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Original Research Paper

Dental Science

ULTIMATELY ERRORS IN PRE EXAMINATION PROCESS ARE THE MAIN CULPRITS IN ANY MEDICAL DIAGNOSTIC LABORATORY

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KEYWORDS :

Introduction;

Quality systems are the mainstay of clinical laboratory management. The comprehensive laboratory testing process must be continually monitored & evaluated to ensure reliable test results & set the foundation for quality improvement. Laboratory testing is roughly divided into three phases Pre analytical phase, Analytical phase, post-analytical phase. Pre-analytical variables account for 32-75% of laboratory errors. (1) The pre- analytical phase comprises process from the time laboratory request is made by a physician until the specimen is analyzed at the lab. Most mistakes often occur before the samples are analyzed. Information characterizing the occurrence of these errors can be useful to provide prevention & reduction strategies. Generally pre examination phase include patient preparation, specimen transportation, specimen collection &storage. (2) (3)

OBJECTIVE –

The aim of the study was to identify the main errors in the pre examination phase of clinical laboratory. Measuring & improving laboratory –related patient outcomes require methods that relate the total quality of laboratory information to more effective patient management including diagnosis, treatment of disease, clinical monitoring & disease prevention.

MATERIAL &METHODS -

Over the period of four months 5500 venous blood samples were collected in different 10 public diagnostic medical laboratories in Delhi. All the errors occurring in pre examination processes from February 2017 to May 2017 were documented. Each sample was followed from the time of blood withdrawal to testing in the equipment. Each step of laboratory processing was recorded ,including standard operating procedures for phlebotomy techniques , patient preparation , sample handling , instrument handling & maintenance (4) examination phase errors such as broken probes, faulty rotors, pumps and feeder systems etc. were monitored to ensure that these errors did not occur during the present study. The second form for collecting data was the NC form from the laboratory having number, date, responsible personnel, description of the occurrence, corrective measure taken, deadline for implementation of corrective measure, whether the corrective measure was in fact helpful and signature of personnel in charge. The recollection rate evaluated corresponds to the percentage of tests that required new collection and was used in the calculation for the specified period

RESULTS —

During four months period 5500 venous blood samples were analyzed in this study for pre-analytical errors. Our study showed a high prevalence of pre-analytical errors at selected 10 diagnostic Labs in Delhi and that there was no significant difference among the ten diagnostic labs in the frequency and types of pre-analytical errors . Delay in sample transportation[39%], expired reagents[27%], hemolyzed and clotted samples [26%] were the most common types of errors, presenting respectively

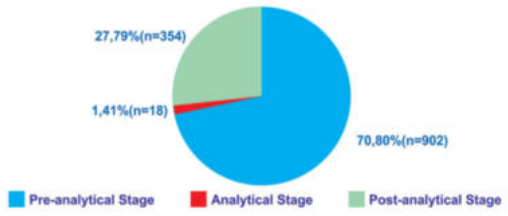

Fig 1 --- Percentage distribution of total errors according to three processes of laboratory

During a four -month period, 5500 venous blood samples were analyzed in this study for pre-analyticalerrors. Each sample was followed strictly from the start of the blood test order by the clinician to the final reporting of the test results. Our study showed a high prevalence of pre-analytical errors at selected 10diagnosticLabs in Delhi and that there was no significant difference between the ten diagnostic labs in the frequency and types of pre-analytical errors . Delay in sample transportation, expired reagents, hemolyzed and clotted samples were the most common types of errors, presenting 39%, 27%,26% and 26%, respectively. Missing physician's request orders was the least occurring error at 10 diagnostic labs in delhi (2.7%) (6) (7). When evaluating the NC forms records, 153 errors involving the pre-analytical phase were found during the studied period

Preanalaytical variables

Patient variables	Specimen collection variables	Specimen handling variables
Diet	Posture	Hemolysis
Body mass	Diurnal variation	Lipemia
Medications	Time of collection	Centrifugation
Gender	Fasting status	Processing Time
Smoking	Tourniquet	Temperature
Pregnancy	Presence of IVs	Sunlight
Exercise	Capillary or venous	Evaporation
Race	Anticoagulant	Aliquoting
Dehydration	Order of draw	Labelling
		Transport conditions

Fig 2. Prevalence of various types of errors and their frequencyof occurance in pre examination phase :

All pre-analytical errors recorded at 10 different diagnostic labs in Delhi were divided in to 15 different types of categories. The pre-analytical errors are shown from the highest to the lowest frequency in the diagram

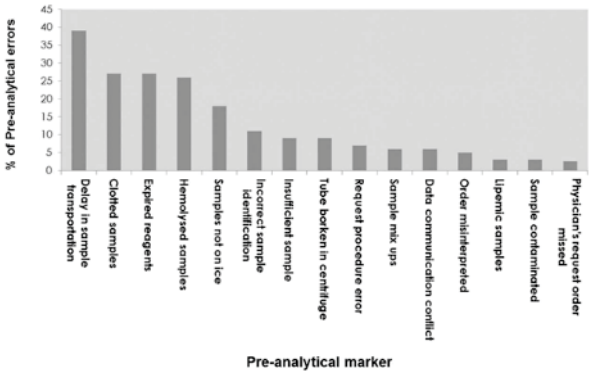

Table 1 -- Rejection rates and frequencies of pre-analytical errors at selected different labs in Delhi

Pre-analytical errors	Frequency (%)	Rejection rate (%)
Delay in sample transportation	39	3
Clotted samples	27	6
Expired reagents	27	7
Hemolyzed samples	26	9
Samples not on ice	1	5
Incorrect sample identification	11	8
Insufficient sample	9	3
Tubes broken in centrifuge	9	8
Request procedure errors	7	2
Sample mix ups	6	3
Data communication conflict	6	3
Order misinterpreted	5	1
Lipemic samples	3	1
Contaminated samples	3	1
Missing physician's request order	2.7	2

Discussion

Pre-examination phase errors have been the focus of research in past decades. Previous studies have focused on the analytical phase of diagnostic tests, and many quality control programs were initiated at diagnostic labs to monitor analytical phase errors. However, post- and pre-analytical errors were neglected worldwide, and currently many studies are focusing on the importance of the pre-analytical phase to obtain accurate lab results. Danish study on laboratory errors showed that 81% of lab errors were pre-analytical, while only 10% of lab errors were analytical.Moreover 82.6% human errors and 4.3% technical errors were observed(8), (9) In the present study, we conducted the first examination of the types and frequencies of pre-analytical errors of laboratories in Delhi . The results were .Consistent with those of previous studies [8±9] showing a high prevalence of pre-analytical errors. The majority of pre-analytical errors at selected different diagnostic labs in Delhi included delays in transport, hemolysis, sample clotting and expired reagents.(10) Interestingly, delayed specimen transport showed an alarming trend at selected hospitals, and many corrective actions are needed to minimize this type of error.Some of the labs located far from blood withdrawal rooms; the samples frequently underwent various temperature fluctuations before reaching the lab for analysis. Some of the samples were transported from the blood withdrawal room, which is not properly air-conditioned, and ambient temperatures typically range from 30±45 degree Celsius during May-October. Blood withdrawal rooms should be located near diagnostic labs to minimize the effect of temperature changes, and specialized containers should be used to transport blood samples. Frequent staff trainings required, Temperature fluctuations resulting from transport delay is a serious pre-analytical error,and many medical staffs are unaware of the instability of temperature-dependent analytes.Examples of temperature-sensitive diagnostic analytes include red and white blood cells, high density-lipoprotein cholesterol, glucose, creatinine, total cholesterol, total testosterone, freetestosterone, alkaline phosphatase, total bilirubin, thiobarbituric acid-reactive substances [11],glucose and potassium. [12] Hemolysis is one of the most common causes of pre-analytical errors, causing considerable harm to the accuracy of analytical tests. Analytes, such as alanine aminotransferase (ALT), aspartate aminotransferase(AST), creatinine, and creatine kinase (CK), are typically overestimated when hemolytic samples are used for analysis, while other analytes, such as albumin, alkaline phosphatase(ALP), chloride, g-glutamyltransferase (GGT), glucose and sodium, were reduced when hemolytic samples were used [13].Expired reagents also sometimes cause errors, Despite the high rate of the pre-analytical errors, the rejection rates of inappropriate samples were low, suggesting that a large number of inappropriate samples were sent for analysis, which in turn caused unnecessary test errors and if not noticed on time might lead to incorrect clinical diagnoses and, on many occasions, unnecessary repetitions of many lab tests. This study was limited to four months observation in ten public diagnostic labs in Delhi. In future, we have plans to include a larger number of data of many labs at both public and private diagnostic labs in the city. Furthermore, investigating all diagnostic lab branches (hematology, virology and microbiology labs) at public hospitals is necessary to evaluate the types and trends of pre analytical errors at other diagnostic labs.(14) (15)

Conclusion

Preanalytic error prevention requires excellent communication and cooperation among all members of the health care team, from the phlebotomist who collects the specimen, to the courier who picks up the samples for transport to the testing laboratory, to the personnel receiving the specimen. (16) , (17) The education of health care professionals involved in procedures for the collecting, handling, preparing, and transporting biological specimens is crucial to understanding the effects of preanalytic variables on specimen quality. Optimal specimen condition and reliable results are achieved by collaboration between the collecting and receiving laboratories. With close attention to established procedures and instructions, preanalytic error is minimized. In turn, patient care improves.The results of this study clearly point out the problems in collection and patient record sectors, corroborating the main problems faced by clinical laboratories regarding failure in quality specification of the pre-analytical phase. (18) Honestly, evaluating and managing the pre-analytical errors in the clinical laboratories is a complex process since it involves many variables and professionl services. However, these errors can be reduced where there are quality control strategies that focus on development, education and training of professionals involved

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