Errors in Clinical Biochemistry Laboratory

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Authors’ contributions

This work was carried out in collaboration between both authors. Author UA designed the study, wrote the protocol and wrote the first draft of the manuscript. Author AP managed the literature searches, analyses of the study performed. Both authors read and approved the final manuscript.

Article Information

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ABSTRACT

Introduction: Clinical laboratories have focused their attention on quality control methods and quality assessment programs dealing with analytical aspects of testing. But studies in recent years demonstrate that quality in clinical laboratories cannot be assured by merely focusing on analytical aspects. But mistakes occur more frequently before (pre-analytical) and after (post-analytical) the test has been performed. Objective of our study is to analyze the causes of errors occurring in our Clinical Biochemistry Laboratory and categorize them, find the frequency and percentage of errors.

Methodology: This study was carried out in a newly established Clinical biochemistry laboratory. Causes of errors were noted down and were categorized in to pre analytical, analytical and post analytical errors. Data has been noted down from April 2015 to December 2015.

Results: Pre analytical errors were contributing significantly to laboratory errors (59.8%) as compared to analytical (30.84%) and post-analytical errors (9.35%). Hemolyzed and clotted samples were the main causes of pre analytical errors (37.5% and 21.87% respectively). Calibration drifts were contributing mainly to analytical errors (39.39%). Transcription error (60%) was the main contributor to the post analytical error.

Conclusion: Errors can be minimized by training the laboratory personnel regarding phlebotomy techniques, storage, transport of specimen, instrument handling. Computerization of entire process will help to minimize the errors. The success of any efforts to reduce errors must be monitored in...
order to assess the efficacy of the measures taken. In the testing process areas involving non-laboratory personnel, interdepartmental communication and cooperation are crucial to avoid errors.

Keywords: Pre analytical; analytical; post analytical errors; clinical chemistry lab.

1. INTRODUCTION

In recent years, there has been increasing interest in quality improvement and patient safety activities in healthcare. The clinical laboratory has a leading role in the field of healthcare quality management with a focus on analytical quality born of its scientific background and was one of the first areas to use quantitative statistical control methods.

The total testing process (or total testing cycle) is based on the original brain-to-brain loop concept described by Lundberg [1,2]. He outlined a series of activities, starting with the clinical question in the clinician’s mind, leading to test selection, sample collection, transport to the laboratory, analysis, reporting back to the clinician, and final interpretation and decision making by the clinicians.

There are three phases of laboratory testing: pre-analytical, analytical and post-analytical. Pre-analytical phase is concerned with specimen collection, transport and processing. Analytical phase is related to testing of specimen and post-analytical phase deals with testing results transmission, interpretation, follow-up, retesting. Some authors have introduced the "pre-pre-" and "post-post-" analytical phases to identify activities associated with the initial selection of tests and with the interpretation by clinicians respectively, to differentiate them for the pure collection/transport activities (pre-analytical phase) and reporting (post-analytical phase) [3,4]. There is some evidence that these steps are more error-prone than other pre- and post-analytical activities [3-8].

Health care sector is most susceptible for errors. Most errors affecting laboratory test occur in the pre-analytical phase. They can occur at any stage of the collection, testing and reporting process and can potentially lead to a serious patient misdiagnosis.

Pre analytical error can occur during patient identification and preparation, selecting the site and site preparation for phlebotomy technique, order of draw, proper tube mixing, correct specimen volume, specimen handling and processing and specimen transport. Errors occurring during the process of analysis are analytical errors. These can be due to faulty techniques, instrument breakdown, reagent contamination, calibration drifts etc. Post-analytical errors occur after the reports are generated in the system but before dispatched to the patients. These could be due to transcription errors, delivery to wrong patients, misplacing of reports etc.

Objective of our study is to analyze the causes of errors occurring in our Clinical Biochemistry Laboratory and categorize them. We also aim to find the percentage of pre analytical, analytical and post-analytical errors.

2. METHODOLOGY

This study was carried out in Clinical biochemistry laboratory, Karwar Institute of Medical Sciences. This is a newly established laboratory attached to this 450 bedded tertiary care hospital. Our laboratory is well equipped with an automated chemistry analyzer, semi auto analyzer, hormone analyzer (chemiluminescence), blood gas analyzer and an electrolyte analyzer. A team of technicians and well trained demonstrators operate the instruments.

Data has been noted down from April 2015 to December 2015. Specimen load of 10,795 has been analyzed in the lab during this period. We have analyzed the total testing process which starts with patients and ends with patients. Since pre-pre analytical and post-post analytical factors are not in our control, we have studied the errors occurred during pre analytical, analytical and post - analytical phases of total testing process.

Phlebotomy is performed centrally where sample is collected by pathology, microbiology and biochemistry technicians in vacutainers /EDTA bottles for OPD patients. In patient blood samples are collected by trained nursing staff. While collecting the samples we have ensured that necessary pre requisite conditions are met before we collected the samples and standard operating procedures are followed. Example, patient is asked to be in fasting state for lipid
profile. Samples are transported by paramedical staffs.

We calibrate our instruments regularly, whenever reagent lot changes, QC values are beyond ±1 standard deviation. Daily maintenance and weekly maintenance are performed regularly for all the instruments. Quality control is carried out daily with commercially available QC material (Erba) level I and II (normal and pathological). Servicing of the instruments is done quarterly in a year.

Hormone analysis is done twice a week. So samples collected on remaining days of the week are centrifuged and serum is stored at -4 degree in the freezer.

Reports generated in the system are entered in to the report form manually, verified by faculty, and dispatched by the para medical staffs.

We have analyzed the errors occurred in our lab over a period of nine months and categorized them in to pre-analytical, analytical and post-analytical errors. Sample collection to entry of the sample in to analyzer is taken as pre-analytical errors, errors due to the defective instrument/reagent or when the sample is within the machine is taken as analytical error. Errors occurring between generation of reports to dispatch to the concerned patients is post-analytical errors. A log book of errors is maintained.

Statistical analysis is done by using descriptive statistics.

3. RESULTS

Frequency of errors and percentage of errors is calculated and expressed in Tables 1-4. Causes for pre-analytical errors along with frequency and percentage are given in Table 1, the same data for analytical and post-analytical errors are given in Tables 2 and 3. Overall percentage of errors is given in Table 4.

4. DISCUSSION

After analyzing the errors we found that, the chances of errors occurring in our lab is 0.99%. This is even though not a major error, error is not acceptable in the field of medicine. Since our laboratory is newly established, initial consideration can be given, but we need to monitor continuously and take measures for improvements.

| Cause of error               | Frequency | Percentage (%) |
|------------------------------|-----------|----------------|
| Hemolyzed sample             | 24        | 37.5           |
| Clotted sample               | 14        | 21.87          |
| Insufficient sample          | 4         | 6.25           |
| Lipemic sample               | 2         | 3.12           |
| Incorrect identified sample  | 1         | 1.56           |
| Illegible handwriting        | 2         | 3.12           |
| Tube broken in centrifuge    | 13        | 20.31          |
| Distilled water contamination| 3         | 4.6            |
| Freezing of reagents         | 1         | 1.56           |
| **Total**                    | **64**    |                |

Pre analytical errors accounted for 59.8% of total errors, analytical is 30.8% and post-analytical contributes to 9.35% to the total errors (Table 4). Majority of the works have proved that pre analytical variables have a major contribution in the quality of the report generated. A report by Bonini and colleagues found that pre-analytical errors predominated in the laboratory, ranging from 31.6% to 75% [9]. Report by Chawla and colleagues on the frequency of pre-analytical errors observed in both inpatients and outpatients, suggests that variable receiving the highest frequency rating was specimen hemolysis at 1.10% in the study. For the outpatients, the error rate was 1.2%, and the variable with the highest frequency rating was insufficient volume for testing [10].

Hemolysis of the specimen is the major pre analytical error in our set up as well. This occurs mostly due to vigorous withdrawal of blood through needle, collection of blood through IV line, forcing of blood in the tube. This can be corrected by practicing proper phlebotomy techniques. Training technicians in phlebotomy is required as corrective measure. Laboratory personnel must ask for new samples when hemolysis is detected. If a new sample cannot be obtained, it is the responsibility of the faculty to
Table 2. Frequency & percentage of analytical errors

| Cause of error                              | Frequency | Percentage (%) |
|---------------------------------------------|-----------|----------------|
| Probe error                                 | 4         | 12.12          |
| Non conformity with QC                      | 4         | 12.12          |
| Random error                                | 1         | 3.03           |
| Calibration drift                           | 13        | 39.39          |
| Reagent contamination                       | 4         | 12.12          |
| Systemic error –probe, lamp                 | 1         | 3.03           |
| Blocked tubing, modules jammed              | 10        | 30.3           |
| Machine shutdown because of voltage flux    | 2         | 6.06           |
| Temperature non maintenance                 | 4         | 12.12          |
| Total                                       | 33        |                |

Communicate the problem to the clinician. The data obtained from the serum indices can be used to monitor the quality of the collection process [11].

Table 3. Frequency & percentage of post-analytical errors

| Cause of error                  | Frequency | Percentage (%) |
|--------------------------------|-----------|----------------|
| Transcription error             | 6         | 6              |
| Prolonged turnaround time       | 4         | 4              |
| Total                           | 10        |                |

Table 4. Total percentage distribution of different types of errors

| Types of error     | Percentage (%) |
|--------------------|----------------|
| Pre analytical     | 59.8           |
| Analytical         | 30.84          |
| Post analytical    | 9.35           |

Negligence on part of the sample handlers leads to incorrect sample identification.

Computerization and bar-coding solves this issue. Barcodes simplify specimen routing and tracking [12].

Poor quality of the glass tubes supplied to the government college teaching hospital lead to breakage of tubes in the centrifuge.

Electricity problem was commonly encountered affecting all instruments in our lab. Voltage fluctuation lead to sudden shut down of the instruments, especially hormone analyzer in spite of battery back up being provided. Another adverse effect of electricity fluctuation of electricity was non maintenance of temperature. Recently this was addressed by the administrators to provide an uninterrupted power supply. Turn around time was improved with this
measure which enabled early diagnosis of medical conditions.

When we evaluate these analytical errors, 50% of them were predictable and corrective measures were taken to minimize these errors. The analytical phase of laboratory medicine is arguably the best performing sector in healthcare with close to 5 sigma performance (0.002%) [16,17].

Post-analytical errors were evaluated and found that more than 60% was due to transcription errors. Manual entry of report forms, sometimes by technicians is responsible for the same. Computerization can solve this problem.

5. CONCLUSION

Limitation of our work is that it is government medical college, financial constraints act as limiting factors for some of the improvement measures. We have tried our level best to implement the measures which are in our control. The success of any efforts made to reduce errors must be monitored in order to assess the efficacy of the measures taken. Quality indicators must be used for assessment. In the testing process areas involving non-laboratory personnel, interdepartmental communication and cooperation are crucial to avoid errors. Therefore the entire health care system must be involved in improving the total testing process.

CONSENT

It is not applicable.

ETHICAL APPROVAL

Institutional ethics committee approval was obtained before starting the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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