A study of pre-analytical variables and quality improvement in testing process of clinical laboratory

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Abstract

Introduction: Laboratory tests are important to diagnose the diseases, to monitor the progress and to see the response to the treatment of patients. Pre-analytical variables include specimen collection, timing, transportation & handling of the sample processing.

Methodology: The data were obtained from Biochemistry Central Laboratory, Descriptive Cross Sectional study design was used and data were entered in excel and analysed by using Epi-info Software version 3.4.3. Descriptive statistics like frequencies and percentages were calculated.

Results: The total number of samples received by the laboratory for a period of two months was 7333 and analyzed for pre-analytical errors in those samples. The most common pre-analytical error was wrong ordering which is 16.73% & followed by hemolysed sample, insufficient quantity, mixed with saline, empty tubes and the least one was mismatched samples.

Conclusion: Quality improvement in the pre-analytical phase helps laboratories to deliver more timely and accurate test results for clinicians.

Keywords: Pre-analytical errors, Turnaround time, Total testing process.

Introduction

Laboratory tests are used to diagnose the diseases, to monitor the progress and to see the response to the treatment of patients. As every laboratorian knows, reporting a wrong result can have potentially devastating effects on the patient. This can be doubly true and may result in receiving the wrong medical or surgical treatment or could not get the proper treatment. Hence it is very important to give precise lab reports. But there are many errors that can take place in different levels like sample collection, transportation, processing and reporting of the samples. If all these levels work smoothly and correctly then only we can expect precise lab reports. For this every lab must implement quality indicators for the systematic monitoring[1,2]. The following diagram shows the total testing process or the turnaround time of the patient samples.
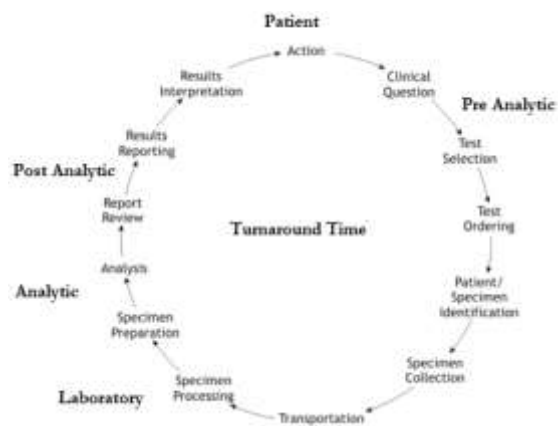
In these errors, pre-analytical errors are more common which is around 46-68.2% followed by Post Analytical 18.5-47% and least was Analytical which is 07-13%[3]. In pre analytical errors incorrect identification, incorrect sample, insufficient sample, sample condition, sample handling and transport are the main. In post analytical errors improper data entry, turnaround time, wrong reporting and wrong analysis of the report with respect to patient condition are most important[4]. With this background an attempt is made to know and to analyze the pre analytical variables of the sample received by the clinical laboratory.

Objective

To assess the pre analytical variables of the sample received by the clinical laboratory.

Methodology

Source of data: The data were obtained from Central Laboratory, Department of Biochemistry, MMC & RI, Mysuru. Ethical clearance certificate for the study was obtained by Ethical Committee of the Institution.

Study type & design: Descriptive Cross Sectional study

Sample size & Study period: All the samples received by the Central Laboratory, Department of Biochemistry for a period of two months.

Sampling Technique: Census Method.

Method of data collection: Using census method all the samples received by the Central Laboratory, Department of Biochemistry for a period of two months were collected to indentify and to analyse the pre-analytical errors. The data was kept anonymous. A pre-tested and semi-structured proforma was used to collect the information. The proforma includes the number of hemolysed samples, insufficient sample, diluted sample, mismatched and wrong order of tests.

Plan of Analysis/ Statistical Tools: The data were entered in excel and analyzed by using Epi-info Software version 3.4.3. Descriptive statistics like frequencies and percentages were calculated.

Results

The total number of samples received by the laboratory for a period of two months was 7333 and analyzed for the pre-analytical errors in those samples.

The Table 1 shows the preanlaytical variables. The table shows that the most common pre-analytical error was wrong ordering which is 16.73% & followed by hemolysed sample, insufficient quantity, mixed with saline, empty tubes and the least one was mismatched samples.

Table 1: Preanlaytical variables among the study sample

	Total No. of Samples	Hemolyzed	Insufficient quantity	Empty Tubes	Mixed with Saline	Mismatched	Wrong Ordering
April 2016	3885	42	3	2	3	1	652
%		1.08%	0.07%	0.05%	0.07%	0.02%	16.87%
May 2016	3448	28	4	2	2	0	575
%		0.8%	0.11%	0.05%	0.05%	0	16.6%
Total	7333	70	7	4	5	1	1227
%		0.95%	0.09%	0.05%	0.06%	0.01%	16.73%

Two months data collected and analysed for the percentage of error

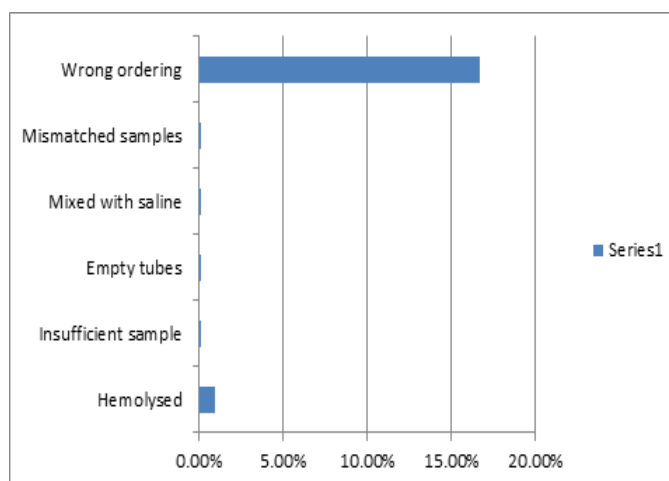Fig. 1 is the Bar diagram showing percentage of preanalytical error for all the samples.

Fig. 1: Bar diagram showing percentage of preanalytical error

Discussion

Managing pre-analytical errors is a major challenge for the clinical laboratory[5,6,7,8]. Proper care should be taken to manage these errors[9,10]. Many studies have identified the errors in all categories of pre-analytical errors as we did[9-3]. Our study revealed that the most common pre-analytical errors were wrong ordering of the tests & followed by hemolysed sample, insufficient quantity of the sample, sample mixed with saline, empty tubes and the least one was mismatched samples.

When we analysed the cause for the wrong ordering of the tests, was found that the concerned ward nurse who was writing all the investigation for the entire patients irrespective of the disorder or diagnosis, this inturn lead to overburdening of the sample load.

The causes for hemolysed samples are haemo-concentration, use of skin disinfectants, forceful drawing and injecting blood into evacuated tube, Which leads to increase in certain parameters like, lactate dehydrogenase, Potassium and Magnessium.[14] The hemolysed samples can be prevented by allowing alcohol to dry before collection, by using an appropriate bore needle, by gentle mixing of sample, by avoiding syringe collection and by avoiding collection from IV line[15].

Other pre-analytical errors were insufficient sample quantity, sample mixed with saline, empty tubes, mismatched samples or incorrect Samples. All these errors may lead to delay in diagnosing and treating patient. These errors can be reduced by giving proper training to the ward sisters or concerned laboratory personnel. Care must be taken starting from collection of the sample to till it reaches the laboratory. That is selection of proper vacutainer, checking and writing the name, identification number of the patient, hospital name, date & time of collection of the samples must be clearly written on the specimen container along with the appropriate test requisition.[16,17] Requisition form should contain chief complaints and provisional diagnosis. High risk specimens such as HIV, Hepatitis B -should be labeled with yellow sticker.

Pre-analytical errors can be minimized if proper guidance & training at various levels starting from the patient, the physician, the junior doctor, the ward nurses, the laboratory technologist, the laboratory assistants and the sample transport personnel. All the concerned laboratory personnel are required to know about the pre-analytical variables, their possible sources and their effects on the test results. In addition to this, the resident doctors have a direct interaction with the paramedical staff, it is very important for them to understand the pre-analytical variables so that they could instruct the paramedical staff accordingly.

If the financial support is given by the institution, the turnaround time can be reduced by computerization of laboratory, by the way to establishing Laboratory Information system(LIS) with Hospital Information System (HIS) & also by transporting samples to the lab immediately and by centrifuging the samples as early as possible so that the reports can be issued at the earliest.

Conclusion

It is important to bear in mind that, as many pre-analytic activities are performed by non-laboratory personnel, interdepartmental cooperation is of crucial importance in avoiding errors. It is thus clear that the entire health care system is involved in improving the total testing process and to reduce the turnaround time. Quality improvement in the pre-analytical phase helps laboratories to provide more timely and accurate test results for clinicians.

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