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*Original Research Article*

# Identifying Errors Involving Clinical Laboratory: A 1 Year Study

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## ABSTRACT

**OBJECTIVE:** It is a known fact that in modern day, laboratory diagnosis is the cornerstone of health care system. It is seen that pre and post analytical phases in a testing cycle contribute majority of the laboratory errors. This study was conducted to recognize the errors that occurs in the three phases of the testing cycle and for improvement in the areas where required.
**METHODS:** The present study was conducted during the period 2012-13 in the central laboratory in M.G.M. Hospital and Medical College. During a 12 month period 97,618 samples were monitored for major pre analytical, analytical and post analytical errors
**RESULTS:** From the study it was documented that total errors were 14,149 of which pre-analytical were 9,867 (69.7%), analytical were 751 (5.3%) and post-analytical were 3,531 (25%).
**CONCLUSION:** Our study showed that most of the errors pre-analytical either during sampling or preparation for analysis. The continuous improvement of the phases of testing cycle seems to be the prerequisite for and effective laboratory service for which cooperation with the clinicians is still the key to improve laboratory quality.
***KEY WORDS:*** Laboratory errors, pre- analytical, post – analytical.

## INTRODUCTION

Like any endeavour on earth, medical science is prone for errors, and clinical laboratories are no exception. And when things go wrong, there is lot of hue and cry, and apart from obvious harm to the patient, the medical person involved, goes through a nightmare of an ordeal. Laboratory Errors may be defined as "any defect from ordering tests to reporting results and appropriately interpreting and reacting on these." [1] It is therefore important to assure that care has been taken in each and every step. Laboratory being science of measurement, is more akin to traditional industrial processes, it lends itself easily to classify errors into Preanalytical, Analytical and PostAnalytical phases of testing. The pre- and post-analytical phases of the process account for 93% of errors. [2]

Laboratory errors are important because laboratory data influence 70% of medical diagnosis and can significantly influence the success and cost of patient treatment. [3] The preanalytical phase comprises all the processes occurring before the sample is processed in the autosampler. They include the wrong tests ordered,

incomplete requisition forms, improper collection, and illegitimate handwriting on forms. The labs have to bear their burden also and may lead to incorrect reporting.

We receive our shares of complaints and queries regarding lab results, so we decided to do systematic study of errors at Central Laboratory, MGM's Medical College and Hospital. Our aim was to understand areas of weakness, and find a solution those problems.

## MATERIALS AND METHODS

We describe the frequency of preanalytical, analytical and postanalytical errors observed in our central laboratory in M.G.M. Hospital and College during a 1 yr period. Our clinical biochemistry laboratory serves a 400 bedded tertiary hospital. Data was collected for both in as well as out patients during 24hrs. Our well equipped laboratory is staffed by individuals that have undergone mandatory training courses in laboratory techniques and undergo regular training. Inpatient phlebotomies are performed by the residents of the respective departments whereas the OPD sample collection is 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 is done on fully automated machines. We perform 3 daily quality control with calibration performed weekly. Any drift noted in calibration requires recalibration of affected parameter.

A total of 97,618 samples received in the central laboratory during a period from April 2013 to April 2014. Out of these, 79,649 samples were collected from the in patients and 17,969 samples were collected in OPD. The samples of certain wards are collected in the home made EDTA, Fluoride and plain bulbs, whereas OPD and certain IPD and all PT samples are collected using evacuated tubes from BD (Franklin Lakes, NJ).

Preanalytical errors are 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 are also recorded. Post analytical errors such as transcription errors and variations are also recorded. The data generated is reviewed routinely. The results were drawn in MS Excel.

## RESULTS

From April 2012 to April 2014, we received a total of 97,618 samples of which total errors documented were 14,149. We found that preanalytical, analytical and post analytical errors were 69.7%, 5.3% and 25% respectively. The highest number of errors were seen in preanalytical phase and the errors were 9,867 (Table 1) Incorrect requisition was the most common error in our study accounting for 57.3% of the total errors. The other preanalytical variables were also studied and their distribution has been tabulated (Table 1).

In the analytical phase the errors were 5.3% of the total (Table 1) and the most common error seen was non conformity with the quality control. Other errors were also documented (Table1) and changes were made to reduce them.

The post analytical phase errors that were documented included transcription errors and turn around time. In total they were 25% in number, of which transcription errors were the most common accounting for 15.5% of the total errors (Table 1).

Table 1: Types and frequency of errors in clinical laboratory

| Error Type | # Defects | % Defects |
|---|---|---|
| **Overall Pre Analytical Error Rate** | | |
| Hemolyzed Samples | 406 | 2.9% |
| Insufficient Samples | 158 | 1.2% |
| Incorrect Label | 122 | 0.9% |
| Incorrect Requisition | 8102 | 57.3% |
| Sample not received | 580 | 4.0% |
| Clotted Samples | 432 | 3.0% |
| Tube broken in centrifuge | 67 | 0.4% |
| Total | 9867 | 69.7% |
| **Overall Analytical Error Rate** | | |
| Non Conformity with QC | 370 | 2.7% |
| Random Error | 123 | 0.9% |
| Calibration Drift | 102 | 0.7% |
| Reagent Contamination | 52 | 0.3% |
| Systemic Error | 104 | 0.7% |
| Total | 751 | 5.3% |
| **Overall Postanalytical Error Rate** | | |
| Transcription Errors | 2186 | 15.5% |
| Prolonged Turn Around Time | 1345 | 9.5% |
| Total | 3531 | 25% |

Since we received both OPD and IPD samples we also divided our errors in the two sections. It was seen that the preanalytical phase errors were most commonly transcription errors but the sample related problems were reduced, i.e, haemolysis, clotted or insufficient sample (Table 2).

Table 2: Comparison of Preanalytical Variables in IPD & OPD Samples

| Error Type | IPD | | OPD | |
|---|---|---|---|---|
| | # Defects | % Defects | # Defects | % Defects |
| | | | | |
| Hemolyzed Samples | 388 | 3.9% | 18 | 0.1% |
| Insufficient Samples | 141 | 1.4% | 17 | 0.1% |
| Incorrect Label | 112 | 1.1% | 10 | 0.1% |
| Incorrect Requisition | 5609 | 56.9% | 2493 | 25.5% |
| Sample not received | 524 | 5.4% | 56 | 0.5% |
| Clotted Samples | 422 | 4.3% | 10 | 0.1% |
| Tube broken in centrifuge | 64 | 0.6% | 3 | 0.05% |
| Total | 7263 | 73.6% | 2604 | 26.4% |

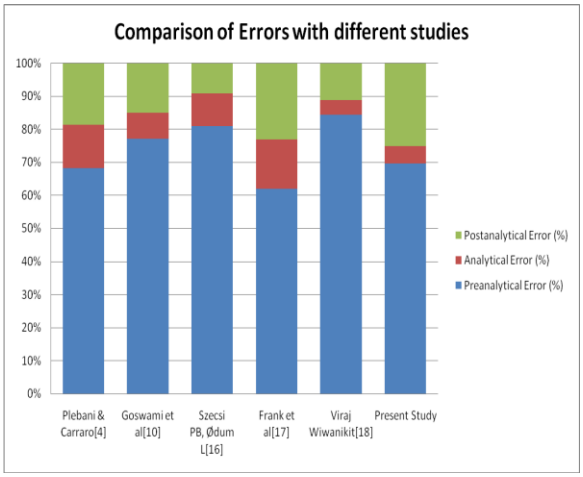

Fig no 1: Comparison with various studies.

## DISCUSSION

Laboratory services are the backbone of modern health care system. With automation effective laboratory service is the amalgamation of precision, accuracy and speed of reports delivered to the patient. Mounting evidence indicates that reliability cannot be achieved in a clinical laboratory through mere promotion of accuracy in analytical phase of testing process. The phases before the sample reaches the laboratory (preanalytical) and the phase after sample is analysed (postanalytical) are equally important. [4]

There has been varied information on the error rate within the whole lab testing procedure (0.1% to 9.3%). [1] We compared our study with many studies (Fig. no 1) carried on the same lines and it was seen that as with our studies our study had preanalytical error as one of the major issue, our analytical error were less as compared to many of these studies and postanalytical errors were more as compared to the other studies.

Lapworth and Teal attributred the majority of their analytical errors are due to sample mix-ups. [5] The majority of preanalytical errors due to hemolysis, insufficient sample, sample not sent or collection in inappropriate bulbs. These errors were more in the inpatient department in our study as the collection is done by the residents who lack the knowledge of correct phelobotomy technique. Incorrect requisition (57.3%) was the major hindering factor in the preanalytical phase in our study. It increased our Turnaround time (TAT) and also lead to repeat testing of the samples thus not only delaying the report but also increasing the cost of the test. 56.9% of requisition were incomplete in IPD & 25.5% in OPD in our study, whereas 0.4% IPD and 0.51% OPD in study by Chawla et al. [6] The incomplete requisitions that were sent could be due excessive load as seen in the OPD or could be due lack of awareness regarding the patient information to the person sending the sample.

Hemolysis and clotted 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. [7] Hemolysis leads to the extravasation of intracellular contents into plasma, leading to false high readings of intracellular enzymes such a SGOT and LDH. [6] It also leads to a prolonged Turnaround Time (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 (2.8% IPD & 0.1%OPD). Out of total samples received in our laboratory, 2.9% were found hemolysed as compared to 0.2% reported by Ricos et al. [8] It was seen in a study in the Hospitals of Tilburg, which stated that 93-97% of mistakes in the laboratory process resulted from human error. [9]

Another common error seen is insufficient sample, with frequency of 1.2% in our study and 7.5% seen in study by Goswami et al. [10] Other types of preanalytical errors seen in our lab are tubes broken in centrifuge (0.4%), empty tube(1.2%) and sample not received (4%).

Automation training of laboratory personnel and adoption of QC has led to an impressive decline in occurrence of analytical errors. [11-13] It was observed that analytical errors were 5.3% in our study, whereas 7.9% in study by Goswami et al. [10] These errors were comprised of systemic error such as malfunctioning of probes, photometric lamps and blockage of tubes, non conformity with internal quality control, random errors due to pipetting difficulty or analysers, calibration issues and contamination of reagents. Systemic errors were 0.7% of the total errors, it lead to delay in documentation of result and dispatch of reports. The non conformity with quality control and calibration problems were 2.7% and 0.7% respectively. Abnormal test results were main reasons that were considered for recalibration. Calibration of a parameter was considered to be within normal limits if the optical density (OD) the material and the factor generated fall within the range specified by manufacturer. [10] In order to achieve accuracy and precision, our lab

participated in the external quality control programme (EQAS). The short comings were regularly followed and changes were made in our quality maintenance.

In the postanalytical phase, the frequency of errors were 25% in or study and 15% in the study by Goswami et al. [10] 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 Turn around 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. [14] Results are also released from our lab with an excessively prolonged TAT, Ricos et al reported 11% of samples analysed were not delivered within the specified time, [8] and in our study the TAT was 9.5%. 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. [15] Prolonged TAT in our lab was seen due incomplete test requisitions, haemolysed and clotted samples and problems in accession numbers.

## CONCLUSIONS

The concept of Total Quality Management encompasses all the steps ranging from receiving of sample to delivery of reports with proper interpretation. Errors increase if no proper action is taken and they can't be eliminated but definitely they can be minimised if a protocol is followed. If we strive to control the extra-analytical errors which do affect our TAT and help the patient in early dispatch of reports it is possible to make an "IDEAL LAB" which every clinician will refer to.

***Consent:***

Since the patients were referred to us by the clinical departments, they were explained about the procedure and consent was taken in the respective OPD.

Areas of conflict: None

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