Original Article

Frequency of Errors in Clinical Laboratory Practice

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ABSTRACT

Background and Objective: **Laboratory errors are one of the major factors that affect the diagnosis, prognosis, treatment and monitoring in patients. The objective of study is to evaluate the frequency and type of errors in different phases of testing at the Pathology Department of the Shalamar Hospital, Lahore and to evaluate the causes of errors.**

Methods: **This observational study was carried out in Shalamar Hospital Laboratories Lahore from 1st July 2011 to 31st December 2011. Errors detected and documented on daily basis.**

Results: **A total of 127,500 samples were received and processed during the six months period. Out of the total samples, 1530 (1.2) errors were detected. Among all errors pre-analytical errors were most common, with a frequency of 70.4%, post-analytical 17.5% and analytical 12.1%.**

Conclusions: **Our study demonstrates the types and frequencies of errors. It is very important to monitor the all phases so to reduce the frequency of error for better reporting of lab results, ultimately which ensures the patient well-being.**

Keywords: **Clinical Laboratory, Errors, Pakistan**

Introduction

According to the International Organization for Standardization (ISO), laboratory error is acknowledged as "any defect from ordering tests to reporting results and appropriately interpreting and reacting to these" (1, 2).

Laboratory errors can occur at any stage from ordering of tests till the receipt of samples in lab (pre-analytical phase), during analysis of test specimens (analytical phase) and finally while reports are prepared, approved and issued (post-analytical phase). Errors at any of these stages may lead to delay in diagnosis, misdiagnosis and a serious hazard for patient's health (1).

Various studies have reported the frequency of errors ranging from 46% to 68.2% during

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the pre-analytical phase (3, 4). Improvements and advancements in automation, internal and external quality control programs, accreditations and laboratory standardization have greatly reduced the number of errors in analytical phase (5). The last few decades have seen a significant decrease in the rates of analytical errors in clinical laboratories, and currently available evidence demonstrates that the pre- and post-analytical steps of the total testing process are more error-prone than the analytical phase. Pre- and post-analytical processes are equally important for ensuring quality laboratory service (2).

We conducted this study to evaluate the frequency and type of errors in different phases of testing at the Pathology Department of the Shalamar Hospital, Lahore and to evaluate the causes of errors.

Materials and Methods

An observational descriptive study was designed to evaluate laboratory errors in clinical laboratory of Shalamar Hospital Lahore, which is a 350 bedded hospital. The laboratory comprises of all the main six disciplines, Clinical Chemistry, Hematology and Blood Banking, Histopathology, Immunology, Microbiology and Molecular Biology. The duration of the study evaluating laboratory errors was six months, from 1st July 2011 to 31st December 2011. Data were collected of samples received from indoor and outdoor patients from 08:00 am-10:00 pm (Indoor & outdoor patients) and from 10:00 pm-08:00 am (indoor patients). A Performa was designed for documentation of these errors.

As per policy, the samples from the inpatients were collected by the phlebotomy staff sent by the lab to different wards from 8.00 am to 10.00 pm. During the night shift the samples were sent by the nursing staff at their own. One postgraduate trainee doctor and three medical technologists were assigned to document the errors on daily basis. All the errors detected before issuing the reports or notified by the clinicians or nursing staff were entered in the proforma. Each time the error was informed to the section head. Standard operating procedures (SOPs) for phlebotomy technique, patient preparation, sample handling, sample rejection criteria, instrument handling and maintenance and other aspects of sample processing were already being followed. Documentation of pre-analytical errors was started at the reception while receiving samples from indoor patients and outdoor patients.

Results

A total of 127,500 samples for analyses were received in the laboratory from indoor and outdoor patients from 1st July 2011 to 31st December 2011. Out of these samples, 42,300 were received from indoor while 85,200 samples were received from outdoor patients. A total of 1,530 errors were detected among the 125,700 samples with the error rate of 1.2%. The total number of errors on indoor samples was 1081 out of the 42,300 tests with an error rate of 2.5% while the total number of errors on outdoor samples was 449 out of the 85,200 tests (error rate of 0.5%).

Of the total number of errors encountered (1530) the frequency (Table 1) of pre-analytical errors was 1,078 (70.4%), analytical 184 (12.1%) and post-analytical 268 (17.5%).

Table 1: Frequency of pre-analytical, analytical and post-analytical errors

Phases	Indoor N (%)	Outdoor N (%)	Total N (%)
Pre-analytical	784 (72.7)	294 (27.3)	1078 (70.4)
Analytical	103 (56.0)	81 (44.0)	184 (12.1)
Post-analytical	194 (72.4)	74 (27.6)	268 (17.5)

Pre-analytical errors encountered were visible haemolysis, quantity not sufficient (QNS), inappropriate container, incorrect labeling, physician test request missed, request slip without sample, illegible handwriting, sample when required not on ice and incorrect request voucher. The frequency of pre-analytical errors was more in indoor samples as compared to outdoor samples (72.7% and 27.2%, respectively). Haemolysis was the predominant pre-analytical error in indoor and outdoor samples.

Problems encountered during the analytical phase of sample processing were, non-conformity with QC, calibration drift, probe error and random error. Post-analytical errors which we documented included transcription errors, wrong delivery of reports to wards and variations in turnaround time (TAT). The wrong entry of results was the predominant error among post-analytical errors (Table 2).

Table 2- Frequency of errors in indoor and outdoor samples

Type of Error	Indoor N (%)	Outdoor N (%)	Total N (%)
Pre-analytical			
Haemolysis	545 (69.5)	183 (62.2)	728
Quantity Not Sufficient (QNS)	38 (4.8)	20 (6.8)	58
Inappropriate container	35 (4.5)	20 (6.8)	55
Incorrect labeling	97 (12.4)	23 (7.8)	120
Physician Test request missed	15 (1.9)	10 (3.4)	25
Request slip without sample	13 (1.7)	6 (2.1)	19
Illegible handwriting	23 (2.9)	15 (5.1)	38
Sample not on ice	10 (1.3)	5 (1.7)	15
Incorrect request voucher	8 (1.0)	12 (4.1)	20
Total	784 (100)	294 (100)	1078
Analytical			
Non-conformity with QC	21 (24.7)	38 (38.4)	59
Calibration drift	36 (42.3)	27 (27.3)	63
Random error	19 (22.4)	22 (22.2)	41
Probe error	9 (10.6)	12 (12.1)	21
Total	85 (100)	99 (100)	184
Post-analytical			
Wrong entry of results	115 (56.9)	54 (81.8)	169
Delayed reporting	51(25.3)	7 (10.6)	58
Wrong delivery of reports to patients	36 (17.8)	5 (7.6)	41
Total	202 (100)	66 (100)	268

Discussion

The quality of patient care depends upon accurate and precise laboratory tests. Many factors can affect laboratory test results during the entire process starting from sample collection, sample processing, and analytical performance up to delivery of reports. Specimen collection and processing prior to analytical testing is very important in laboratory test quality and for accurate and precise reporting for proper diagnosis, management and prognosis of disease. Errors in laboratory system have rarely been

reported in our set-up. Our study showed a total error rate of 1.2% which may be considered within acceptable statistical limits and signifies the quality of this tertiary care hospital laboratory. The major number of errors in this study was in pre-analytic phase and is in accordance with other previous studies (2, 6, 7). The study by Lippi *et al*. highlights the frequency of pre-analytic errors up to 70% which is more than analytical and post-analytic errors (3).

The pre-analytical errors in our study were more in indoor samples as compared to outdoor samples even though the total number of outdoor samples received was double than that of indoor samples. The frequency of haemolysis among pre-analytic errors in indoor samples was more during the night shift, an observation similar to that of Akan *et al.* (2006) (5). The reason for this increased frequency of haemolysis during night shift could be due to sample collection by the nursing staff having less knowledge and skills of sample collection and transport as compared to phlebotomists sent to wards during morning and evening shifts. This highlights the need for training of nursing staff for sample collection or provision of lab phlebotomist during the night shift also.

The error rate in analytical phase was 12.1% among the total errors. The advancements in automation, implementation of internal quality control program and participation in proficiency testing are the factors which cause reduction of errors in analytical phase. Carraro and Plebani's study (7) showed 68.2% pre-analytical errors, 13.3% analytical errors and 18.5% post-analytical errors. Our study highlights distribution of errors in analytical phase between indoor and outdoor samples was 56% and 44%, respectively. Regarding the analytical phase, most of the errors were due to the calibration drift (34.2%), and non-conformity of QC (32.1%). It was observed that the internal quality control samples were run regularly during the day time so the validity of results was relatively good and error rate in analytical phase was less in indoor samples during morning and evening shifts as compared to the samples received in lab from indoor and outdoor patients during night shift. Most analytic errors were instrument related, including the malfunctioning of instruments that resulted in unacceptable quality control.

Laboratory information system (LIS) has greatly improved the overall performance of the lab. However, in our study, most errors (56.9%) in the post-analytic category were related to the lack of implementation of LIS in all sections due to which the results were not transferred by direct interface from the instruments to the LIS. Sections without interface facility had a higher error rate as compared to the sections where instruments were interfaced with the LIS.

One of the reasons for wrong delivery of report or delayed reporting is that the lab porters, who used to deliver the reports, were not informed if the patient had shifted from one ward to another location. Of these, 17.8% errors of indoor samples were not communicated to the treating physicians either due to lack of the details of the exact patient location or due to the lack of awareness to retrieve reports through hospital information system. This resulted in delayed turnaround time. The second most common problem was missing computer entry of one or more of the tests marked on the request form. This also resulted in delayed reporting of patient results.

In our study, errors in the pre-analytical (70.4%) and post-analytical (17.5%) phases occurred much more frequently than in the analytical phase (12.1%). These findings are consistent with evidence from other studies that demonstrate a large percentage of laboratory errors in the pre-analytical and post-analytical phases (7-10).

In the post-analytic category, most errors were

related to the inappropriate use of the LIS when the results were transferred from the instruments to the LIS. A direct interfacing of the instruments to the LIS system showed significantly improved error reduction. In our study, rates of pre-analytical errors ranged from <0.1% to 23.5% for different error types at different working hours. The main problem was associated with the computer system (e.g. patient input errors and unrecognized barcodes). These problems could be solved manually, but it affected the total response time to the clinician. The second most common problem was the discrepancy between tests marked on the request form and what was entered in the computer. This is important because missing tests can cause delay with patient management. Most of the discrepancies between the requisition and LIS entry originated from input error of the requested test (11).

Conclusion

It is possible to reduce the errors in laboratory medicine during whole testing process but impossible to completely eradicate errors. In a hospital lab with large work load, careless attitude of the persons involved in whole process can cause problems, and therefore, manual entry of patient data and lab numbers must be replaced by electronic entries. For reduction of sample collection related errors continuous training programs of staff should be implemented. Moreover strategies for evaluation of error detection must be adopted to document the errors occurring in all three phases. This will help in identifying the errors and also improve the efficiency of lab by adopting measures to reduce and eliminate these.

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