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Study of Pre-analytical variables in clinical biochemistry laboratory

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Abstract:

In the era of advances in science & technology, laboratory diagnostics have led to transformation from manual clumsy testing methods to fully automated science ensuring accuracy and speed. Maintaining quality in laboratory results, keeping errors minimum is a daunting task. The pre analytical phase is an important component of laboratory medicine, which involves many personnel, prone to errors. The awareness toward recognition of pre-analytical errors and by the introduction of strategies to achieve total laboratory quality is finally within our hands.

A prospective study was done for a period of six months before and six after adopting corrective measures in clinical Biochemistry lab of Government Medical College & Hospital, Aurangabad. All types of Pre analytical errors were recorded and studied. Percentage of sample rejection, before & after adopting corrective measures were calculated and found that from July 2020 to December 2020 six months the pre-analytical errors were 1819 (10.5%) and after adopting corrective measures for 6 months i.e., Jan 2021 to June 2021, the pre-analytical errors found to be reduced to 432 (1.8%). The efforts towards the standardization of pre-analytical phase and awareness to the various critical variables of the laboratory must be enhanced. The awareness towards recognition by pre analytical errors and introduction of strategies to achieve total laboratory quality is finally within our reach to improve the biochemistry results and leading to good patient care.

Key words: Pre analytical, variables, accuracy.

Introduction

Modern day medicine practice is purely evidence based which focuses on the valid laboratory reports for effective and timely management of patients. Despite of advanced automation considerable errors occur at clinical diagnostic labs (1).

Laboratory testing involves mainly three phase. The Pre-analytical phase, Analytic phase and post analytical phase. The pre-analytical phase is an important phase which encompasses all

the processes from the time of a laboratory request made by the physician until the specimen is analysed in the lab, which accounts up to 70% of errors during total diagnostic process (2).

The most common pre-analytical errors include 1. inappropriateness of text order, 2. patient identification error 3. timing error in sampling and preparation 4. Haemolytic or Lipemic samples, 5. inappropriate transport and 6. inappropriate sample collection tube (**3**).

The purpose of our study was to evaluate different types of pre-analytical errors in clinical biochemistry laboratory & compare the frequency of errors, before and after following the corrective measures in the clinical biochemistry Laboratory such as 1. training the staff posted in clinical lab of biochemistry .2. immediate communication to physician attending the patient regarding the error,3. appointing special lab staff for sample receiving into lab noting the time & details of sample 4. Circulating manual guide for sample collection & transport.

Material & Methods:

A prospective study was done for total one year from i.e., for a period July 2020 to December 2020 six months and after adopting corrective measures, six months i.e., Jan 2021 to June 2021, in clinical biochemistry lab, conducted at Department of Biochemistry Government, Medical College & Hospital, Aurangabad. The clinical biochemistry laboratory is equipped with fully automated biochemistry Analysers, Electrolyte Analysers and Automated Immunoassay Chemiluminance Analyser, Cobas 0411 and POCTs for sample processing & testing.

The frequency and types of analytical errors were monitored for all samples received into the lab before the analytical phase was undertaken. All the lab personnel were instructed about the pre-analytical errors monitoring and documentation on daily basis. These errors were reviewed on weekly basis. Pre-analytical variables were recorded in sample rejection log book, systematically under the following Categories: 1. Improper request forms (sample requisition). 2. Incorrect identification/Improper labelling. 3. Insufficient volume (quantity of sample collected). 4. In-vitro haemolysis. 5. Improper tube (usage for sample collection). 6. Sample not received.

The analysis of such errors was done by calculating the percentage. Percentage calculations of samples rejected for each month & the sample rejection rate was calculated by number of samples rejected / total number of samples analysed X 100.

Percentage of sample rejection, before & after adopting corrective measures were calculated and found that from July 2020 to December 2020 six months the pre-analytical errors was 1819 (10%) and after adopting corrective measures, six months i.e., from Jan 2021 to June 2021, the pre-analytical errors were found to be reduced to 432 (1.8%).

Observation & Results:

Table 1; The percentage of Pre-analytical variables recorded during July 2020 to December 2020

Month	Improper test order	patient identification error	Sample Insufficient	Haemolysed samples	Sample not received	Wrong tube	Sample rejected Error %	Total samples received.
Jul-2020	65	55	55	72	55	14	316 (13.5%)	2334
Aug-2020	63	48	53	68	60	10	302 (9.3%)	3445
Sep-2020	58	56	55	62	58	11	300 (9%)	3327
Oct-2020	68	64	62	60	57	13	324 (9.9%)	3279
Nov-2020	62	78	48	68	55	12	323 (10.8%)	2999
Dec-2020	60	82	55	72	55	10	334 (12%)	2779
Total	376 (19.8%)	383 (20.2%)	328 (17.3%)	402 (21.2%)	340 (17.9%)	70 (3.7%)	1819 (10.5%)	18163

Table 2: The percentage Pre-analytical variables recorded after corrective measures were adopted during period January 2021 to June 2021.

Month	Improper of test order	Patient identification error	Sample Insufficient	Haemolytic samples	Sample not received	Wrong tube	Error %	Total samples
Jan-2021	8	9	12	6	7	0	42	5057
Feb-2021	7	10	5	7	6	1	36	4366
Mar-2021	9	8	9	9	8	2	45	3703
Apr-2021	6	6	8	9	8	1	38	3309
May-2021	11	9	7	9	5	2	43	3664
Jun-2021	6	6	8	11	12	0	43	4436
Total	47(19%)	48(19%)	49(19.5%)	51(20%)	46(18.6%)	6(2.4%)	432 (1.8%)	24535

Discussion:

Pre-analytical errors have a major impact on diagnostic accuracy laboratory results. There have been tremendous work & established quality control criteria for analytical phase of testing but there is paucity of standards for pre-analytical phase. The implementation of quality indicators in the laboratory is essential not only to detect the error but also to formulate quality

improvement strategies. The efficiency of the use of quality indicators is demonstrated by the improvement found in performance. To achieve this goal, we assessed the frequency of rejections due to various variables in the samples received.

An American pathologist program: conducted a study enrolling 660 laboratories and showed that pre- analytical errors were 4·8%(**4**). The College of American Pathologists, including 126 labs, concluded that misidentification is a common laboratory error were (**5**)

In our study, out of total blood, sample, received were 18163 during July 2020 to Dec 2020, out of which samples rejected with pre -analytical variable errors were 1819. And after adopting corrective measures in our lab out of total blood samples received during Jan 2021 to June 2021 were 24535 out which went into rejection were 432.

Hence the percentage of samples rejected for each month, found to be drastically reduced after corrective measures, finally found that were sample rejection rate was 1.8 % after six months of adopting methods to curb the errors.

In our study, we observed 10% of different types of & frequencies of pre-analytical errors in clinical biochemistry lab at our institute. Among all types of pre-analytical errors, the most common error was found to be haemolysis, which accounted for 21.2% of total sample similar to many other studies (**6**). Haemolysis has profound influence on various parameters like potassium, AST, ALT, LDH, creatinine, ck, albumin ALP, chloride, GGT, glucose & sodium. Parameters like Potassium, Alanine Transaminase (ALT), Creatinine, Creatine Kinase (CK) are overestimated when haemolysed sample are used for analysis, whereas parameters like albumin, alkaline phosphatase (ALP), chloride, gamma-glutamyl transferase (GGT), glucose, bilirubin and sodium are underestimated when haemolysed sample are used for analysis. The various causes for haemolysis found to be cleansing the venepuncture site with alcohol and not allowing the site to dry appropriately (at least 30 sec), syringe draws, vigorous mixing of the samples, transferring the sample into a tube by pushing down on the syringe plunger to force blood into a tube and not allowing the serum specimen to clot for the recommended amount of time can result in fibrin formation in the serum (**7**).

Patient identification is the critical first step in blood collection. In the 2007 Laboratory Services, National Patient Safety Goals from The Joint Commission, goal # 1 is accuracy in patient identification. Patient misidentification errors are potentially associated with the worst clinical outcomes because of the possibility of misdiagnosis and mishandled therapy. In our study, we found 20.2 %. incorrectly identified samples which accounted for of the rejection, may be probably, due to heavy work load and it is important to identify a patient accurately so that blood is collected from the correct person. Drawing blood from the wrong person, or labelling the correct patient's sample with a different patient's label can certainly contribute to laboratory error. When identifying the patient, have them provide their full name, address and identification number. Hospital inpatients should be wearing an identification band with the above information, which the phlebotomist should confirm before the venepuncture. Phlebotomists should pleasantly introduce themselves to the patient and clearly explain the procedure to be performed. It is always a courtesy to speak a few words in a patient's native language giving full information. The next common error that we come across in our study was inadequate sample, accounting for 17.3% sample rejection. Every analytical process requires specified amount of serum/plasma for analysis. The main reason behind this error

was the phlebotomist were lacking the knowledge about the testing volume, difficulty in sampling in paediatric cases, debilitating diseases, not reading the test requisition form properly by the laboratory personnel (number of tests requested in test requisition form), large number of patient's samples need to be collected in the specified timings and shortage of manpower (**8**).

All the technical staff were trained to educate the staff regarding sample collection, order of draw, pre-analytical variables and their influence on various parameters with quality control checks. A comparative study was done to know the frequency of pre-analytical errors before and after staff training. We found that after training the staff, there was overall reduction in the frequency of errors before and after training the staff.

To overcome pre-analytical errors, the following corrective measures have been recommended by Lippi G et al, Sciacovellia L et al, and Jo Gile T of which majority were adopted in our laboratory.

1. Skilled staff: skilled and adequate staff to maintain collection standards, which give an extra verge of expertise. (**9**)

2. Phlebotomists: with proper knowledge pertaining to phlebotomy (trained personnel)

3. Regular educational competency assessments should be encouraged to allow (new and old personal) an opportunity to recognize and manage errors.

4. Vacutainers: Proper knowledge regarding use of evacuated tube system to the lab personal pertaining to sample volume and use of anti- coagulants. (**10**)

5. Transport: laboratory personnel guided regarding importance of transport the specimens promptly to the laboratory at the earliest after collection to avoid errors related to delay.

6. Advanced Technology: Usefulness of barcode scanners system for individual sample recognition. (**11**)

Conclusion:

Quick, effective communication between all healthcare providers is key element in reduction of human errors.

Our study recommends that training of staff and monitoring on various aspects of sample collection, handling, processing, transportation, quality control and updating advances in laboratory automation, and report dispatch leads to an utmost improvement in laboratory performance. Pre-analytical errors are not unavoidable, but can be minimized by proper exhaustive program silhouette for laboratory personnel like orientation program regarding total quality management to attain better laboratory testing, monitoring, reporting and performance in terms of accuracy, precision and will eventually assist physicians to have favourable insights in patient's care.

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