Preanalytical variables and its impact on total quality management of clinical biochemistry laboratory- A tertiary referral rural hospital study

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Abstract

Introduction: Advances in science and Technology have led to transformation of laboratory diagnostics from manual, cumbersome testing methods to fully automated science, ensuring accuracy and speed. Quality is the core issue for all laboratories and this requires total quality management in the laboratory process in the preanalytical, analytical and post analytical phases.

Objectives: To study and evaluate the types, frequency and magnitude of errors in our tertiary health care clinical Biochemistry Laboratory in the preanalytical testing process and its overall impact on Total Quality Management System of our laboratory.

Materials and Methods: A prospective observational study, samples received for analysis between Jan 2015 to Dec 2015 in the clinical biochemistry section was evaluated for various preanalytical errors. We evaluated the frequency and types of preanalytical errors found in our laboratory by monitoring specimes requested for laboratory analyses from both inpatient and outpatient divisions and statistically analyzed.

Results and Discussion: Of the total 1,38,275 analytical requests, 6446 (4.66%) samples were rejected due to various errors in preanalytical variables.

For the inpatient samples, preanalytical error rate was 4.20% (4107 samples), the preanalytical variable with highest frequency of occurrence was specimen hemolysis/ Lipemic sample (1.00%) 980 samples. For the outpatient sample preanalytical error rate was 5.75% (2339). The variable with highest frequency was requisitions with incomplete patient treating physician information 1.37% (559). Preanalytical errors in laboratories are very common and play a very important role in patient care and treatment.

Lipemic/hemolytic samples are known to affect the parameter to be analysed and incomplete patient information leads to error in reporting the patient's results, which means the post analytical error becomes unavoidable and incomplete treating physician information leads to delayed reporting of critical values.

Conclusion: Our study observation showed each preanalytical variable to occur at different frequency and plays a very important role in the Total Quality Management system of the diagnostic lab which needs to be addressed on priority.

Keywords: Preanalytical, Analytical, Post analytical, Total quality management, Quality assurance.

Introduction

Recent advances in laboratory technology have made available new and more reliable means for the automated analysis of various Body fluids and Blood indices.[1] However, producing a reliable quality laboratory report in a health care system does not entirely depend on the content of precision, accuracy, sensitivity, specificity and advances in laboratory technology for the analytical process alone. Identifying and correcting the mistakes arising at various levels of the testing process needs to be addressed. Testing areas where errors arise includes pre-analytical, analytical and post-analytical phase which depends on their source and time of presentations respectively.[1]

Total quality management (TQM) with respect to clinical laboratory particularly for biochemical analysis means that every variable that could possibly affect the quality of test results has been controlled by the five key components of TQM. The major 5 key components for the establishment of quality and reliability in the laboratory diagnostics of health care systems include (a) Quality laboratory process (QLPs), (b) Quality control (QC), (c) Quality Assurance/Assessment (QA), (d) Quality Improvement (QI) and (e) Quality policy (QP). These key components work in a feedback loop and should be integrated with each other.[2] Errors affecting any of the above mentioned key components can affect the entire quality management system of the laboratory at large. Studies have shown the errors with respect to preanalytical variables to account for more than one third to 50% of all laboratory errors.[3]

Monitoring the type of preanalytical error and its magnitude occurring in individual laboratory and the knowledge regarding its burden on the TQM would significantly contribute in formulating quality goals and measures in achieving these goals which would vary from laboratory to laboratory and will help in improving the overall quality and reliability in the laboratory diagnostic process.[4] This has created an interest in us with an aim to study and evaluate the types, frequency and magnitude of errors in our tertiary health care clinical biochemistry laboratory in the preanalytical testing process and its overall impact on total quality management system of our laboratory. Further we also have made an attempt to formulate certain corrective measures that would eliminate these possible preanalytical errors that occur in future.

Materials and Methods

Ours is a prospective observational study done in the Biochemistry section of Central Clinical Laboratory at Sri R. L. Jalappa Hospital attached to Sri Devaraj Urs Medical College constituent of Sri Devaraj Urs Academy of Higher Education and Research, a tertiary care Superspeciality center in Karnataka, R. L. Jalappa Hospital and Research Centre (RLJH&RC) is an 1100 bed hospital. Frequency of preanalytical errors observed in our clinical biochemistry laboratory during 1-year period from January 2015 to December 2015 was entered in Microsoft excel and statistically analysed using SPSS version 16.0.

Percentage calculations of samples rejected for each month and the sample rejection rate was calculated by number of samples rejected / total number of samples analyzed X 100.

Inpatient phlebotomies are performed by clinical department staff, whereas blood specimens from outpatients are collected on site at a centralized collection center by laboratory personnel. The samples are delivered to the lab by the paramedical staff from the wards and laboratory supporting staff from the OPD respectively. The samples are collected using evacuated tubes (vacutainers evacuated tubes from BD Franklin Lakes NJ USA). The lab provides routine testing of biochemical parameters which includes routine chemistries, hormone assays and glycated hemoglobin useful in clinical diagnosis and management. In the Clinical Biochemistry section the instrument used was Vitros-250 dry chemistry autoanalyzer for routine sample processing. On receiving the samples, the trained laboratory technical staff visually detects any errors without patient samples and request forms. When an error occurs, entries are made in the sample rejection register which will be verified by laboratory in charge. The data generated is reviewed on a weekly basis and the same shall be discussed during the daily clinical audit. The data collection procedure included review of blood samples and body fluids received from the inpatient as well as from the outpatient departments. Samples were considered unsuitable for processing according to the following sample rejection criteria: wrong entry and labeling of hospital number and name, inappropriate volume, wrong or missing patient identification, inappropriate container, visible hemolysis before and/or after centrifugation, samples clotted (EDTA), lipemic samples and wrong entry of investigations before & after billing.

All the above parameters were considered and viewed as quality indicators for the continual improvement in the TQM of the laboratory process.

Results

A total of 1, 38,275 patient samples were received in the clinical biochemistry laboratory from both inpatient and outpatient departments of the R.L. Jalappa hospital for analysis. Study period was from January 2015 to December 2015. Out of 1,38,275 total samples received; 97634 samples were from patients admitted in the wards and 40,641 samples were collected at the central clinical laboratory collection centre from outpatient.

Results of the study are presented in Table 1 and Fig. 1, 2 & 3. The present study observed the highest error rate of 8.66% during the month of April 2015 as compared to the error rate range between 2-6% during the rest of the months for the period of January 2015 to December 2015 and the sample rejection rate during the year was around 4.66%. With the total number of 1,38,275 samples received during the year 6,446 samples being rejected due to various errors in various preanalytical variables as shown in Table 1.

Fig. 1 shows the graphical representation of the total number of samples received and the number of samples having preanalytical error during that particular month.

Fig. 2 shows the frequency and percentage of most commonly reported types of preanalytical errors with inpatient samples during the period of study. For the inpatients samples, we observed a preanalytical error rate of 4,107 (4.20%) for the total number of samples 97,634 that was received. The variable with highest frequency of occurrence was specimen hemolysis/Lipemic samples with (980) 1.00% and the remaining (618) 0.63% to (215) 0.22% was due to samples with incomplete information (age, gender, physician's name), insufficient volume of sample, wrong labeling of hosp. No., name in vacutainers, collecting tube cap changes after sample collection, wrong entry of hospital number/ lab number in requisition forms, vacutainers, number of samples clotted (EDTA), number of samples collected in inappropriate containers, Wrong entry of investigations before and after billing and number of samples lost/not received respectively.

Fig. 3 shows the frequency and percentage of most commonly reported types of preanalytical errors in our lab with outpatient samples during the period of study. For the outpatient sample we observed a preanalytical error rate of 2339 (5.75%) for a total number 40641 of samples received and the variable with highest frequency of occurrence was samples with incomplete requisition forms (559) 1.37% especially no information regarding patient age and gender and the name of the treating physician, followed by lipemic/ hemolysed sample (371) 0.91% insufficient sample volume accounting for about (268) 0.70% and rest of the errors (162) 0.41% to (143) 0.35% was due to collecting tube cap changes after sample collection, wrong labeling of hospital number., name in vacutainers, wrong entry of hospital number/ lab number in requisition forms, vacutainers, number of samples clotted (EDTA), number of samples lost/not received, number of samples collected in inappropriate containers and wrong entry of investigations before and after billing respectively.

Table 1: Total number of samples and preanalytical errors per month

Month	Number of samples per Month			Number & Percentage of Pre analytical errors per month	
	OP	IP	Total	Preanalytical errors/ month	Percentage
January	3700	6025	9725	615	6.32
February	6123	8341	14464	480	3.31
March	3925	8522	12447	922	7.4
April	3000	6636	9636	835	8.66
May	2673	8570	11243	515	4.58
June	3015	8045	11060	421	3.8
July	2708	8982	11690	301	2.57
August	2880	8251	11131	483	4.33
September	3700	8555	12255	521	4.25
October	3320	8745	12065	225	1.86
November	2847	8134	10981	608	5.53
December	2750	8828	11578	520	4.49
Total	40641	97634	138275	6446	4.66

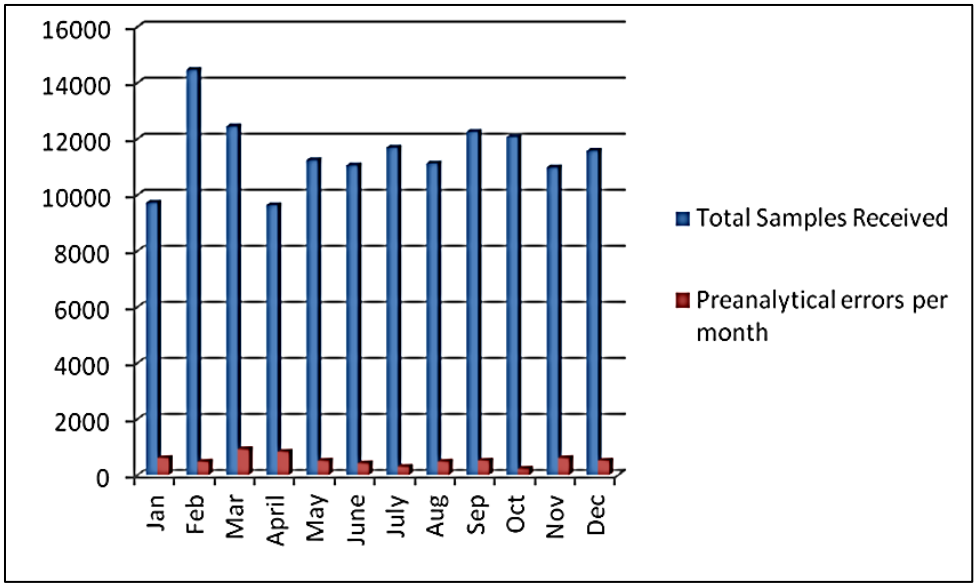

Fig. 1: Total number of samples and preanalytical errors per month

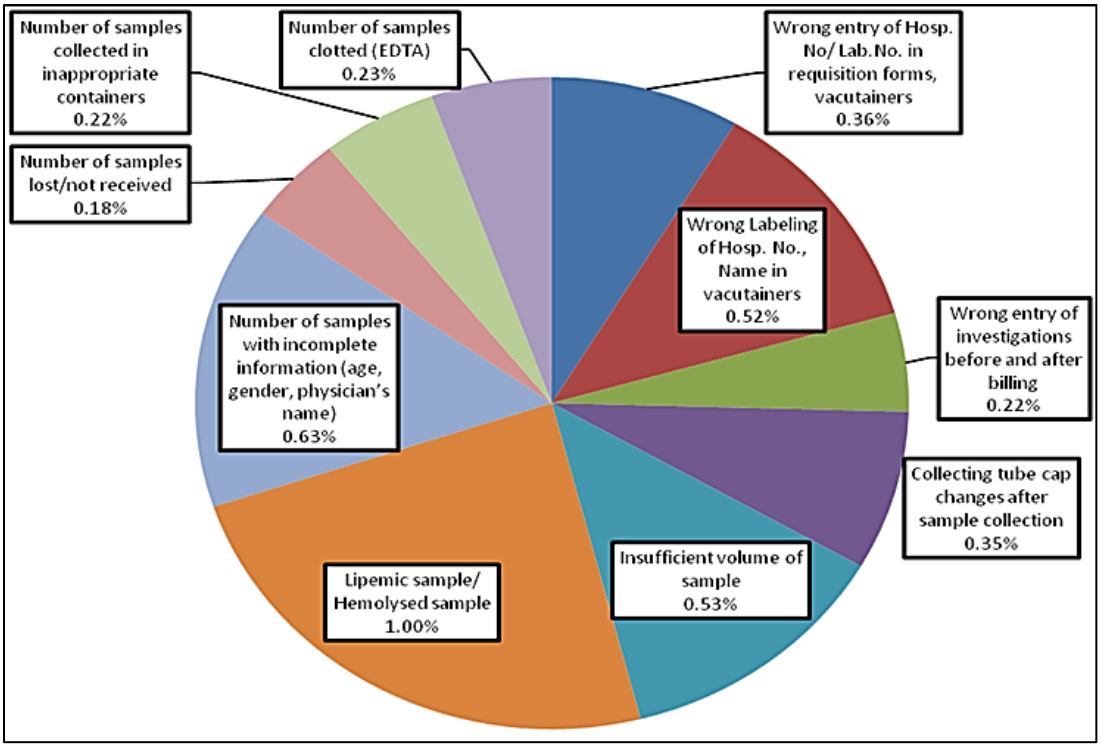

Fig. 2: Frequency of the different preanalytical errors observed in a total of 97634 inpatient samples

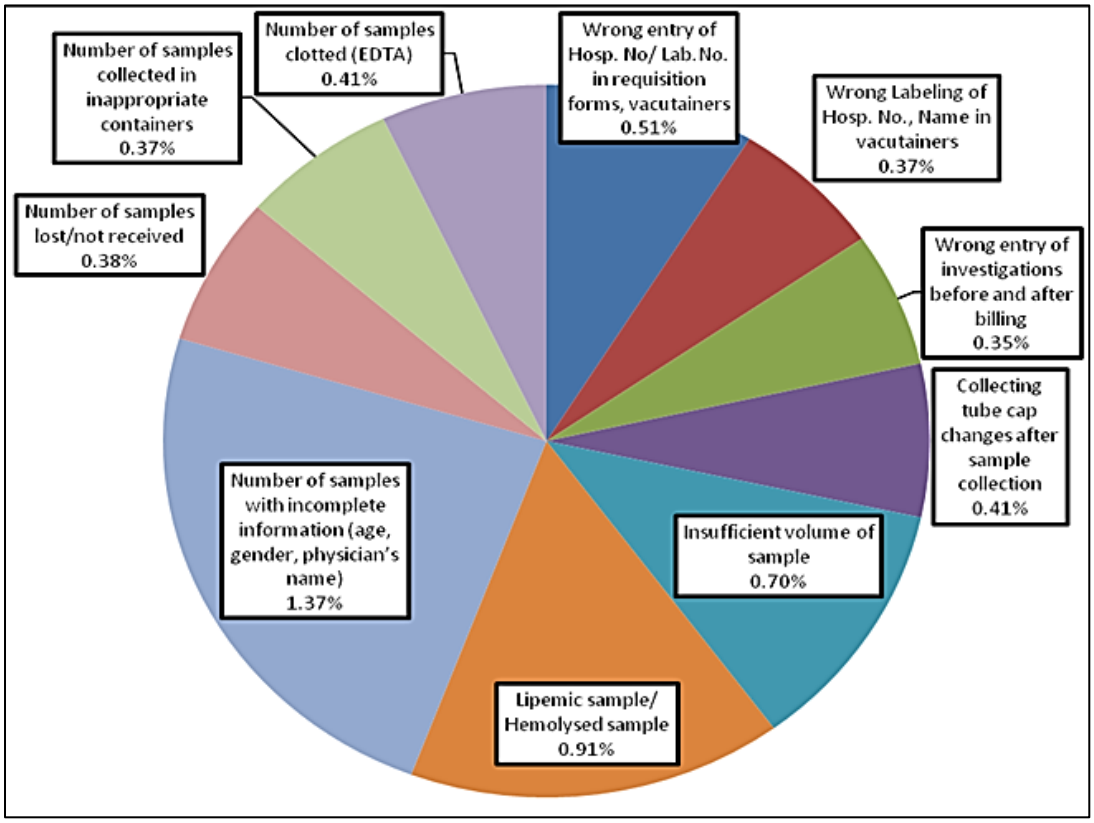

Fig. 3: Frequency of the different preanalytical errors observed in a total of 40641 outpatient samples

Discussion

Quality in general means conformance to the requirement of users or customers, with respect to health care systems, the users of health care laboratories are doctors, nurses and their customers are the patients. Laboratory errors have significantly decreased in the last

four decades with advances in technology such as automation, lab lean process and application of six sigma, analytical errors have decreased considerably but most of the errors documented occur in the preanalytical phase.[5]

Studies have shown that clinical laboratories are affected around 60-70% of all critical decisions by physicians such as admission, discharge and during therapy to patients.[6] Hence it is the duty of the concerned laboratory to generate quality laboratory report by minimizing the laboratory errors to zero in particular and contribute in reducing medical errors to acceptable levels in general.

However all laboratory procedures are prone for errors because of the increasing rate of human intervention which largely includes the preanalytical phase of the testing process.[4] The total testing process in a clinical laboratory are divided mainly into 3 phases 1) preanalytical 2) analytical 3) post analytical errors in any of the steps can invalidate the quality of analysis diminishing the quality goals of the laboratory. It has been documented that around 70% of the laboratory errors are due to preanalytical testing process.[6] This considerably affects the Total Quality management process (TQM) of the laboratory. Quality assurance system an integrin part of feedback loop of TQM system of a laboratory is found to be significantly affected by errors which occur during the preanalytical phase.[6]

In our study we observed that 6446 (4.66%) of the total samples received in our laboratory during the year 2015 were rejected due to error in the various preanalytical variables such as 1) Lipemic/hemolysed samples 2) samples with incomplete requisition forms with regards to patient's age, gender and the name of treating physician, 3) insufficient volume of sample. Other factors which contributed a minor include wrong entry of hospital number/lab number which caused difficulty in primary sample identification, exchange of collection tube caps after sample collection which caused difficulty during sample segregation and transport, wrong labeling of hospital number/name on sample vacutainers, clotted samples in EDTA vacutainers due to improper mixing of blood with anticoagulant after collection. Collection of samples in improper containers and the least frequent error was missing samples. The root cause analysis for the above preanalytical error was found to be due to knowledge regarding sample collection procedures and lack of communication among health care workers.[7]

In our study we found that around 1% of the samples received for analysis were hemolysed and some lipemic samples which are known to cause variable effects on assays. Our findings were consistent with the study conducted by Jones et al.,.[8] Main causes for this preanalytical error could be due to excessive pressure in the syringe plunger which results in turbulent flow, venipuncture site other than anticubital fossa i.e. from forearm where veins are small, tortuous and has shown increased incidence of hemolysis, use of antiseptics like alcohol as disinfectant if not dried properly or dried manually, longer duration of application of tourniquet, traumatic venipuncture or double puncture of veins can also result in hemolysis of the sample. Therefore in order to avoid obtaining hemolysed sample the staff involved in collecting samples must be trained appropriately to maintain collection standards and the laboratory has to establish training curricula for all staff involved in phlebotomy.[7] Periodic training and revision training, standard operating procedures for venipuncture are required to avoid hemolysis of the patient sample.[9,10]

Samples may be lipemic mainly because the patient preparation was inadequate for the required test, which might lead to spectral interference during the process of sample assay. Studies have also demonstrated that preanalytical errors are less common when dedicated and trained laboratory persons collect blood samples as compared to incompletely trained nursing or other health care personnel as variables related to phlebotomy technique and procedures can introduce preanalytical error.[11]

The next commonest preanalytical error included the number of samples with incomplete information (age, gender, physician's name). Around 0.63% (618) and 1.37% (559) from samples received from inpatient and outpatients respectively were samples with incomplete requisition forms with regard to patient age, gender, the referring physician's name, which is an error by health care personnel not under the direct contact of the clinical laboratory. These errors affects the reporting system of the laboratory with regard to assessing the correct reference values for the analyte requested, avoid unnecessary test repetition and inform the treating physician on time if a critical value for that particular analyte is observed.[11,12]

Laboratory professionals should provide proper training or information to the treating physician and to insist upon the bedside phlebotomist to take care of proper filling of test request forms. This helps laboratory personnel for better biological validation and also important for the clinicians perspective to understand the concept of biological variations that may arise. Computerization of test requesting by physicians, lab lean process, application of six sigma rules could reduce the frequency of the errors.[13,14]

In our study, the pre analytical error, accounting for insufficient volume of sample was 0.53% (520) and 0.70% (268) from samples received from inpatient and outpatients respectively. The laboratory should document periodically and review the requirements regarding sample volume needed for various tests including the dead volume required in analyzer and serum blank in order to avoid collecting insufficient quantities and also considering the repetition of the test if required.[15]

Conclusion

In conclusion, Laboratory services are the backbone of the modern health care sector and are the major supportive service for better patient care. Effective laboratory service is the amalgamation of precision, accuracy and speed of reports delivered to the patient. Inspite of rapid advances in laboratory science, it is still susceptible to various manual and systemic errors. Most errors affecting laboratory test results occur in the preanalytical phase as observed in our study also, primarily because of the difficulty in achieving standardized procedures for sample collection and largely attributable to human mistakes fortunately majority of these errors are preventable.

The measures to prevent these preanalytical errors should include excellent communication appropriate training of staff involved in sample collection, labeling, transport and cooperation among all members of the health care team. Laboratories should implement strict quality assurance programmes (eg: ISO 15189) to provide quality laboratory services which will necessitate dedication, commitment, technical competence, quality technical procedures and a holistic problem solving mechanism by all the health care personnel involved in patient management.

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