ORIGINAL ARTICLE

Assessment of Total Laboratory Errors in Clinical Chemistry Laboratory: Experience at a Tertiary Care Hospital

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Abstract

Background: Efficient Laboratory services are the backbone of the modern healthcare facility. 70% of all medical decisions are based on laboratory data. We need to assess errors in the testing process to reduce their negative effect on patient outcomes and the entire healthcare sector.

Objective: To assess total laboratory errors in terms of pre-analytical, analytical, post-analytical in the clinical chemistry laboratory.

Materials and Methods: This cross-sectional study was conducted in Clinical Chemistry Laboratory, Sheikh Zayed Hospital, Rahim Yar Khan from 1st January to 30th June 2021. All blood samples received in Chemical Pathology Section for routine chemistry analysis in 6 months were included in the study using a consecutive sampling technique. 61891 blood samples were assessed for the following pre-analytical errors: Hemolysis, icterus, lipemia, incorrect order of draw, insufficient quantity, wrong tube, mislabeled specimen, missed patient information. Analytical errors were a violation of westgard rules while post-analytical errors included uninformed critical results, prolonged turnaround time and data transcription errors. Urine and other body fluids such as cerebrospinal fluid (CSF), ascitic fluid, pleural fluid, pericardial fluid received for chemical analysis were excluded. Data analysis was done using SPSS 16.

Results: Out of the total laboratory errors 5574(9%), pre-analytical errors were the most frequently occurring errors (80.95%) followed by post-analytical errors (18.25%) and analytical errors (0.80%). The most frequently occurring pre-analytical error was hemolysis (64.38% of 80.95%). The most frequently occurring post-analytical error was uninformed critical results (70.79% of 18.25%).

Conclusion: Pre-analytical errors have the highest percentage in total laboratory errors followed by post-analytical errors. Errors in the analytical phase are less due to Internal Quality Control & laboratory automation.

Keywords: *Pre-analytical, analytical, post-analytical, laboratory errors, clinical chemistry.*

INTRODUCTION

Laboratory facility is the backbone of the modern healthcare system [1] and almost 70% of all medical decisions are based on laboratory data [2]. Laboratory results directly influence the patient safety and problem in any phase of the total testing process could affect the diagnosis and management plan of patients [3]. The testing process in clinical laboratories consists of every step from test requests to reporting of results and their effect on patient care [4]. This testing process consists of 3 phases: Pre-analytical, Analytical and Post-analytical. According to the International Organization for Standardization (ISO) 15189:2012, the pre-analytical phase comprises all the steps from test requisition, specimen collection, transportation and specimen registration up to the specimen being ready for analysis. The analytical phase involves specimen analysis while the post-analytical phase includes result interpretation, approval from the lab director and reporting these results to the clinicians [5]. The quality of laboratory services can be improved by targeting all the phases of the total testing process as errors can occur in any phase of the testing process [6]. While analytical standards have been developed by recognized quality control criteria, there is a scarcity in the development of standards for the pre-analytical phase. This phase is most prone to errors as the steps involved in it are directly dependent on humans and are out of direct laboratory control [7]. The pre-analytical phase has a remarkable contribution to the total lab errors (46-68% of total errors) [8]. Frequently occurring pre-analytical errors are inappropriate tests requests, uncompleted request forms, unclear handwriting, problem in patient identification, unsuitable sampling time, wrong order of draw, hemolysis or lipemia, improper specimen transportation and storage [9]. These pre-analytical errors can result in incorrect reporting and the laboratory has to experience the financial burden due to these errors. Following pre-analytical errors, post-analytical errors have a high rate (18–47% of total errors) [10]. Common post-analytical errors are prolonged turnaround time (TAT), uninformed critical results, data transcription error and inappropriate result interpretation [11]. Analytical errors (7-13% of total errors) are mainly caused by instrument fault, problems in quality control, and test interferences [12].

The present study aims to assess the prevalence of errors (pre-analytical, analytical and post-analytical) in the total testing process in the chemical pathology laboratory

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in order to educate the clinicians and laboratory staff to minimize most of these preventable errors and to reduce the negative impact of these preventable errors on a patient outcome such as test repetition, prolonged hospital stay and increased cost.

MATERIALS AND METHODS

This cross-sectional study was conducted in Clinical Chemistry Laboratory, Sheikh Zayed Hospital, Rahim Yar Khan from 1st January to 30th June 2021. All blood samples received in Chemical Pathology Section for routine chemistry analysis in 6 months were included in the study using a consecutive sampling technique. 34961 (56.49%) samples were received from inpatient departments and emergency where phlebotomy is performed by resident doctors, house officers and nursing staff while 26930 (43.51%) samples were collected at outpatient department (OPD) sample collection point where phlebotomy is done by trained phlebotomists. Gel tubes were used for sample collection. Inspection data sheets were designed to help in the evaluation of pre-analytical, analytical and post-analytical errors for clinical chemistry tests. These data sheets were based upon Quality Indicators (QI) listed by the International Federation of Clinical Chemistry and Laboratory Medicine Working Group "Laboratory Errors and Patient Safety" (IFCC WG LEPS) [13] (**Table 1**).

Table 1: Quality indicators in the pre-analytical, analytical and post-analytical phases.

Quality indicators of pre-analytical phase
Number of hemolysed samples/total number of samples Number of icteric samples/total number of samples Number of lipemic samples/total number of samples Number of incorrect order of draw samples/total number of samples Number of insufficient quantity samples/ total number of samples Number of wrong tube samples/total number of samples Number of mislabeled samples/total number of samples Number of samples with missed patient information/total number of samples
Quality indicators of analytical phase
Number of IQC values that exceed the selected target /total quality control run
Quality indicators of post-analytical phase
Number of reports delivered outside the specified time/total number of reports Number of critical values not communicated/total number of reports Number of data transcription errors/total number of reports

Following pre-analytical errors were noticed: Hemolysis, icterus, lipemia, incorrect order of draw, insufficient quantity, wrong tube, mislabeled specimen, missed patient information. Analytical errors were a violation of westgard rules while post-analytical errors included uninformed critical results, prolonged turnaround time and data transcription errors. A well-trained team of three doctors, one medical laboratory technologist and 3 technicians participated in data collection. Data was collected in the Chemical Pathology section during all shifts each day in the study period. Data collection was closely followed by the principal investigator. The chemical pathology section is equipped with a fully automated chemistry analyzer Beckman Coulter AU 680 for performing all routine chemistry tests. Data analysis was performed using SPSS 16.

RESULTS

A total of 61891 blood samples were received in the chemical pathology section during 6 months duration for routine chemistry tests. Of these 34961 (56.49%) samples were received from indoor and emergency while 26930 (43.51%) samples were collected at the outpatient department (OPD) sample collection point. Out of total sample, 5574 (9%) lab errors were identified. **Fig. (1)** depicts the frequency of different lab errors.

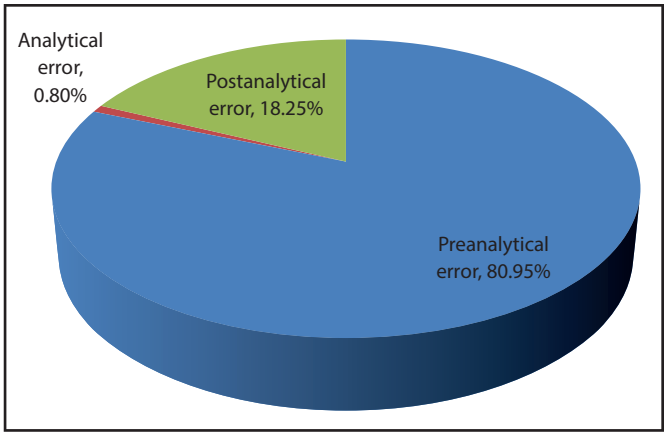

Fig. (1): Break-up of total lab errors (n=5574).

Among 61891 blood specimens, hemolysis was the most frequent pre-analytical error (n=2905, 4.69%) followed by Icterus (n=1170, 1.89%), missed patient information (n=159, 0.26%), mislabeled specimens (n=110, 0.18%), incorrect order of draw (n=50, 0.08%), wrong tube (n=42, 0.07%), insufficient specimen quantity (n=41, 0.07%) and lipemia (n=35, 0.06%). 3098 (5.0%) samples were rejected due to hemolysis, insufficient quantity, wrong tube, mislabeled specimens and the most common cause of sample rejection was hemolysis (93.7%). Specimens labeled as missed patient information would have been rejected if the patient's name, unit or admission number was not mentioned on the request form but it was mentioned on all request forms so samples were not rejected. Incorrect order of draw was identified after specimen analysis when the result showed hyperkalemia and hypocalcaemia which did not correlate with the patient's clinical condition. Analytical errors in internal quality control were a violation of 10x, 41s, 22s, R4s and 13s westgard rules. Out of 920 control runs in 6 months 45 runs (4.89%) showed a violation of 10x, 41s and 22s westgard rules which were most frequently seen in glucose and calcium. 10x was most frequently violated as shown in Table **2**. Whenever any westgard rule was violated, the error and its cause were identified and rectified before the sample batch was run. Violation of 13s and R4s was not observed during the study period. In the post-analytical phase, 1017 (1.72%) errors were

Table 2: Frequency of Analytical Errors (Total control runs=920).

Analyte	Westgard Rules		
	22s	44s	10x
Glucose	1	5	4
Urea	0	0	5
Creatinine	0	1	4
Bilirubin	0	0	5
ALT	0	2	6
Calcium	1	5	4
Amylase	0	1	1
Total	2	14	29
Frequency (%)	0.22%	1.52%	3.15%

observed. Uninformed critical results (n=720, 1.22%) contributed to the majority of the post-analytical errors followed by excessive turnaround time (n=289, 0.49%) and data transcription errors (n=8, 0.01%).

DISCUSSION

Considering the total testing process in the clinical laboratory, it is evident that the pre-analytical phase is most prone to errors. Any of the pre-analytical errors may lead to inappropriate test results and the safety of the patient might be compromised [14]. In our study, these errors contributed to 80.95% of total lab errors. This figure was lower than a study conducted in Ethiopia (89.6%) [1] but higher than the results reported in an Indian study (77.1%) [15]. Laboratory tests are mostly affected by hemolysis. Hemolysis can occur when collection tubes are filled forcefully, shaken vigorously or centrifugation of specimens is done before clotting is complete [16]. Analytes mostly affected by hemolysis are potassium, creatine kinase (CK), bilirubin, lactate dehydrogenase (LDH) and aspartate aminotransferase (AST) [16]. Lipemia is a turbid/milky appearance of the sample due to the aggregation of lipoprotein particles. Lipemic samples have the highest fraction of Chylomicrons [17]. The most common causes of lipemia are sampling after the meal, intravenous lipids and type 2 diabetes mellitus [18]. Serum electrolytes are the most commonly affected analytes by lipemia [17]. Icterus is elevated bilirubin concentration in serum, which can be caused by a variety of physiological and pathological conditions in both children and adults. Icterus causes negative bias in serum creatinine, cholesterol and triglyceride [19]. Test results are also affected by the order of draw so for accurate test results correct order of draw should be observed during phlebotomy [20]. If the order of draw is not followed properly, possible cross-contamination from EDTA tube to chemistry tube can lead to high serum potassium levels [7] with low serum calcium and ALP levels due to chelation of divalent cations.

In our study, 5.0% of samples were rejected for various reasons. This figure was almost equal to a study conducted in India (4.91%) [21] but higher than rejection rates reported in Ethiopia (3.8%) [1] and Turkey (0.65%) [22]. In our study the most frequent cause of sample rejection was hemolysis (93.8%) which is higher than the study conducted in Ethiopia (33.3%) [1], Pakistan (9.7%) [23] and Turkey (8%) [22]. Most of the hemolyzed samples were received from inpatient departments and this was caused by increased workload, forceful filling of tubes and a periodic influx of nursing students in the hospital. Hemolysed samples were informed telephonically in respective units and samples were repeated in the same shift. Insufficient quantity, wrong tubes and mislabeled samples collectively contributed to 6.2% of rejected samples which is much lower than studies conducted in Ethiopia (30.0%) [1] and Pakistan (53.4%) [23]. Pre-analytical errors can be reduced by phlebotomy training, computerized test request system, automated specimen identity system via barcodes, serum indices (hemolysis, lipemia and icterus) [24] and following the correct order of draw as suggested by Clinical Laboratory Improvement Amendments (CLIA). Quality indicators (QIs) are an effective tool in accurately estimating quality, identifying problems that may need to be addressed, and monitoring the processes over time [25]. College of American Pathologists (CAP) has specifically listed a few pre-analytical quality indicators which should be checked including patient recognition, test request accuracy and specimen appropriateness [24]. This improves the precision, accuracy and competence of the laboratory. Labs can become aware of their pre-analytical conditions by maintaining a monthly sample rejection record.

Regarding the analytical phase of the total testing process, internal quality control (IQC) is a vital component of the framework for laboratory quality to monitor the analytical systems. It is done by measurement of analytes in control material having known concentration of analytes. Control measurements are usually plotted as Levey-Jennings (LJ) chart and interpreted using Westgard rules [26]. Westgard rules are 13S, 22S, 41S, R4S and 10x. In the present study analytical errors contributed to 0.80% of total lab errors which is much lower than the study conducted in Ethiopia (2.6%) [1]. Unacceptable performance of IQC was observed in 45 (4.89%) control runs which are lower than Indian (5.07%) [21] and Ethiopian (14.4%) reports [1]. The most frequently violated westgard rule was 10x. However, R4S and 10x rules have little value in detecting shifts in the mean [27]. For all laboratories, it is mandatory to administer and track the quality essentials [28]. Evolution in automation and instrumental technology have simplified work in terms of analytical quality in laboratory diagnostics and improved the quality of results [7].

In the present study, the frequency of post-analytical error was 18.25% among total lab errors which is higher than studies conducted in Ethiopia (9.3%) [1] and India [3.2%] [15]. Even though excessive TAT (8.6%) and transcription errors (11.7%) contributed much in some literature [1, 15], in this study, uninformed critical results contributed to the majority of post-analytical errors. The most important aspect of the post-analytical

phase was reporting of critical value. During 6 months period, 1800 critical value cases were observed and 720 of them were not communicated to the concerned clinicians. Telephonic communications complicated the process of notifying within a defined time. Failure to notify critical values could be life-threatening if the patient is left untreated. Excessive TAT was observed in reporting 0.47% specimens. Power breakdown, shortage of reagent grade water, technical issues of the instrument and unexpected workload could be the cause of not reporting results within a defined period [1]. Data transcription errors were seen in reporting 0.01% specimens. Implementation of an Electronic Laboratory Information Management System (LIMS) can improve the post-analytical phase and might eradicate transcriptional errors and delay in results [1].

Overall statistics showed that the error frequency was 80.95% in the pre-analytical phase, 0.8% in the analytical and 18.25% in the post-analytical phase. Results reported in Ethiopia were slightly different from this study as the distribution of errors was pre-analytical 89.6%, analytical 2.6% and post-analytical 7.7% [1]. An Indian study showed that Pre-analytical errors were most common, with a frequency of 77.1% followed by post-analytical errors 15% and analytical errors 7.9% [15]. However, a study conducted in the Netherlands showed that post-analytical errors contributed to 18.5% of total laboratory errors [29] which is in line with our study. This variation in the relative frequency of errors observed in the different phases of the total testing process may be due to differences in work complexity, methods of error detection and implementation of a quality management system. The frequency of errors in the total testing process may vary from institution to institution and time to time.

CONCLUSION

It is concluded that pre-analytical errors are the most frequent lab errors followed by post-analytical and analytical errors. Pre and post-analytical phases have been improved significantly after proper phlebotomy training and sensitization of nursing and laboratory staff. Errors in the analytical phase are less due to stringent Quality Control and automation in the laboratory. It is required to address the deficiencies associated with each step of the testing process, especially the pre-analytical phase. Compliance with good laboratory practices can significantly reduce the occurrence of laboratory errors.

ETHICS APPROVAL

Ethical approval was taken from Institutional Review Board before commencing the study.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA

Authors confirm that data supporting the results of this study are available in the article.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHOR'S CONTRIBUTION

SSHZ gave study concept and designed basic methodology. MS collected the data and performed statistical analysis. Initial manuscript draft was written by MS. SSHZ and MTG were involved in manuscript revision and proof reading. All authors read and approved the final manuscript.

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