Section: Pathology

Original Research Article

PRE-ANALYTICAL ERRORS IN A TERTIARY CARE CENTRE WITH FOCUS ON PREVENTABLE CAUSES

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Abstract

Background: Accuracy of laboratory investigation and timeliness in reporting results play an important role in patient care affecting clinical decisions about patient admission and management. Approximately 60-70% of errors in laboratory testing are noticed in the pre-analytical stage which includes selection of appropriate tests, specimen collection, handling, transportation and preparation of samples. **Aim of the study:** To estimate the rate of preanalytical errors and to aid in improving quality of laboratory diagnosis. **Materials and Methods:** A hospital based cross sectional study was carried out on samples received in clinical pathology laboratory in the Department of Pathology from 1st September 2017 to 31st August 2018. **Results:** Out of the 55,927 samples received during 1-year period, a total of 157 samples were rejected and 164 errors were noted accounting for a total of 0.29% of preanalytical error. Six rejected samples showed >1 preanalytical error. The major causes of preanalytical error were clotted sample accounting for 0.153% of rejection, insufficient sample (0.025%), hemolysed sample (0.019%), excess sample (0.014%). Thirty-four samples were rejected due to incomplete data on requisition slips, accounting for 0.06% of errors. Other preanalytical errors noted were diluted sample, wrong vacutainer and aged sample. **Conclusion:** Improving the quality of diagnosis and timely treatment of diseases based on laboratory tests enhances patient care, quality of treatment, patient satisfaction and aid in resource conservation. So, creating awareness among health care personnel about the preanalytical errors is the immediate and immense need of the hour.

INTRODUCTION

Laboratory investigations play an important role in patient care affecting clinical decisions about patient admission and medication which are based on accurate laboratory results.[1]This accuracy is possible only by striving for 'Quality'. Quality in laboratory medicine is defined as, the guarantee that each activity in total testing process is correctly performed, providing valuable medical decision making and effective patient care.[2]

Laboratory testing is a highly complex process and as stated by George Lundberg, the total testing process (TTP) develops through a virtual loop, referred as "the brain to brain cycle". TTP is divided into three phases- preanalytical, analytical and post-analytical.[1,3] In the past few decades, there has been a 10-fold reduction in the analytical errors due to improvements in reliability, standardization of analytical techniques, reagents and instrumentation. Improved advances in quality control, quality assurance and information technology have also contributed for reducing diagnostic errors.[4]

The preanalytical phase is an important and integral part of laboratory testing with a significant impact on the laboratory diagnostics. Approximately 60-70% of errors in laboratory testing occur in this phase. Major sources of preanalytical errors include missing sample or test request, in-vitro hemolysis, clotted sample, wrong vacutainer, insufficient sample, contamination from infusion site, inappropriate blood to anticoagulant ratio leading to rejection of sample. These errors can be attributed to patient preparation, sample collection, handling, transportation and storage of specimen.[2,3] All these factors affect patient satisfaction and their duration of stay in the hospital.[5] Hence, the present study was undertaken with the objective to estimate the rate of preanalytical errors and to improve quality of laboratory diagnostics.

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MATERIALS AND METHODS

This was a hospital based cross sectional study and was carried out on all the samples received in the clinical pathology section of Central laboratory over a period of one year, starting from 1st September 2017 to 31st August 2018.

All the samples rejected as per the criteria like hemolysis, clotted sample, insufficient sample, diluted sample, wrong vacutainer, wrong identification, wrong test asked, inappropriate blood to anticoagulant ratio, aged sample and test request with incomplete patient data, were included in the study and were entered in a "Sample rejection register" which included the patient details, investigation asked and reason for sample rejection. Intervention was performed promptly, by informing the concerned health personnel about the rejection of sample, the reason for rejection and the steps to be taken to rectify the problem.

Ethical clearance was taken from the institutional ethical clearance committee prior to this study. Care was taken to maintain patient confidentiality throughout the study duration.

Statistical Analysis

Data was analysed using Mean ±SD.

RESULTS

Out of the 55,927 samples received, 157 samples were rejected and 164 preanalytical errors were noted, which accounted for 0.29% of preanalytical error. More than one cause of rejection was noted in 6 samples.

Out of 157 rejected samples, 61 samples were from male patients and 96 samples were from female patients. The different types of preanalytical errors noted are tabulated in Table 1. Most of the preanalytical errors noted in the present study were due to improper sampling techniques. Clotted sample was the major cause of error among these, with 86 samples, accounting for 0.153% of error rate, followed by insufficient, hemolysed and excess samples in 14, 11 and 8 samples, respectively. The other major cause of errors was due to problems with request slips, with inadequate patient details or test details seen in 35 samples, accounting for 0.06% of error rate.

On Department wise analysis of preanalytical errors, it was found that, most of the samples rejected were from Medicine and Paediatrics department, 49 samples and 38 samples, respectively. This was followed by Obstetrics & Gynaecology and Surgery department with 29 and 22 sample rejections, respectively. Departments with the least sample rejections were ENT, Psychiatry and Urology. (Figure1)

Table 1: Types of Preanalytical errors

S. No.	Cause of rejection	No. of samples	Percentage
1	Clotted sample	86	0.153%
2	Sample with inadequate patient data	35	0.06%
3	Insufficient sample	14	0.025%
4	Hemolysed sample	11	0.019%
5	Excess sample	08	0.014%
6	Dilute sample	05	0.008%
7	Wrong vacutainer	03	0.005%
8	Inadequate Blood Anticoagulant ratio	01	0.001%
9	Aged sample (> 24hours)	01	0.001%
Total number of errors		164	0.29%

Table 2: Comparison of Preanalytical error rate

Cause of rejection	Present study	Chawla9 et al	Najat10	Darcy5 et al
Clotted sample	0.153%	-	0.49%	0.05%
Hemolysed sample	0.019%	0.74%	0.47%	0.05%
Insufficient volume	0.025%	0.23%	0.16%	0.04%
Inadequate patient data	0.06 %	0.47%	0.2%	0.01%
Lipemic samples	-	0.07%	0.05%	<0.01%
Preanalytical error rate	0.29%	1.52%	3.3%	0.31%

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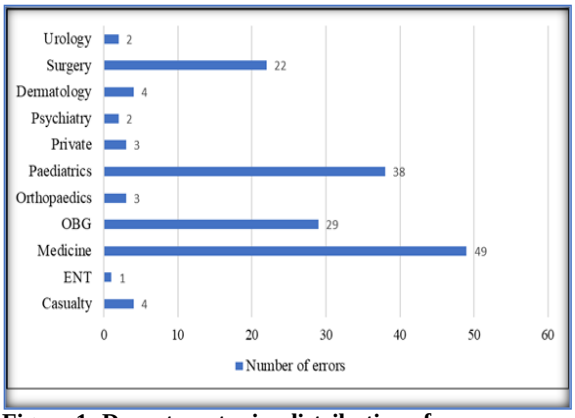

Figure 1: Department-wise distribution of errors

DISCUSSION

Diagnosis and treatment of most of the diseases depends largely on the accuracy as well as precision of the laboratory results. An incorrect report could have devastating consequences for the patient, if not intervened and corrected in a timely manner. So, errors in the laboratory results demand immediate attention and swift rectification for better patient management.

An error can occur at any stage/ phase of testing, right from ordering of tests to the reporting of results. Laboratory testing consists of 3 phases, namely, pre-analytical, analytical and post analytical. The preanalytical phase starts from the moment a test is asked by the physician until the sample is ready for analysis.[6] The analytical phase lasts from the moment the test in question is started up to the time at which a result is obtained. The post-analytical phase begins next and lasts until the patient or clinician is handed the report of the said test. Errors can occur during any of these phases, which need to be identified and addressed promptly.

Conventionally, in laboratory medicine, there has been a lot of focus on the analytical phase, which deals with results, and which indirectly depends upon the sample collection, transportation and all the other steps before the sample is brought to the laboratory. Studies have shown that the quality assurance in a laboratory focuses primarily on the analytical phase while the major cost of testing goes to the pre-analytical and post-analytical factors.[7] Thus, in order for a laboratory to be efficient, it needs to monitor even these factors meticulously. This can only be achieved by interdepartmental cooperation, well trained laboratory personnel and nursing staff, following standard operating procedures, laboratory automation and having a good quality assurance mechanism in place.[7,8]

Although prevalence of error rate, within a laboratory, varies greatly in the literature, from 0.1% to 9.35, no laboratory is immune to it.[9] Many studies have shown that up to 70% of errors arise from the pre-analytical phase which includes inappropriate tests, test request with inadequate patient information, improper sample collection, delay in transport and inadequate patient details, to name a few.[10,11] In the present study, the preanalytical error rate was noted to be 0.29%, out of the 55,927 samples received during 1-year period. Similar findings were noted by Darcy et al.[5] in a Q-Probes study involving 52 institutions, with an error rate of 0.31%. Chawla et al .[9] and Najat et al.[10] however, have noted higher preanalytical error rates of 1.52% and 3.3% respectively. (Table 2)

The majority of the sample rejections in the present study were due to clotted sample, insufficient volume and hemolysis. These causes alone accounted for more than 67% of all the errors and are generally human errors which could be attributed to the lacunae in knowledge and training. These errors can be minimized to an extent by using the vacutainer sample collection tube systems, where the sample tubes are under vacuum and blood is drawn automatically into the tubes by vacuum up to the predetermined volume. This method ensures that the ratio of blood to the anticoagulant is maintained. Not only that, this technique also reduces the risk of direct exposure to blood as it is a closed system.[12] Other studies have also reported that bulk of their preanalytical errors or sample rejections are due to these causes.[5,9,10]

Another major cause of rejection noted in our study was inadequate patient data accounting for 0.06% of error rate. It was observed that many requests had incorrect or incomplete patient details. This is a frequent problem which the laboratory staff have to deal with and more often than not the laboratory staff painstakingly correct the information by getting in touch with the respective in-patient departments. These errors are generally due to high workload of the clinicians. These errors can only be corrected by interdepartmental cooperation, insistence on complete information by the laboratories and sincere efforts on part of the clinicians.[9] Integrating automation like Lab Information Management System and Hospital Management systems into the workflow, can minimize these errors, as the task of repeated filling of the patient data is taken care of by barcoding or by electronic requisition slips.

CONCLUSION

The preanalytical phase has a significant effect on the turnaround time of the laboratory results and consequently on the patient‘s safety. Greater emphasis needs to be put on the pre-analytical phase, which is the error prone area and demands immense awareness and vigilance from the laboratory personnel as well as the clinicians. Hence, the findings of this study will be used to alert the health care personnel and discuss strategies of minimizing preanalytical errors, which will be followed by a compliance study.

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