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Evaluation of errors in a clinical laboratory: a one-year experience

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Abstract

Background: Efficient laboratory service is the cornerstone of modern health care systems. Scientific innovations have contributed to substantial improvements in the field of laboratory science, but errors still prevail. These errors are classified as preanalytical, analytical and postanalytical, depending upon the time of presentation.
Methods: The data for 67,438 routine venous blood specimens were scrutinized, and errors were documented over the period of 1 year in the clinical biochemistry laboratory of Govind Ballabh Pant Hospital in Delhi, India.
Results: Preanalytical errors were most common, with a frequency of 77.1% followed by postanalytical 15% and analytical 7.9%, respectively.
Conclusions: Our study illustrates the importance of proper venipuncture procedures, analytical expertise and correct transcription of numerical data for precise and accurate reporting of results to clinicians. There is an urgent need for close inter-departmental cooperation to meet the goal of ensuring patient well being.
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Keywords: analytical errors; clinical laboratory; postanalytical errors; preanalytical errors; turn around time.

Introduction

Laboratory errors may be defined as ''any defect from ordering tests to reporting results and appropriately interpreting and reacting on these'' (1). Clinical laboratories have long focused their attention on quality control (QC) methods and quality assessment programs dealing with the analytical aspects of testing. However, a growing body of evidence accumulated in recent decades demonstrates that quality in clinical laboratories cannot be assured by merely focusing on analytical aspects only. Pre- and postanalytical processes are equally important for ensuring quality laboratory service. Process analysis has demonstrated that laboratory errors occur primarily in the preanalytic phase, influencing patient outcomes and costs (1, 2). Literature suggests that preanalytical and postanalytical errors account for 93% of the total errors encountered in the laboratory (3).

Materials and methods

We describe the frequency of preanalytical, analytical and postanalytical errors observed in our clinical chemistry laboratory in Govind Ballabh Pant Hospital during a 1-year period. Our clinical biochemistry laboratory serves a 600-beded tertiary hospital. Data were collected only for hospitalized patients during routine hours. Our well-equipped laboratory is staffed by individuals that have undergone mandatory training courses in laboratory techniques. Since our hospital is preparing for accreditation by the National Accreditation Board for Hospitals and Healthcare Organizations (NABH), laboratory technical staff along with the paramedical staff are regularly undergoing regular training under the aegis of the QC cell of the hospital. Standard operating procedures (SOPs) for phlebotomy techniques, patient preparation, sample handling, instrument handling and maintenance and other aspects of sample processing have been documented and displayed. Sample analysis is performed using two fully automated autoanalyzers – OLYMPUS (AU 400, Tokyo, Japan). Although calibration is performed weekly, calibration traceability and internal QC is monitored daily. Weekly calibrations were performed under the protocol developed by the Quality Cell in our department. Any drift noted in calibration requires recalibration of the affected parameter. All ancillary equipment such as auto pipettes, centrifuges and refrigerators are calibrated by an authorized central agency at regular intervals.

Preanalytical errors are documented in the laboratory after careful scrutiny of the samples and the accompanying requisition slips by laboratory technicians. Preanalytical errors that we encountered include visible hemolysis after centrifugation, inappropriate volume (deficit in the volume required to perform the analysis), incorrect or missing patient identification, inappropriate container and lipemic samples. Problems encountered during the analytical phase of sample processing such as non-conformity with QC, random and systemic errors, are also recorded. Postanalytical errors such as transcription errors and variations in turn around time (TAT) are documented.

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Results

From July 2008 to June 2009, a total of 67,438 routine venous blood specimens were received in the laboratory. Errors were detected in 954 samples, with a total error rate of 1.4%. Preanalytical, analytical, postanalytical phases contributed to 1.1%, 0.1% and 0.2% of errors, respectively. The contribution of the different phases towards the total number of errors was 77.1% (preanalytical), 7.9% (analytical) and 15% (postanalytical). We found the highest prevalence of errors in the preanalytical phase, a total of 736 in the 1-year observational period (Table 1). Hemolysis was the most common error due to incorrect procedures for sample collection, a total of 508 samples being affected. Insufficient volume of the blood sample drawn was the next most common cause for unsuitable specimens (72 samples); other common errors were due to errors in the requisition slip, or due to illegible hand writing (69 samples), identification errors (44 samples), empty tubes (10 samples), missing tubes (16 samples) and tubes broken in the centrifuge (6 samples) (Table 1). Of the 736 samples that showed preanalytical errors, 623 were rejected (due to hemolysis, lipemia, insufficient quantity, absent sample and illegible hand writing) contributing to 0.9% of rejections during the 1 year that this analysis was performed.

In the analytical phase, we identified 75 errors, accounting for 7.9% of total errors (Table 1). The most frequently detected analytical problem was due to systemic error (36 events) followed by random errors (15 events). Other sources of analytical errors were calibration drift (10 events), contamination of reagents (8 events), and non-conformity with QC (6 events).

In the postanalytical phase, 143 errors were observed (Table 1). Transcription errors contributed to the majority of

Table 1 Types and frequency of errors in clinical laboratory.

Type of error	Frequency	%	Cause of error
Preanalytical			
Hemolyzed sample	508	53.2	Wrong phlebotomy technique, incorrect transport centrifugation before sample is clotted
Insufficient sample	72	7.5	Lack of knowledge regarding sample volume required, difficult sampling as in pediatric and old patients
Lipemic sample	7	0.7	Collection under non-fasting state? hyperlipidemia
Incorrect identification	44	4.6	Lack of knowledge/lax attitude
Empty tube	10	1.0	of the phlebotomists/staff
Requisition slip without sample	16	1.7	involved in sample collection
Illegible hand writing	69	7.2	and test ordering
Tube broken in the centrifuge	6	0.6	Improper centrifugation technique
Physician's request order missed	4	0.4	Carelessness at the level of the laboratory staff
Total	736	77.1	
Analytical			
Non-conformity with QC	6	0.6	Old QC, improper storage
Random error	15	1.6	Unknown cause
Calibration drift	10	1.0	Reagent instability, reagent changeover, expiry of calibration data with time
Reagent contamination	8	0.4	Reagent mix up, improper storage
Systemic error: probe, lamp, blocked tubing	36	3.8	Inherent technical problem/ routine wear and tear
Total	75	7.9	
Postanalytical			
Transcription errors	112	11.7	Manual error in copying numerical data from the printout on to the requisition slips
Prolonged turn around time	31	3.2	Problem arising due to inadequate water supply, irregular electricity, instrument problem
Total	143	14.9	

postanalytical errors (112 requisition slips). Thirty-one instances of excessive TAT were recorded over the one-year period.

Discussion

Laboratory services are the backbone of the modern health care sector. Effective laboratory service is the amalgamation of precision, accuracy and speed of reports delivered to the patient. In spite of rapid advances in laboratory science, it is still susceptible to various manual and systemic errors. Various types of errors that we, as clinical biochemists, encounter in the laboratory are classified as preanalytical, analytical and postanalytical, depending upon the time of presentation.

There is heterogeneous information on the error rate within the whole laboratory testing process, ranging from 0.1% to 9.3% (1). The distribution of mistakes, as observed by Plebani and Carraro was: preanalytical 68.2%, analytical 13.3%, and postanalytical 18.5% (4). Evidence from recent studies demonstrates that a large percentage of laboratory errors occur in the pre- and post-analytical steps (5–8). Our findings are in accordance with these studies.

Incorrect phlebotomy practice, lack of knowledge and non-compliance of the phlebotomist accounts for the majority of preanalytical errors due to hemolysis, inappropriate sample volume and collection using the incorrect container. Missing or incompletely filled requisition slips also hamper sample processing and contribute to preanalytical errors. It is common knowledge that hemolyzed, lipemic and icteric samples interfere with the analytical measurement of various parameters such as glucose, creatinine and cholesterol. The presence of hemolysis or lipemia resulted in a request for a fresh sample. However, it was not possible to exclude icteric samples as our hospital specializes in gastroenterology and gastrosurgery, and hyperbilirubinemia is common. Thus, all reports were dispatched with a note cautioning the interpretation of the test results due to accompanying icterus. Information concerning drug history was also taken into consideration when dispatching reports. Our rejection rate was 0.9%, compared to 1.4% reported by Ricós et al. (9) and 0.7% observed by Alsina et al. (10). Hemolyzed samples were the most commonly encountered problem in our laboratory (53.2%). Of the total samples received in our laboratory in 1 year, 0.7% were found to be hemolyzed, compared to 0.2% reported by Ricós et al. (9). This can also be expressed that 81% of the total number of samples rejected by our laboratory was due to hemolysis. Alsina et al. reported an incidence of 29.3% of hemolyzed samples in their retrospective analysis of data from 105 laboratories (10). The next most frequent cause of sample rejection was insufficient sample volume, with frequency of 7.5%. Incomplete patient information due to illegible hand writing or inappropriately filled requisition slips (13.9%) interfered with prompt notification of critical values to the clinician. Other types of preanalytical mistakes reported by our laboratory staff were lipemic samples (0.7%), empty vacutainers (1.0%) and tubes breaking during centrifugation (0.6%). Of the total number of samples received during the year, the observed frequency of incorrect patient identification and illegible handwriting was 0.1% for both types of errors. This is identical to that reported by Ricós et al. (9).

Automation, training of laboratory personnel and adoption of QC programs has led to an impressive decline in the occurrence of analytical errors (11–13). We observed a frequency of 7.9% for analytical errors in our clinical laboratory. These errors were comprised of systemic errors such as malfunctioning of probes, photometric lamps and blockage of tubing, non-conformity with internal QC, random errors due to pipetting difficulties or the analyzer, or related to problems such as fibrin clots and short samples, calibration drift, and contamination of reagents. Systemic errors, which amounted to 3.8% of the total errors, were the most frequently documented analytical error. Sample processing was delayed until the problem was identified and rectified by the service engineer. Random errors due to fibrin clot and other unidentified causes contributed significantly to analytical errors (1.6%). Repeat calibration needed to be performed in ten instances (1.0%), over and above the routine calibrations that are performed. Abnormal patient results due to calibration drift was the reason for repeat calibrations. Calibration of a parameter is considered to be within limits if the optical density (OD) of the reagent and the factor generated following the calibration procedure falls within the range specified by the manufacturer. New QC material was reconstituted six times (0.6%) due to abnormal QC results. This can be attributed to inappropriate storage of QC by the laboratory staff. Inaccurate results due to reagent contamination were the least frequent error encountered in our laboratory (0.4%). In our pursuit for achieving maximum analytical precision and accuracy, we enrolled our laboratory in two External Quality Assurance Programs (EQAS). Results are analyzed during our departmental meetings and any observed shortcomings addressed on a priority basis. This instills a sense of confidence in our staff.

In the postanalytical phase, the frequency of errors was 15%. Of these, transcription errors accounted for 11.7%. Due to the lack of a laboratory information system (LIS) in our hospital, manual transcription of numerical data is prone to error. Although we double check results in our laboratory, the risk of transcription error remains. Few results were released from our laboratory with an excessively prolonged TAT, 3.2% in frequency due to unforeseen and unavoidable problems. Ricós et al. reported that 11% of the samples analyzed could not be delivered within the specified time limit (9). Reduction of TAT should improve the quality of service. Timeliness is most important to the clinician, who may be prepared to sacrifice analytical quality for faster TAT (14), but laboratorians prefer to maintain analytical quality as well as reduce TAT. Apart from delays in the analytical phase, delayed and lost test requisitions, specimens and reports were major contributing factors prolonging the TAT. Extensive labor resources were allocated for locating missing samples/information.

Conclusions

The role of clinical laboratories in diagnostic medicine has been well established. Errors in the laboratory can lead to inaccurate reports dispatched to clinicians, affecting health care services greatly. Ensuring the credibility of results is of utmost importance. While many clinicians probably believe that most errors in the laboratory are analytical, there are data showing that the preanalytical and postanalytical phases are the greatest contributors to laboratory mistakes. Though it is impossible to completely eliminate errors, it is possible to reduce them. We conclude that training of phlebotomists and technicians, bar coding of samples, implementation of a LIS, adoption of standardized procedures along with participation in external quality assessment programs and accreditation schemes can help to reduce laboratory errors to a minimum.

Conflict of interest statement

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