Preanalytical, Analytical and Postanalytical Errors in Chemical Laboratory

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Abstract: <u>Objective</u>: To evaluate and analyse causes and prevention of preanalytical, analytical and postanalytical errors in a clinical chemistry laboratory. <u>Method</u>: The present study has been conducted in a pronounced laboratory in India. A retrospective analysis of the results obtained from the clinical laboratory for errors in the preanalytical, analytical and post analytical phase has been carried out on patients from both IPD & OPD from january 2014 to december 2014. Laboratory personnel were asked to register rejections, and causes for rejection of ward as well as out-patient samples collected in the laboratory. <u>Result</u>: The study showed that out of 200978 samples processed the most common error seen in laboratories was preanalytical i.e 305, then comes analytical i.e 5 and at the last comes post analytical i.e 4. Preanalytical errors included 156(51.1%) cases of hemolysis and 130(42.6%) cases of clotted blood. Rest 19 cases were due to less quantity or wrong sampling. Analytical errors were mainly due to typing mistakes. <u>Conclusion</u>: Of all the samples received in the lab, the overall percentage of errors came out to be 0.15%.

Keywords: Hemolysis, Post analytical, Pre analytical, Analytical errors

1.Introduction

Now-a -days diagnosis is heavily dependent upon reliable laboratory data. The clinical laboratory plays an important role in the patient-centered approach to the delivery of healthcare services. Physicians rely on accurate laboratory test results for proper disease diagnosis and for guiding therapy.¹

Labs are doing various tests which include hematology, biochemistry, immunoassay, clinical pathology etc. Traditionally lab practice can be divided into three phases:

- 1. Pre-analytical: starts from test request and ends at sample processing
- 2. Analytical: begins when sample is prepared in the laboratory for testing and ends when the test result is interpreted and verified by the technologist.
- 3. Post-analytical: results are released to the clinician, and s/he interprets them and makes diagnostic and therapeutic decisions accordingly.

Additionally, the term "pre-pre-analytical phase" has been used for the initial part of the pre-analytical phase, focused on test selection and identification of test needed, and the term "post-post-analytical phase" has been used for the interpretation of results by the clinician.²

Mostly ,errors occur in preanalytical phase .Plebani and Carraro performed a large comprehensive study that determined—of all errors detected—68.2% originated in the preanalytic phase, compared with 18.5% in the postanalytic phase, and 13.3% during the analytic phase.³The common causes of errors in the total testing process as compiled by Plebani are- In Pre-pre-analytical phase the common causes are inappropriate test request, order entry, patient/specimen misidentification, sample collected from infusion route, sample collection (hemolysis, clotting, insufficient volume,

etc.), inappropriate container, handling, storage and transportation.

In Pre-analytical phase the common causes are sorting and routing, pour-off and labeling, centrifugation (time and/or speed).

In Analytical phase common causes are pipetting errors, equipment malfunction, sample mix-ups, interference (endogenous or exogenous), undetected failure in quality control.

In Post-analytical phase errors are due to erroneous validation of analytical data, failure in reporting/addressing the report, excessive turn-around-time, improper data entry and manual transcription error, failure/delay in reporting critical values.

Post-post-analytical errors are due to delayed/missed reaction to laboratory reporting, incorrect interpretation, inappropriate/inadequate follow-up plan, failure to order appropriate consultation.

2. Material and Method

Current study was a retrospective one and it was carried out in pronounced laboratory in India .Duration of study was one year, from Jan 2014 to Dec 2014. All samples received during this period in laboratory were included. Sample collection for OPD patients was centralized for different sections of central laboratory, like haematology, immunoassays, biochemistry. IPD samples were collected in wards, ICUs and OTs and transported to IPD sample collection centre by attendants of the respective wards. From collection centres proper samples and properly filled forms were distributed to our lab for analysis. We follow different procedures for OP and IP patients.

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First of all OP patient are billed at the reception according to the tests asked by the doctors.Then patients sample is collected in vaccum tubes and collection time is noted.

Then immediately sample is transferred to our lab in chiller boxes. The samples are then processed and values get transferred automatically. Then reports are validated by a pathologist. After validation these reports are printed .Reports are also being shown online so that other staffs can also see the reports.

In case of IP patients our technitian will go and collect already withdrawn sample, it is then brought to our lab in chiller boxes. These samples are already billed online by the ward nurses. After processing and validation ,the reports are printed. Our one attender will dispatch the reports to the respective ward .Sometimes ward attenders also come to take the reports. All the IP reports also are being displayed online. Different types of registers are also maintained for any rejection, repeat or critical values.

3. Results

According to our study, 200978 blood samples were collected over a period of 1 year ,out of which 73830 were from OPD patients and 127148 were from IPD patients. Preanalytical errors were observed in 305 samples, which is approximately 97% among all the errors. The distribution of the different types of errors was then calculated (Table 1). The majority of the rejected samples were hemolyzed. Hemolysis was responsible for rejection of 156 samples, which accounts for 51.1% of the total number of samples received during this period.Clotted samples were 130 which accounted to 42.6%. The amount of blood was insufficient for complete analysis in 8 cases i.e 2.6%.(FIGURE 1) Hemolysis arises most commonly from mechanical trauma to the specimen (e.g., use of inappropriate size syringe with IV line collections, use of very small gauge needles, improper transfer of specimens from syringe to an evacuated tube or improper line collection procedures). Clotting of anticoagulated specimens arises from inadequate mixing.



Figure 1

Analytical errors were only 5 and post analytical errors were 4.

Month Pre analytical Analytical Post analytical Jan 28 0 0 20 Feb 0 1 14 0 0 March 34 0 0 April May 32 1 1 June 32 2 0 30 0 July 0 23 2 0 August September 24 0 0 10 0 October 1 0 November 19 0 December 39 0 1

In our study it was seen that majority of cases were seen in month of December i.e 39 cases. Next comes month of April which showed 34 cases. Most number of cases of preanalytical error were from ICU (162 cases).(TABLE 2).The reason for most of the cases in December month is because of increased workload(TABLE 3)and lack of proper handover (TABLE3).Also new technicians and nurses are being appointed in month of December which is the cause for preanalytical errors.

Table 2: Preanalytical Errors

Month	Casuality	ICU	Ward	Total(Month Wise)
Jan	2	18	8	28
Feb	1	10	9	20
March	0	6	8	14
April	3	15	16	34
May	3	23	6	32
June	2	22	8	32
July	4	12	14	30
August	0	14	9	23
September	1	10	13	24
October	0	7	3	10
November	0	10	9	19
December	4	15	20	39
Total No.Of Cases	20	162	123	305



4. Discussion

The laboratory cannot function in isolation. It is dependent upon other departments, mainly the clinical division for properly filled requisition slips and samples for analysis.

According to our study most common type of error is preanalytical i.e 0.15% (305/200978 samples). Plebani and Carraro observed same results in their paper that the great majority of errors result from problems in the preanalytical phase(49-73%) mainly and then in post-analytical phases(38-66%).³ A report by Bonini and colleagues found that preanalytical errors predominated in the laboratory ranging from 31.6% to 75%.⁴ In 2008 to 2009, Chawla and colleagues found the frequency of pre-analytical errors in the

Table 1

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inpatients to be 1.9% whereas for the outpatients, the error rate was 1.2%.⁵

Hemolysis accounted for the majority of rejections in our study. Preanalytical errors showed 156(51.1%) cases of hemolysis. However the introduction of vacuum tubes along with the closed system of blood collection has made blood collection efficient and easy. Hemolysis of samples occurs when blood is forced through a fine needle, tubes are shaked vigorously, and centrifuging the sample specimens before clotting is complete.

In study done by Ranjna Chawla et al it was found that hemolysis was responsible for rejection of 607 samples, which accounts for 1.1% of the total samples.⁵ In a study by Jay and colleagues, the majority of hemolyzed samples (>95%) could be attributed to in vitro processes resulting from incorrect sampling procedure or transportation.⁶ Hemolysis leads to the extravasation of intracellular contents into the plasma, leading to false high values of various parameters. It also leads to a prolongated turnaround time (TAT) due to the need for fresh samples for processing the request.

Second most common cause of preanalytical error in our study was clotted blood. Out of 305 preanalytical errors, 130 rejections were due to blood clotting(42.6%). Aysenur Atay et al found clotted specimen as a cause of preanalytical error to be 24% in their study.⁷

Another factor leading to rejection of blood samples in our study was insufficient blood volume because analytical process requires a fixed volume of serum/plasma for analysis. In our study the number of blood samples which were insufficient for complete analysis were 8 i.e 2.6%.

According to study done by Ranjna Chawla et al the amount of blood was insufficient for complete analysis in 0.08% (ie, 36 out of the 45,084 samples).However AysenurAtay et al found higher percentage of inadequate samples in their study which came out to be 34%.

The main causes may be due to ignorance of the phlebotomists, difficult sampling as in pediatric patients, patients with chronic, debilitating diseases, and patients on chemotherapy whose thin veins are difficult to localize. Difficult sampling and patient non-compliance further aggravates this problem.

The analytical errors were second commonest as compared to pre analytical and post analytical errors. We got only 5/305 i.e 1.63% of cases of analytical error. A study done by AS Sakyi et al showed 0.1% (108/58,950) of analytical errors⁸ whereas Goswani *et al.* observed 3.8% systemic analytical errors in his studies.⁹The reason for this error is mostly due to pipetting difficulties, contamination of reagents, and malfunctioning probes . In our settings, training of laboratory staff and participation of internal and external QC programs contributed immensely to the remarkable decline in our analytical errors .Our laboratory has spent decades improving analytical quality by establishing internal quality controls (IQC) and external quality assessment (EQA).IQC is done via QC samples which is provided by biorad. Every morning our lab is doing QC and in case of any deviation we perform the calibration.

We also have LJ charts which on entering the values of the samples get automatically formed. These charts help us to catch any deviation beyond 2SD easily. EQA is done online.

Post analytical errors formed the least common error in our study. We got 4/305 i.e 1.3 % of cases. Carraro P, Plebani M got (23.1%) of cases whereas Goswani et al and AS Sakyi got 3.2% and 0.83% respectively. The main cause of this error is typing mistake which is usually of fractions. To avoid this error we are starting interface.

5. Conclusion

Preanalytic, analytical and post analytical 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. Our study showed that out of 200978 samples processed the most common error seen in laboratories was preanalytical, then comes analytical and at the last comes post analytical. Of all the samples received in the lab, the overall percentage of errors came out to be 0.15%.

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