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Original Article

Biochemistry Section

Analysis of Errors in a Clinical Laboratory of a Tertiary Care Hospital, Odisha, India

KAVITA AGGARWAL[1], SUMIT JHAJHARIA[2], TAPASWINI PRADHAN[3], VIYATPRAJNA ACHARYA[4], SAURAV PATRA[5], SRI KRUSHNA MAHAPATRA[6]

ABSTRACT

Introduction: Medical and laboratory errors can be caused due to many reasons, including communication problem, inadequate training of the staff members, improper identification. Quality indicators can help in objective measurement of errors in various crucial steps.

Aim: To determine the nature and frequency of preanalytical, some of the analytical and postanalytical errors in the clinical laboratory with the help of quality indicators.

Materials and Methods: This was a retrospective study and data was collected for preanalytical, some of analytical and postanalytical errors from December 2020 to May 2021, from the central laboratory and were classified under various quality indicators. MS Excel was used to analyse the data and descriptive statistics such as number and percentage were used to present the data.

Results: Out of the total 677,887 samples received from both Outpatient Department (OPD) and Inpatient Department (IPD) in the central laboratory for clinical chemistry, preanalytical error was found in 482 samples (0.071%) and most common was haemolysis and billing errors. Out of total 677,887 samples received repeat testing was done in 287 samples (0.042%), Turnaround Time (TAT) exceeded in total 2,29,629 samples (33.87%) and transcription errors/amended report were seen in 41 (0.006%).

Conclusion: Sample haemolysis, billing errors, insufficient sample and clotted sample are the most common preanalytical errors encountered in clinical laboratory. The TAT was exceeded in one third of the samples. These errors can be minimised by repeated training, annual competency assessment and more automation in preanalytical phase.

Keywords: Haemolysis, Laboratory errors, Preanalytical errors, Quality indicator

INTRODUCTION

There is enormous amount of pressure on medical institutions, doctors, other health care workers, patients and communities due to increased workload and rising costs in developed as well as developing countries. There are innumerable challenges in healthcare industry due to extreme shortages of staff, which can lead to many unavoidable medical errors in healthcare.

Medical error has been defined as an unintentional act (either of "omission" or "commission") or one that does not achieve its intended outcome, the failure of a planned action to be finished as intended (an "error of execution"), using an incorrect plan to achieve a goal (an "errors of planning"), or a deviation from the method of care which could or might not cause harm to the patient [1,2].

The existing resources are not sustainable and are under extreme strain due to higher demand for services and support; therefore hospitals are increasingly replacing manual methods to technology and automation to reduce the strain on an already fragile system. Adoption of automation and digital technology around the world has helped a lot in eliminating manual, error-prone procedures and replacing them with digital solutions that increased the accuracy of patient identification, streamline processes, saving the critical time and improving the quality of patient care.

India's healthcare sector is not adopting technology as fast as its counterparts in the rest of the world due to various reasons one of them being cost. This can lead to errors both in diagnostic as well as therapeutic procedures. Medical and laboratory errors can be caused due to many reasons, including communication problem, inadequate training of the staff members, improper identification of the patient are some of the errors to name a few. In the year 2000, United States America (USA) Institute of Medicine (IOM) estimated that greater than one million preventable errors occur every year and of these between 44,000 and 98,000 results in death [3]. Medical error is the third main cause of death after heart disease and cancer [4]. In a Harvard study by Jha AK et al., reported that 5.2 million medical errors are happening in India every year [5]. Wilson RM et al., highlighted that medical errors causing deaths may be more rampant in low and middle-income countries [6].

Laboratory test results have a huge impact on diagnosis and patient management in approximately 60-70% of all diagnosis and treatment. Therefore, laboratory services should be more safe and error free. Although there is ten-fold reduction in the analytical error in the past decade due to automation in the analytic techniques, standardisation of reagent quality, instrumentation and advances in information technology in the analytical aspect, but quality cannot be assured by merely focusing on analytical procedure. Quality control and quality assurance methods have also contributed a lot in achieving a good analytical procedure [7]. Preanalytical and post analytical part constitute the major part of error in laboratory that is approximately 70-80% [8,9]. Although preanalytical and postanalytical errors can be due to action taken by others involved in the testing process like physicians, staff nurses and phlebotomists which are beyond the laboratory's control.

Grading laboratory errors on the basis of their seriousness can help in identifying the error which needs priority to focus on quality improvement and corrective/preventive actions can be timely taken to reduce these errors. Quality indicators can help in objective measurement of errors in various crucial steps. Plebani M developed a model of quality indicators to evaluate and monitor preanalytical phase in clinical laboratory [10]. This study was planned to determine the nature and frequency of preanalytical, some of the analytical and postanalytical errors in our clinical laboratory with the help of quality indicators.

MATERIALS AND METHODS

The present retrospective observational study was conducted in June 2021 analysing the data of December 2020 to May 2021 in central laboratory of a tertiary care teaching hospital Kalinga Institute of Medical Sciences (KIMS) Bhubaneswar, Odisha, India. Laboratory is accredited since last six years. Institutional Ethics Committee clearance was obtained for the present study vide letter (no. KIIT/KIMS /IEC/689/2021).

The central laboratory of KIMS is equipped with high end automated analysers to perform various routine and specialised tests like Complete Blood Count (CBC), blood culture, blood glucose, renal function test, liver function test, iron profile, cardiac profile, hormone assay, vitamin estimation, inflammatory markers, tumour markers and histopathological test and biopsy. Internal and external quality controls are run according to the National Accreditation Board for Testing and Calibration Laboratories (NABL) criteria for a large laboratory. Retrospective data of preanalytical, some of analytical and post analytical errors for a period of six months was taken from the central laboratory and were classified under various quality indicators.

STATISTICAL ANALYSIS

Descriptive statistics such as number and percentage were used to present the data. Data analysis was performed using MS Excel.

RESULTS

Out of the total 677,887 samples received from both OPD and IPD in the central laboratory for clinical chemistry, preanalytical error was found in 482 samples (0.071%). The most common errors were haemolysed blood sample comprising of 148 samples (0.021%), billing were the second common cause of error seen in 129 samples (0.019%) and the third common cause of error was insufficient sample volume in 100 samples (0.014%). The other causes of error were inappropriate sample container in 83 samples (0.012%), sample without TRF (Test Requisition Form) in 15 samples (0.0002%) and identification errors in 2 samples (0.0002%) as shown in [Table/Fig-1].

In case of pathology samples out of the total 72,870 samples received for complete blood count, 360 samples (0.49%) were clotted samples and 2 biopsy samples (0.076%) were received without formalin out of the total 2,619 biopsy samples received in six month duration as shown in [Table/Fig-2].

[Table/Fig-3] shows the data of analytical and postanalytical phase which included number of tests repeated, TAT, transcription errors/ amended report and number of complaints received. Out of total 677,887 samples received repeat testing was done in 287 samples (0.042%), TAT was exceeded in total 2,29,629 samples (33.87%) and transcription errors / amended report were seen in 41 (0.006%).

DISCUSSION

From the simplest blood tests to the most complex oncology diagnostic solutions, laboratories around the country have become an essential part of the healthcare system and errors in the laboratory have detrimental effect on clinical outcome. Laboratories should make every effort to decrease the number of errors in all the three phases namely preanalytical, analytical and postanalytical phase.

Month	Total No. of sample received	Identification error	Sample without TRF	Billing error	Inappropriate sample container	Insufficient sample volume	Haemolysis	Total error each month	Percentage of total error
December	95685	0	5	30	15	36	31	117	0.122%
January	108157	2	3	25	13	13	20	76	0.070%
February	107098	0	4	24	3	4	33	68	0.063%
March	130838	0	2	22	11	21	26	82	0.062%
April	114063	0	1	16	31	5	25	78	0.068%
May	122046	0	0	12	15	21	13	61	0.050%
Total	677887	2	15	129	83	100	148	482	0.071%

[Table/Fig-1]: Type and percentage of preanalytical error for a period of six months.
TRF: Test requisition form

Months	Whole blood samples	Clotted sample	Percentage of clotted samples	Total number of biopsy samples	Biopsy sample without formalin (n)	Percentage Biopsy sample without formalin (%)
December	10918	84	0.76%	436	0	0
January	12534	84	0.67%	436	0	0
February	12156	56	0.46%	523	0	0
March	15020	57	0.37%	618	2	0.32%
April	12394	23	0.18%	479	0	0
May	9848	56	0.56%	127	0	0
Total	72870	360	0.49%	2619	2	0.07%

[Table/Fig-2]: Type and percentage of error in pathology samples.

Months	No. of test repeated	Percentage of test repeated	Turn around time (No. of sample exceeding TAT)	Percentage of sample exceeding TAT	No. of transcription error/ Amended report	Percentage transcription error/Amended report
December	49	0.051%	27040	28.25%	6	0.006%
January	84	0.077%	35779	33.08%	6	0.005%
February	38	0.035%	34014	31.75%	4	0.003%
March	59	0.045%	44238	33.81%	3	0.002%
April	31	0.024%	34063	29.86%	11	0.009%
May	26	0.020%	54495	44.65%	11	0.009%
Total	287	0.042%	229629	33.87 %	41	0.006%

[Table/Fig-3]: Type and percentage of some analytical and postanalytical errors.
TAT: Turnaround time

In the current study after analysis of total 677,887 samples received from both OPD and IPD in the central laboratory for clinical chemistry, preanalytical errors were found in 482 samples (0.071%). In the previous study done by Sushma BJ and Shrikant C, preanalytical error in 670 samples (3.45%) out of the total 19411 sample analysed over a period of four months was reported [11]. In comparison, the present study found to have significantly less number and percentage of errors which can be explained by the fact that our central laboratory is NABL accredited since last six years ascertaining that quality has improved over time.

The most common preanalytical error observed in the present study was haemolysed blood sample in 148 samples (0.021%), similar to a study done by Bhutani N and Bhutani N in emergency biochemistry laboratory who reported haemolysis as the most common cause of preanalytical error [12]. Haemolytic specimen is still a major concern to laboratory specialists worldwide as it may occur in vivo and in vitro. In vivo haemolysis can be due to some diseases like inherited or acquired haemolytic anemias, whereas in vitro haemolysis is the result of improper or mishandled procedures during specimen collection. Haemolysed sample is not suitable for analysis of potassium, bilirubin, creatinine, various enzymes like Lactate Dehydrogenase (LDH), Gamma-glutamyl transferase (GGT), Creatine Phosphokinase (CPK) etc. It can influence the accuracy of the results. Many of the newer automated analysers use the haemolysis index to detect sample haemolysis. About 40-70% of the sample rejection is due to haemolysis [13,14]. Satisfactory skills, good level of knowledge and experiences are essential to collect a quality sample [9].

Surprisingly, the second common cause of error in 129 samples (0.019%) was billing error. None of the previous studies have reported this error, in the present study this error can be due in illegible hand writing of the clinicians or transcription error of the receptionist.

The third common cause of error was insufficient sample volume in 100 samples (0.014%), which is in concordance with Bhutani N and Bhutani N; and Venkat Raghavan ATM et al., [12,15]. Inadequate sample can be due to various reasons like lack of knowledge and skill in phlebotomist about the amount of sample required for the test, difficult venous assess in case of paediatric samples and chronic debilitating diseases like cancer patients on chemotherapy. Other causes of preanalytical errors were inappropriate sample container in 83 samples (0.012%), sample without Test Requisition Form (TRF) in 15 samples (0.0002%) and identification errors in 2 samples (0.0002%), which is in accordance with previous studies depicting similar findings [11-17].

In order to reduce identification error, the laboratory should confirm that the sample has been obtained correctly and from the individual that is being tested. The Clinical and Laboratory Standard Institute (CLSI) recommends patients should be asked to state their full name, address, birth date or age, and/or unique identification number. The laboratory technician, nurse, or treating physician must compare this information with that listed on the identification wristband that must be worn by the patient and the test requisition form or system generated labels for that patient [16].

In case of pathology samples out of the total 72,870 samples received for Complete Blood Count (CBC), 360 samples (0.49%) were clotted samples. In an overview of the results of four years of the preanalytical quality control program 29% of all rejections were due to haemolysis and 14% were due to clotted sample [18]. Clotted sample is the most common cause of sample rejection in the pathology laboratory as reported by many studies [11-17].

In the present study, only 2 biopsy samples (0.076%) were received without formalin out of the total 2,619 samples received in six month duration, an encouraging finding indeed, as biopsy sample is a precious sample therefore error should be as low as possible.

Regarding the analytical and postanalytical phase we could obtain data for the number of test repeated, TAT and transcription errors/amended report. Out of total 677,887 samples received repeat testing was done in 287 samples (0.042%), repeat testing of critical results to confirm them before reporting the results is an accepted practice in many laboratories, but it have been found that this practice has no additional benefit and repeat testing only increase TAT. If the internal and external quality control are satisfactory, repeat testing is unnecessary, as results in the reference range are accepted without being repeated. There is no need to repeat critical results unless they fail the delta check [19,20].

The TAT was exceeded in total 2,29,629 samples (33.87%), which is very high. Automation in the preanalytical phase helps to prevent human error, which is highlighted by the fact that currently laboratory workers are handling ever-increasing workloads alongside a reduction in personnel, which leads to physical and mental exhaustion. Automated robotic workstations can reduce the number of laboratory errors that occur in sorting and labelling of samples, thereby improving the integrity of those samples throughout the steps of sample processing [21].

To reduce TAT, some institutions have developed facilities to provide near-patient testing and Point-Of-Care-Testing (POCT), for the tests like blood gases analysis, cardiac markers like troponins and serum electrolytes. But such alternative sites of testing may compromise preanalytical factors such as specimen collection, collection in appropriate vials, and maintenance of the integrity of specimens. Transcription errors/amended report were detected in 41 samples (0.006%). Transcription errors are random and mostly human error due to wrong entry of results, which can be eliminated by automation, use of bar codes and digitalisation.

Easily understandable policies should be formulated by the laboratories for collecting, handling, and transporting samples. Standard Operating Procedures (SOPs) must be enforced for phlebotomy, which include proper procedures for specimen collection; universal precautions to be taken for disposal of syringes, needles, and other materials used during the specimen collection process.

After analysing the nature and frequency of preanalytical errors, corrective and preventive action can be taken to reduce these errors thereby improving clinical outcome. This can only be achieved by undergoing repeated training and continuing education program undertaken annually or as required, followed by annual proficiency and competency assessment. This training program should be targeted for all non laboratory and laboratory personnel involved in specimen collection.

Limitation(s)

Authors could not segregate the sample according to the OPD, IPD and Emergency Department sample due to retrospective nature of data. Segregation could have pinpointed the cause of various errors detected. However, the strength of the study lays in the fact the sample size was quite large which may have given the true picture of various errors in clinical laboratory.

CONCLUSION(S)

Sample haemolysis, billing errors, insufficient sample and clotted sample are the most common preanalytical errors encountered in our clinical laboratory. The TAT was exceeded in one third of the samples. These errors can be minimised by repeated training, annual competency assessment and more automation in preanalytical phase consisting of automated specimen container preparation tube (vacutainer selection and labelling specific for each patient), sampling (automated venous sampling system and real-time digital vein imager) and transporting (Pneumatic tube system). Postanalytical section automation covers auto-verification, recapping, automated specimens archiving, retrieval, decapping in the case of a rerun, and secondary specimen sorting for off-line analysers.

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PARTICULARS OF CONTRIBUTORS:
1. Associate Professor, Department of Biochemistry, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India.
2. Associate Professor, Department of Biochemistry, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India.
3. Professor, Department of Biochemistry, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India.
4. Professor, Department of Biochemistry, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India.
5. Consultant, Department of Biochemistry, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India.
6. Professor and Head, Department of Biochemistry, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Kavita Aggarwal,
Associate Professor, Department of Biochemistry, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India.
E-mail: kavitakims@gmail.com

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