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Original Research Article

Incidence of Pre-analytical Phase Errors: A Retrospective Study in Biochemistry Lab of a Tertiary Care Hospital

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Abstract

Objective: Aim of the present study was to find the incidence of errors in pre-analytical phase and various factors contributing to the same. Every laboratory strives to minimize errors at every level of sample analysis. Number of errors in pre-analytical phase is maximum and leads to wastage of resources and time.
Methodology: It is a retrospective study conducted in biochemistry laboratory of a tertiary care hospital. Pre-analytical errors were assigned to various pre-defined categories.
Results: Total of 138240 samples were collected in one year period extending from July 2019 to June 2020. Incidence of pre-analytical errors was found to be 1.6%. 2212 samples out of 138240 were found to have one or the other predefined errors.
Conclusion: 1.6% samples received in biochemistry lab were found to have errors. An error in requisition form was the most common cause. Such errors can be addressed by training and coordination.
Keywords: Pre-analytical phase, errors, clinical biochemistry, error incidence.

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1. Introduction

Evidence based medicine has made laboratory tests more relevant. Biochemistry lab in a clinical setup helps in reaching and confirming a diagnosis, validating the clinical progress, effectiveness of the treatment or in some other cases, ruling out certain conditions.

Importance of error free reports from biochemistry lab can never be overemphasized. Any error can not only lead to missed disease, misdiagnosis but has the potential to seriously harm the patient. Quality in lab testing adds to safety of the patient. [1,2]

Insurance companies and private institutes providing health cover to its employees rely heavily on lab reports for exact diagnosis and the relevance of treatment provided to patients based on lab reports.

Sequence of every lab test can be divided into three parts[2]:

1) **Preanalytical phase** – starting from the point when a decision is made to get the biochemistry done to the point when the sample is ready for analysis.
2) **Analytical phase** – encompasses analysis of the sample and validation of the result.
3) **Post-analytical phase** – includes interpretation of the result by the lab consultant and communication to the treating consultant through a printed report.

Automation has taken over the analytic phase in a big way. Tests are run by machines in a preprogrammed manner, including quality checks. That translates into very few possibilities of error.

Post analytical phase again has very less chances of errors as it is handled by lab consultant.

Preanalytical phase has the maximum variables and hence is more prone to errors[3]. Samples are collected by multitude of persons in different areas of the hospital. These include resident doctors as well as nursing staff. Training and efficiency level of all varies. Other variables include knowledge about types of containers and quantity of sample needed. Parameters to be filled in requisition form and timing of samples, add to the myriad of variables. Errors in pre-analytical phase can result either in sample rejection or erroneous results.

In this retrospective study, we have analysed errors in pre-analytical phase that resulted in sample rejection or revision of requisition form. This study was conducted in a tertiary care super specialty hospital, over a period of one year.

2. Material and Methods

The current study was conducted in retrospective manner at a tertiary care super specialty hospital. Period of study was July 2019 to June 2020. Specimens were collected through standard phlebotomy procedure in OPD sample collection or in the different IPD areas. All stakeholders were trained to collect samples in appropriate quantity, in color coded vacutainers.

Two identifiers – patient name and unique hospital ID number [UHID] – were used to identify all samples.

Samples were accompanied by requisition form with list of tests needed and details of patient including age, gender, provisional diagnosis and any other relevant information.

Samples for biochemistry were incubated at 37^0 C for 30 minutes followed by centrifuge at 3000 RMP for 10 minutes to separate cells and serum. Color and appearance of serum was noted. Serum was sipped into autoanalyzer and the test was run.

Time was noted at the sample collection, receiving in the lab, incubation, centrifuge and reporting, wherever relevant.

Samples were rejected in lab at various stages whenever any of the following discrepancies was found:

1. Wrong vacutainer
2. Inadequate quantity
3. Incomplete identification label on vacutainer
4. Dilute samples[From IV lines]
5. Haemolysis
6. Incomplete/ Error in requisition form.

3. Results

During the study period, total of 138240 samples were collected for biochemistry tests. These were received in the laboratory from different areas of the hospital. After inspection or initial processing of incubation and centrifuge, the faulty samples were rejected based on criteria listed above.

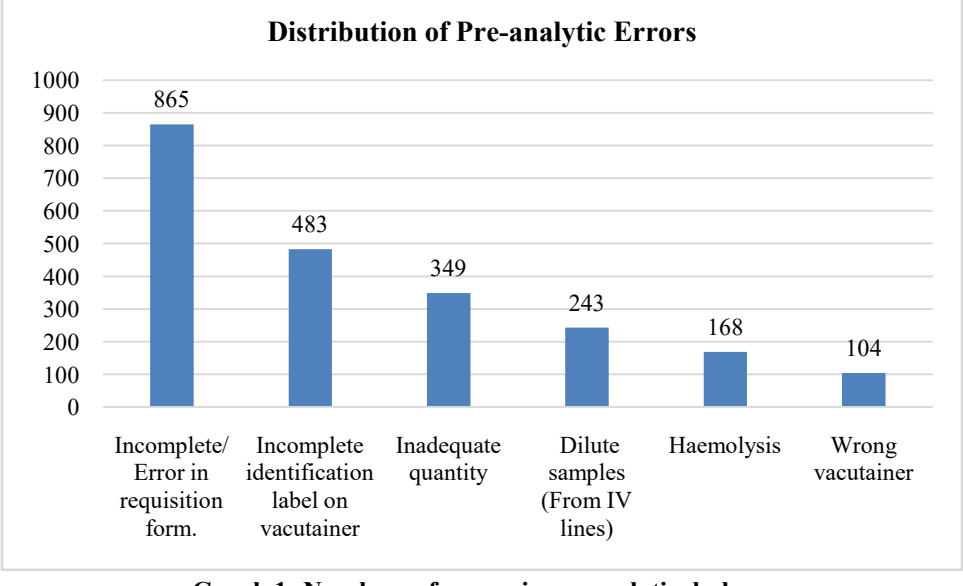
Out of 138240 samples, 2212 [1.6%] were found to be faulty and were rejected.

Reason wise distribution of errors was as per Table 1.

Table 1: Distribution of errors in preanalytical phase

	Number	%
Incomplete/ Error in requisition form.	865	0.63
Incomplete identification label on vacutainer	483	0.35
Inadequate quantity	349	0.25
Dilute samples [From IV lines]	243	0.18
Haemolysis	168	0.12
Wrong vacutainer	104	0.08
Total	2212	1.6

Most common pre-analytic error in this study was incomplete requisition form or requisition form with errors -865 and constituted 39.1% of all the errors. This was followed by incomplete identification label on vacutainer – 483, which was 21.8% of total errors. Number of inadequate quantity where adequate volume of serum could not be collected was 349 [15.8%]. Dilute samples, which were drawn from IV side or from canula numbered 243 [11%]. Haemolysis was found in 168 samples [7.6%]. Wrong vacutainer was used in 104 [4.7%] cases. (Graph 1)



Graph 1: Numbers of errors in preanalytical phase

Percentage distribution of errors in pre-analytic stage out of total samples [138240] collected during the study period is presented in Table 2.

Table 2: Percentage distribution of errors in pre-analytical phase

	Number	%
Incomplete/ Error in requisition form.	865	0.63
Incomplete identification label on vacutainer	483	0.35
Inadequate quantity	349	0.25
Dilute samples [From IV lines]	243	0.18
Haemolysis	168	0.12
Wrong vacutainer	104	0.08
Total	2212	1.6

4. Discussion

Reported errors in pre-analytical stage of biochemistry testing range from 0.3 to 32.66% [2,4-12]. All the studies found pre-analytical stage to be most prone to errors due to various contributing factors.

In the present study, most common error [39.1%] in the pre-analytical stage was incomplete or erroneous requisition form. Essential component of requisition form are – name, age, gender, UHID, tests required, time of order and time of sample collection, provisional diagnosis and relevant report of previous tests. These parameters help in establishing the accuracy of the sample, turnaround time and clinical correlation. One or the other missing information component constituted the error. It could have happened due to work pressure, inadequate knowledge or urgency.

After requisition form, incomplete identification label was the next most common error [21.8%]. Minimum requirement of label in our institute is two identifiers - patient name and unique hospital identification number [UHID]- and request number which relates the sample with requisition form and hospital information system. Usual problem was, instead of full UHID, only last four digits were written or the handwriting was not legible.

Inadequate quantity constituted 15.8% of all the errors. Majority of the samples were from neonatal intensive care unit [NICU]. It happened due to combination of neonates with difficult veins and drawing staff who were not experienced and expert. Other reason was, more tests were ordered after the sample had reached the laboratory or the sample had already been run once.

Dilute samples contributed to 11% of errors. Most of the samples were from intensive care units [ICU] with patients who had indwelling central lines. Samples were collected in haste due to criticality of the patient without following the standard operating procedure for sample collection from intravenous lines. Many times patients were on life saving infusions and it was almost impossible to discontinue the infusion for prescribed time before collecting the sample.

Haemolysed samples were responsible for 7.6% of errors. Haemolysis was recognized after incubation and centrifuge. We could recognize the cause in drawing the blood forcefully by pulling back the plunger of the syringe forcefully causing frothing in the sample and other reason was pushing the blood forcefully in the vacutainer.

Wrong vacutainer was the least common error in our study – 4.7%. It happened in cases of not so common tests when the staff was not sure about the type of vacutainer to be used. Rarely it happened when sample was collected for number of tests and the staff failed to realize the need for different vacutainers.

Study conducted by Alavi *et al*[4] found errors in 1.48% of all the samples received. This is quite close to findings of the present study. Most common error in Alavi *et al* was unlabeled samples [35.8%]. This was the second most common error in the present study [21.8%]. Dilute sample occurrence was similar in both the studies- 11.8 and 11% respectively.

Cakirca conducted the study and found the preanalytical errors in 0.6% of samples [5]. Most common error in that study was hemolysed samples [74.1%]. This was contributed to many likely factors- forceful evacuation of syringe into tube, prolonged tourniquet application, vigorous mixing of sample and use of inappropriate needles.

Dudani found non conformities in the preanalytical stage in 32.65% samples [6]. 43.9% errors consisted of insufficient sample as compared to 15.8% in present study. Reason for insufficient sample was same in both the studies – samples from NICU constituted the majority number. Incomplete label on the sample constituted 21.99% errors. This is very similar as the figure of 21.8% for the same error in the present study.

Study conducted by Arul P *et al* recorded 0.43% errors in samples collected during the study period [7]. Most common error was inadequate sample [0.2%]. Wrong vial was the least common error which is the same finding as present study.

Bhuyar found 5.2% samples with errors in that study [8]. Most common error was haemolysed sample – 75.16%. 98.7% of forms accompanying the sample were found to be incomplete. Incomplete forms also constituted the most common error in present study 39.1%.

Narang *et al* detected preanalytical errors in 0.3% of samples [9]. Insufficient quantity was the second most common error after clotted samples. Proportional ratio of inadequate samples was 20%, as compared to 15.8% in

present study. The present study did not include clotted samples as only the biochemistry samples were included which are collected in plain vial.

Sayki *et al* had an incidence of 3.7% errors in sample collection in their study [10]. Hemolysed samples were the most common error followed by insufficient sample quantity.

Study conducted by Upreti *et al* found 1% samples with errors in preanalytical stage [11]. Misidentification of the sample was the leading error, followed by inadequate sample. Requisition form was not included in the study. Inadequate samples were found to be from pediatrics ward and ICU. In the present study, most of inadequate samples were from NICU only as majority of patients in ICU with difficult veins had central lines in situ.

Chawla *et al* reported preanalytical error incidence of 1.9% in their study which is close to findings of the present study [12]. Haemolysed samples constituted the majority of errors followed by wrong slip/vial and inadequate sample.

All the centers face the same challenges in the preanalytical phase of sample testing. Total errors and their distribution vary upon specialties being catered to and the level of staff training.

5. Conclusion

Error free sample collection is the first step in quality management of any laboratory. Sample should be accompanied by requisition form that provides all the relevant information. Errors detected before the sample is actually run, reduce the incidence of faulty reports. Pre-analytical errors add to wastage of precious time and sometimes delay the emergency treatment of the patient. Number of rejected samples should be measured and analysed regularly as part of total quality management of a lab. Such errors can be substantially reduced by proper training, preferably by hands on technique and unhindered coordination between lab and the personnel collecting samples.

Conflict of Interest:

Authors have no conflict of interest to declare.

References

[1]. Saurav Patra M, Mukherjee B and Das AK. Preanalytical errors in the clinical laboratory and how to minimize them. *Int J Bioassays* 2013; 02:551-553.

[2]. Sushma BJ, Shrikant C. Study on "Pre-analytical Errors in a Clinical Biochemistry Laboratory": The Hidden Flaws in Total Testing. *Biochem Anal Biochem* 2019; 8: 1-6.

[3]. D Fraser Davidson. A survey of some pre-analytical errors identified from the Biochemistry Department of a Scottish hospital. *Scott Med J;* 2014 May; 59[2]:91-4.

[4]. Alavi N, Khan SH, Saadia A, Naeem T. Challenges in preanalytical phase of laboratory medicine: rate of blood sample nonconformity in a tertiary care hospital. *eJIFCC* 2020;31[1]:021-027.

[5]. Cakirca G. The Evaluation of Error Types and Turnaround Time of Preanalytical Phase in Biochemistry and Hematology Laboratories. *Iran J Pathol* 2018;13[2]:173-178

[6]. Dudani S. Study of pre analytical errors in a medium sized pathology laboratory. *Int J Med Lab Res* 2018; 3[1]:27-32.

[7]. Arul P, Pushparaj M, Pandian K, Chennimalai L, Rajendran K, Selvaraj E, Masilamani S. Prevalence and types of pre-analytical errors in hematology laboratory of a tertiary care hospital in South India. *J Lab Physicians* 2018; 10: 237-40.

[8]. Bhuyar BK. A Study of Pre-Analytical Errors in a Hospital Based Clinical Biochemistry Laboratory. *International Journal of Biotechnology and Biochemistry.* 2017; 13[2]: 111-121.

[9]. Narang V, Kaur H, Selhi PK, Sood N, Singh A. Preanalytical Errors in Hematology Laboratory – an Avoidable Incompetence. *Iran J Pathol* 2016; 11[2]:151-154.

[10]. Sayki AS, Laing EF, Ephrain RK, Asibey OF, Sadique OK. Evaluation of Analytical Errors in a Clinical Chemistry Laboratory: A 3 Year Experience. *Annals of Medical and Health Sciences Research*. 2015;5[1]:8-12.

[11]. Upreti S, Upreti S, Bansal R, Jeelani N, Bharat V. Types and frequency of preanalytical errors in haematology lab. *Journal of Clinical and Diagnostic Research* 2013; 7[11]: 2491-2493.

[12]. Chawla R, Goswami B, Tayal D, Mallika V. Identification of the Types of Preanalytical Errors in the Clinical Chemistry Laboratory: 1-Year Study at G. B. Pant Hospital. *Lab Medicine* 2010; 41[2]: 89-92.