Original article

Quantification of Pre-Analytical Quality Indicator in a Clinical Laboratory

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Abstract:

Introduction: Quality in laboratory medicine have a significant role in ensuring the adequate and complete total testing process. Clinical laboratory and testing process is an integral part of modern medicine as it has a direct effect on the patient. As per the requirement of certification or accreditation bodies, different laboratories use different ways of developing quality indicators (QI), which helps to monitor, progress and maintain the quality of the laboratory services. ***Materials and Methods***: A cross sectional retrospective study carried out in the Hematology Laboratory of a tertiary care hospital. Data of pre-analytical quality indicators was collected for months from August 2015 to January 2016. Pre-analytical quality indicators analysed for sample collections were clotted sample, hemolyzed sample, incompletely filled form, wrong labelled sample, insufficient sample volume and patient waiting for sample collection after registration in the laboratory- turnaround time (TAT). Turn around time for patient waiting for sample collection is 15 minutes from the registration of the request form. ***Results:*** The overall sample received during the six months was 2,03,337 among these pre-analytical errors found in 1067. The highest rate indicators were clotted sample 589 (0.28%), followed by insufficient sample volume 376(0.18), incompletely filled form and wrongly labelled sample 67(0.03%), Hemolyzed sample 35(0.017%). 94.49 % of the patient waiting time for the sample collection from registration was within the Turnaround time (TAT). ***Conclusion:*** The development of a quality indicator for clinical laboratory medicine helps to improve quality in processing and testing of samples. Quality indicator plays a vital role in continuous improvement activities of clinical practice, which are aiming to deliver quality result and reducing the errors.

Keywords: Pre-analytical errors; Quality indicator; Turnaround time

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Introduction:

Quality in laboratory medicine has a significant role in the total testing process (TTP), to assure valuable medical result reporting and well-organised patient care[1]. Medical Laboratory testing is a part of modern medicine, which involves several steps from ordering of test until the generation of results and treatment[2]. Diagnosis is mainly depending upon accurate laboratory data[3]. According to the International Standards for Clinical Laboratory Accreditation (ISO15189:2012) "quality indicator can measure, how well an organisation meets the needs and requirement of users and the quality of all operation processes"[4].

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Quality Indicator (QI) is an information of the processes or observation occurring in the laboratories. This QI help in taking corrective and preventive action when there is a deviation from the defined outline. As per certification or accreditation standards, laboratories develop their ways of measuring the quality indicators to monitor and improve quality and patient safety.[5] The chief goal of the laboratory is patient care by reducing errors at pre-analytical, analytical and post-analytical phases of laboratory cycle.[6,7,8]

The maximum risk to patients during the pre-analytical period is about 40 to 70 %.[9] The process flow includes test request by clinicians, identification of the patient, collection of samples, labelling and transportation of sample.[1,2] Errors may occur due to wrongly identification of patient, improper venipuncture, improper sample collection, hemolysis sample, clotted sample, inadequate sample, inappropriate container, inappropriate blood to anticoagulant ratio, inadequate mixing, improper processing, error in transport, delay in transport or inappropriate storage, missing of sample or missing of test request form, contamination from infusion route.[1,10] We attempted to quantify the selected pre-analytical indicators in clinical laboratory practice of a tertiary care hospital.

Methodology

The study conducted in a tertiary care hospital on obtaining the approval from the Institutional research committee, Institutional ethics committee and laboratory in charge. Samples were received both from collection centres (outpatient department) and wards (in the patient department) for testing in the laboratory. The samples are checked for pre-analytical quality indicators and, documented in the register before the analysis. These documented pre-analytical quality indicators were related to vacuum tubes for haematology (EDTA tube) and coagulation study(citrated vacuum tube). Before the analytical phase, samples were checked for a clot, haemolysis, incompletely filled request form, insufficient sample volume, wrong labelled sample. Turn around time (TAT) of patient waiting for the collection of the sample was also noted as a pre-analytical indicator. The data for the study was collected both from the laboratory register and laboratory information system (LIS) to quantify selected pre-analytical indicators. The collected data recorded and analyzed using Microsoft Excel.

Ethical Clearance: The ethics committee of the Kasturba Medical College and Hospital, Manipal approved the study.

Result:

Total of 203337 samples was received from outpatient and inpatient department for six months, among them, 1067 (0.52%) had pre-analytical errors. Clotted sample was the most frequent pre-analytical error (Table 1). Patients visited for sample collection were 309974 out of this 92.5% patient were within the time of waiting for sample collection in the collection area (<15 minutes TAT) (Table 2).

Table 1: Pre-analytical errors in the hematology laboratory during the study period (n= 203337)

Quality indicators	Total number of pre-analytical errors	Percentage of pre-analytical errors
Clotted sample	589	0.29
Inadequate sample	376	0.18
Wrong labelled sample	33	0.016
The incompletely filled test request form (TRF)	34	0.017
Heamolysed sample	35	0.017
Total error	1067	0.52

Table 2: Turnaround time (TAT) - Patient waiting for sample collection after registration in the sample collection centre laboratory during the study period (n= 309974) patients registered for sample collection.

Turnaround time (TAT) - Patient waiting for sample collection after registration in laboratory	Total patient registered for sample collection = 309974	Percentage
Within TAT (<15 minutes of waiting)	286731	92.50
Above TAT (>15 minutes of waiting)	22943	7.50

Discussion:

The analytical phase errors have significantly decreased due to automation, but most of the errors found during the pre-analytical period affect patient care[1]. Nowadays, laboratories are involved in the accreditation process to ensure that report generated

from the laboratory should be quick, precise and reliable. The pre-analytical phase is one of the essential steps in sample analysis.

Compared to other studies, pre-analytical error in our laboratory is low, and this may be on account of the initiation of proper training to the laboratory personnel.[11] The distribution of error in each category as per our methodology is shown in table.1. These errors occurs because of heavy workload, shift duties or different responsibilities.[12] The most common error among them was receipt of the clotted sample (0.28%) while receiving the whole blood sample. Clotting of the sample is one of the findings in our study. Upreti S *et al.*,[11] identified the pre-analytical error due to clotted sample was 0.13%, which is slightly lower than our study. Clotting of the sample in anticoagulated container occurs due to delay in mixing or inadequate mixing of blood after collection. It may also occur due to delay in sample collection or problematic vein during phlebotomy and also prolonged usage of a tourniquet, which increases in collection time. Sending of samples with big clots can be avoided by re-verification, but finding minute clot is difficult.[13]

A second cause of the pre-analytical error was due to an insufficient quantity of blood sample (0.18%), which could be due to the difficulties in selecting veins in chronic debilitating diseases patients, a patient with the problematic vein, uncooperative children and patient avoiding second-time prick usually occurs in intensive care units and pediatric wards.[11] Tubes should fill adequately, otherwise, it causes over dilution or excess of anticoagulant, which in turn gives an erroneous result.[14] The insufficient quantity of blood sample (0.18%) is less as we follow the vacuum tube system.

Other pre-analytical errors cause include a hemolysis sample (0.17%), wrong label (0.16 %) and incompletely filled forms (0.16%).

These type of errors occur mainly because of the lack of checking or verification of samples and requisition before sending for analysis. The reason for the hemolysis sample may be because of extreme force and direct exposure to high temperature. Filling the vacuum tube through a syringe by opening the cap, which will rupture the red cells. Improper labelling tubes and tube filling occurs if phlebotomist is not taking proper care during sample collection or labelling the tube after sample collection. Patient identity and test tube labelling are important during sample collection. Firdausi Begum in 2014 studied about "A pre-analytical errors in a hospital-based clinical biochemistry laboratory, and formulation of measure for correction" pre-analytical error was hemolysed sample (0.17%), and 98.70% of requisition form did not carry all the required information regarding the patient and the sample.[11] Computerised test order connected to patient medical history can minimise these errors.

Almost 7.5% (22943/309974) of patient waiting for sample collection after registration in the OPD was above the turnaround time (>15 minutes of waiting). Delay in sample collection has a significant impact on patient care, it may be due to less staff comparing sample load, or the system is unstreamlined. Errors can be reduced by training the people involved in the pre-analytical phase of sample processing through organising CME, training or workshops.[1,17, 18]. In a study by Ekta Tiwari et al.,[3] majority of the rejected sample were hemolysed, clotted sample and the insufficient amount of blood, in their result, most numbers of pre-analytical errors was from ICUs and ward. So the blood sample collected from outpatient and inpatient department were centralised to reduce error. In our study, samples were collected from various part of the hospital, and the errors observed maybe because of less skilled staff on duty and lack of awareness on precaution to be taken during the sample collection.

Upreti S *et al.*[11] in their study, a total of 135808 sample was received in the hematology lab, out of which 1339 (1%) was pre-analytical errors. Narayanan and Guder[15] address that pre-analytical error can be reduced by maintaining the quality of samples, optimal sample size, use of anticoagulant transportation, storage, handling of the lipemic and hemolytic sample.

Pre-analytical quality control is most important to get an accurate test result.

Bharat V *et al.*[17], in their study pre-analytical errors were maximum in both the inpatient (IPD) and outpatient (OPD) cases (65.43%) than the post-analytical errors (34.57%). But pre and post-analytical errors were more common in inpatient department cases (72.40%) than outpatient department (27.60%) cases. These errors lead to a repeat/rejection of the sample. In our study, we found that most of the mistakes are from wards (IPD) and intensive care units.

Conclusion

Pre-analytical errors found in laboratory reflects the quality of laboratory testing. So in favour of patient care, hard-working, sincere and dedicated staff should be employed to reduce severe consequences due to the errors in the pre-analytical phase. Barcoding and token system are the best way to reduce the patient waiting for the sample collection. There should be a Laboratory Information System (LIS) in place to regularly monitor the laboratory phases. The errors occurring during the three phases of the sample testing process needs to be discussed in the monthly laboratory meeting and required corrective - preventive action to be taken to reduce the errors.

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