization and implementation of effective quality control (QC) schemes, the total laboratory process remains error prone. IOM defines laboratory error as 'Any defect from ordering tests to reporting results and appropriately interpreting and reacting on these'.[1]

The role of the clinical audit in detecting this type of error and in improving clinical performance is being increasingly recognized; laboratories need to monitor adverse incidents, to learn how to minimize risk by studying them, and to establish procedures to prevent them.[2] Laboratory being science of measurement, is more akin to traditional industrial processes, it lends easily to classify errors into (a) Pre-analytical, (b) Analytical and (c) Post-analytical phases of testing.[3]

Use of clinical laboratory test results in diagnostic decision making has become an integral part of clinical medicine. More than 70 % of the most important decisions of medical diagnosis are based on laboratory test results.[4] It is impossible in laboratory medicine, as in any other human activity, to completely eliminate errors, but it is possible to reduce them. It is advisable to adopt techniques for error prevention and evaluation to reach the goal of error reduction. Present study was aimed to study errors in pre-analytical, analytical and post analytical phases of testing cycle at central clinical laboratory of a tertiary hospital.

MATERIAL AND METHODS

Present study was single-center, descriptive, observational study, conducted in department of pathology & biochemistry, at Central Clinical Laboratory in M.G.M. Medical College and Hospital over a period of 2 years during October 2014 to 2016. Study was approved by institutional ethical committee.

The laboratory personnel's in our well-equipped laboratory have undergone mandatory training courses in laboratory techniques and undergo regular training. Inpatient phlebotomies were performed by the residents of the respective departments whereas the OPD sample collection was done by Department staff. Standard Operating Procedures (SOPs) for phlebotomy techniques, patient preparation, sample handling, instrument handling and maintenance and other aspects of sample handling and processing have been documented and displayed. Sample analysis was done on fully automated machines.

A total of 1,88,819 routine venous blood specimens were received in the Central Biochemistry Laboratory. Out of these, 1,29,590 samples were collected from the in patients and 59,229 samples were collected in OPD. The samples of certain wards were collected in the home made EDTA, Fluoride and plain bulbs, whereas OPD and certain IPD and all PT samples were collected using evacuated tubes from BD (Franklin Lakes, NJ).

Preanalytical errors were documented in the laboratory after careful scrutiny of the samples and the accompanying requisition forms, inappropriate volume, incorrect or missing patient identification, lipemic samples and samples not received. Problems during the analytical phase of sample processing such as non-conformity with quality control, random and system errors were also recorded. Post analytical errors such as transcription errors and variations were also recorded.

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as

statistically significant.

RESULTS

From October 2014 to October 2016, a total of 1,88,819(59,229 from OPD and 1,29,590 from IPD) routine venous blood specimens were received in the Biochemistry Laboratory. Errors were detected in 17,607samples out of (9.32 %). Pre analytical, analytical, post analytical phases contributed to (5376 out of 17,607) 30.53%, (794 out of 17,607) 4.5% and (1196 out of 17,607) 6.79% of errors, respectively. Highest prevalence of errors seen in the 30.53% pre analytical phase. Among the total 188819 samples received, 129590 samples were from in-patient and the remaining 59229 were from out-patient departments. A total of 1456 (2.45%) errors were detected in samples received from out-patient and 5910 (4.56%) errors were detected in in-patient samples.

Table 1: Number of Errors in Pre-analytical, Analytical, Post-analytical Phases

Division	Number of samples	Number of pre-analytical error	Number of Analytical error	Number of post-analytical error
Out patient	59229	1003	193	260
In patient	129590	4373	601	936
Total	188819	5376	794	1196

Pre analytical errors were detected in 5376 out of 17,607 samples (30.53%). Incorrect requisition was the most common error in pre analytical phase contributing 48.54% followed by clotted samples (16.90%), samples not received (13.54%), hemolysed samples (7.34%), insufficient samples (7.01%) and incorrect labels (5.39%). Tubes broken in centrifuged was the least common error (1.24%).

Table 2: Type of Pre-analytical errors

Error Type Pre Analytical	No. of Errors	% of Errors
Hemolysed Samples	395	7.34
Insufficient Samples	377	7.01
Incorrect Label	290	5.39
Incorrect Requisition	2610	48.54
Samples Not Received	728	13.54
Clotted Samples	909	16.90
Tube Broken In Centrifuged	67	1.24
Total	5376	100

Analytical errors were detected in 794 out of 17,607 samples (4.50%). Among the analytical error type, non-conformity with quality control was the most common error responsible for 61.20% whereas, random error, calibration drift, systemic error and errors as reported by clinicians contributed for 11.20%, 13.97%, 11.33% and 2.26% respectively.

Table 3: Type of Analytical errors

Error Type Analytical	No. of Errors	% of errors
Non-Conformity With QC	486	61.20
Random Error	89	11.20
Calibration Drift	111	13.97

Systemic Error	90	11.33
Errors as Reported by Clinician	18	2.26
Total	794	100

Post analytical errors were detected in 1196 out of 17,607 samples (6.79%). Among post analytical type error was the most common error (61.87%) followed by prolonged turn-around time (38.12%).

Table 4: Type of Post-analytical errors

Error Type Post Analytical	No. of Errors	% of Errors
Transcription Errors	740	61.88
Prolonged Turn Around Time	456	38.12
Total	1196	100

Pre-analytical errors noted in present study were incorrect requisition (48.54 %), clotted samples (16.9 %), samples not received (13.53 %), hemolysed samples (7.35 %), insufficient samples (7.02 %), incorrect label (5.38 %) & tube broken in centrifuged (1.24 %). Pre-analytical errors were common in IPD as compared to OPD & difference was statistically highly significant.

Table 5: Comparison of Pre-Analytical Variables in IPD & OPD Samples

Error type	IPD(n=129590)		OPD (n=59229)	
	No. of errors	Percentage of error	No. of errors	Percentage of error
Hemolysed Samples (n=395)	321	5.98	74	1.37
Insufficient Samples (n=377)	306	5.7	71	1.32
Incorrect Label (n=290)	268	4.98	22	0.4
Incorrect Requisition (n=2610)	2185	40.64	425	7.9
Samples Not Received (n=728)	523	9.72	205	3.81
Clotted Samples (n=909)	710	13.2	199	3.7
Tube Broken In Centrifuged (n=67)	60	1.11	07	0.13
Total (n=5376)	4373	81.37	1003	18.63

($\chi2$= 85.76, P<0.001, degree of freedom=6. This result is significant at $p < 0.01$).

In present study, common analytical errors were non-conformity with QC (61.2 %), random error (11.2 %), calibration drift (13.97 %), systemic error (11.32 %) & errors as reported by clinician (2.26 %). Analytical errors were common in IPD as compared to OPD & difference was statistically highly significant.

Table 6: Comparison of Analytical Variables in IPD & OPD Samples

Error type	IPD(n=129590)		OPD (n=59229)	
	No. of errors	Percentage of error	No. of errors	Percentage of error
Non-Conformity With QC (n=486)	346	43.57	140	17.63
Random Error (n=89)	78	9.82	11	1.38
Calibration Drift(n=111)	91	11.46	20	2.51
Systemic Error (n=90)	74	9.31	16	2.01
Errors as Reported by Clinician(n=18)	12	1.51	06	0.75

| Total (n=794) | 601 | 75.62 | 193 | 24.28 |

(χ2=17.52, P<0.001, degree of freedom=4. This result is significant at p < 0.01).

Common post-analytical errors were Transcription Errors (61.87 %) & Prolonged Turn Around Time (38.13 %). Transcription Errors & Prolonged Turn Around Time were common in IPD as compared to OPD & difference was statistically highly significant.

Table 7: Comparison of Post-Analytical Variables in IPD & OPD Samples

Error type	IPD(n=129590)		OPD (n=59229)	
	No. of errors	Percentage of error	No. of errors	Percentage of error
Transcription Errors (n=740)	647	54.10	93	7.77
Prolonged Turn Around Time (n=456)	289	24.16	167	13.96
Total (n=1196)	936	78.27	260	21.73

(χ2=95.796, P<0.001, degree of freedom=1. This result is significant at p < 0.01).

DISCUSSION

Medical laboratories play a significant role in the healthcare system and the decision-making of clinical doctors about their patients. Clinical tests enjoy a high status in screening, treatment follow-up, and assessment of response to treatment. The Technical Specification released by the International Organization for Standardization (ISO/TS 22367) defines laboratory error as "failure of planned action to be completed as intended, or use a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them." This comprehensive definition has several advantages and, in particular, encourages a patient-centered evaluation of errors in laboratory testing.[5]

To identify the most critical steps in the total testing process and to set up a plan for a corrective strategy, laboratory errors can be distinguished as
(a) errors exclusively inside the laboratory (analytical errors) and
(b) errors caused by organizational problems outside the laboratory (e.g., sample-patient mismatch during the blood withdrawal performed by non-laboratory personnel).[6]

In present study, errors were detected in 17,607 samples, with a total error rate of 9.32%. The contribution of the different phases towards the total number of errors was 30.53% (pre analytical), 4.5% (analytical) and 6.79% (post analytical).

There has been varied information on the error rate within the whole lab testing procedure (0.1% to 9.3%).[6] Hawkins et al,[7] mentioned that the proportion of errors associated with pre- and postanalytical phases of testing is 4–5 times higher than that seen in analytical phase with preanalytical phase representing over half of the errors in published studies. In another study, preanalytical factor consists of 46–68.2% of total errors while a high error rate 18.5–47% of total errors has been found in postanalytical phase.

In a study by Plebani *et al*.,[4] they found out that despite a 34% reduction in error rate, the pattern of 62% preanalytical, 15% analytical, and 23% postanalytical phase errors remained basically unchanged. Analysis of results of this study shows that about 65.09% of errors occur in preanalytical phase, while about 23.2% and 11.68% occur across analytical and postanalytical phases, respectively.

According to different studies, there is a considerable difference between in- and outpatients with the 0.60% versus 0.039% for the two categories, respectively.[8] It seems that most of these differences are related to human factors including personal skills in

venipuncture (drawing blood) and the sheer volume of laboratory tests carried out for inpatients.[6,9]

Preanalytical errors are reported to be up to 70% in various studies. Since the quality is interconnected, precision and accuracy are not the only guarantors of the quality. From the very beginning, all three stages need to be under monitoring and quality control with precision and accuracy. The objective behind quality control is to minimize laboratory errors.

Clotted (16.9%) and hemolysed (7.34%) samples were the next most common errors in our study. Hemolysis of samples occurs technique when blood is forced through a fine needle, shaking the tubes vigorously and centrifuging the sample before clotting is complete. Hemolysis leads to the extravasation of intracellular contents into plasma, leading to false high readings of intracellular enzymes such a SGOT and LDH. It also leads to a prolonged TAT due to need for fresh samples for processing the request. The frequency of hemolysis was found to be more for IPD samples as compared to the OPD samples, the plausible explanation could be the sample collection by trained staff in the OPD (5.98% IPD & 1.37%OPD). Out of total samples received in our laboratory, 2.24% were found hemolysed as compared to 2.9% reported by Kale et al.,[10].Insufficient sample is another common error seen with frequency of 7.01% in our study and 7.5% seen in study a by Goswami et al.,[11]

Automation training of laboratory personnel and adoption of QC has led to an impressive decline in occurrence of analytical errors. It was observed that analytical errors were 4.50% in our study, whereas 5.3% by Kale et al.,[10] and 7.9% by Goswami et al.,[11]

Among the analytical error type, non-conformity with quality control was the most common error responsible for 61.2% whereas, random error, calibration drift, systemic error and errors as reported by clinicians contributed for 11.20%, 13.97%, 11.33% and 2.26% respectively.

In the postanalytical phase, the frequency of errors were 6.79% in our study and 15% in the study by Goswami et al.,[11] In spite of having Laboratory information system (LIS) there were typing errors seen in our lab. Although the reports are rechecked risk of some errors still remain. Today Turnaround time (TAT) is one of the parameters to measure performance of any laboratory. TAT is the time from receipt of sample to generation of report. The causes of increased TAT are generally pre analytical or post analytical. Reduction in TAT is an essential part of good quality assurance. Timeliness is most important to clinicians, who may be prepared to sacrifice analytical quality for faster TAT. Prolonged TAT in our lab was seen due incomplete test requisitions, haemolysed and clotted samples and problems in accession numbers.

It has recently been demonstrated that the introduction of new technologic facilities (online connection between laboratory and wards) without proper organization can worsen, rather than improve the communications between laboratories and clinicians. The lack of immediate notification and/or clinical utilization of a critical value can have an effect on outcome as negative as a wrong result. As pointed out by Lundberg[12], proper interpretation and action must be accomplished before the laboratory test loops are actually completed. It should be reminded that all three stages of laboratory tests need to be under thorough monitoring to improve the quality of results.

CONCLUSION

Since more than half of the laboratory errors occur during preanalytical phase, proper training and knowledge of the intervening factors that can influence laboratory results are essential to minimize laboratory errors. In the analytical stage of this study, errors for inpatients and outpatients did not differ meaningfully and were mainly due to factors that

could be prevented by an accurate and precise quality control procedure. Ambiguities about the standard methods and appropriate transporting times for different laboratory tests are also of great importance in decreasing preventable errors.

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