

# STUDY OF THE ERRORS IN HEMATOLOGY LABORATORY IN A TERTIARY CARE HOSPITAL

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**Abstract: Background:** *Error in any laboratory starts from the moment any investigation is being planned till it is interpreted and clinical judgment is made. Entire process is difficult to perform without error.*

**Aim :** *Study of the Errors in hematology laboratory in a tertiary care hospital. TeerthankerMahaveer Medical college and Research center (Moradabad). Purpose: To investigate for errors and causes of errors related to different hematological tests in hematology laboratory.*

**Methodology:** *In this observational study, a total of 304,358 tests (95,991 outpatient department [OPD] and 208,367 inpatient department [IPD]) were received in haematology laboratory. These errors were further categorized as Pre-analytical, Analytical and Post-analytical.*

**Result:** *The Pre-analytical errors constituted maximum number of errors i.e.in 501samples (94.7% of total errors) which constituted major chunk of errors which is close to 0.16%, which was followed by post analytical errors which was found in 17cases (3.21% of total errors) with frequency of 0.0036% ;Analytical errors were detected in least number of cases i.e.11reports (2.07% of total errors)*

**Conclusion:** *Errors in hematology laboratory which is classified as Pre-analytical, analytical, and post-analytical errors remain the biggest limitation to laboratory service and it thus has impact on healthcare management and cost involved. Majority of reasons involved behind analytical errors is within the scope of laboratory and thus can be reduced to a great extent by training of laboratory staff, participation in quality system and regular monitoring of equipment's. We found analytical error to be close to 2% most of which were related to auto clumps which can be resolved by incubation at body temperature most of the time as these are cold auto agglutinins which poses analytical problem, especially in winters. We found Post analytical error also to be insignificant (3.2%), most of which was due to wrong entry of results, such errors can also be avoided and minimized by close and frequent monitoring of laboratory reports.*

**Keywords:** *Haematology, laboratory, Pre-analytical errors, quantity not sufficient.*

## **INTRODUCTION**

Error in any laboratory starts from the moment any investigation is being planned till it is interpreted and clinical judgment is made. Entire process is difficult to perform without error. We as laboratory physicians and other personnel are working on to find solution to this difficult situation so that prompt and necessary corrective action can be taken in a timely manner.<sup>[1]</sup>

Accuracy and reliability of results are crucial with respect to clinical decision making which

depends upon laboratory results in almost 70% of cases.<sup>[2]</sup>

Each laboratory thus must participate in quality assurance program to ensure standardized, reliable test results are issued to patients and their care givers.<sup>[3]</sup>

Such errors can be categorized three stage: -

- 1) Pre-analytical,
- 2) Analytical and
- 3) Post analytical

Pre-analytical errors accounts for the maximum proportion of errors.<sup>[4-7]</sup> It involves sample collection technique, handling and processing of samples, physiological conditions and other variables. Some of these variables e.g. specimen variables etc. can be predicted and on being watchful can be taken care of ; whereas many uncertain variables are beyond the control and which must be understood in order to interpret correctly typical example being cold agglutinin in winter seasons.<sup>[8,9]</sup>

These pre-analytical errors include:

- Ordering test on the wrong patient,
- Misidentification of patient,
- Ordering the wrong test,
- Missing sample
- Missing test requisition forms,
- Wrong identification,
- Sample collected from infusion route,
- Hemolyzed sample
- Clotted sample
- Insufficient quantity of sample,
- Inappropriate sample containers,
- Wrongly labeled containers,
- Improper transportation
- improper storage .<sup>[10,11]</sup>

Pre-analytical errors constitutes majority (46–68%) of laboratory error followed by Post-analytical errors (19–47%)<sup>[6]</sup> Analytical errors accounts for minimum percentage (13-32%) of error i.e. less than one third.<sup>[5]</sup> the analytical error begins from specimen preparation until interpretation or validation by the person reporting in the laboratory.<sup>[11]</sup> such errors could be related to the instruments or from interference complex of the analytical sample. The analytical errors are further categorized as random errors and systematic errors. Random errors show low precision; however systematic errors shows low accuracy.

Some patterns of random errors are: -

- 1) Pipetting error,
- 2) Transcript errors,
- 3) Improper Specimen numbering and labeling,
- 4) Fluctuating colorimeter reading.

Systematic errors ensues because of incorrect procedures and error in standardization techniques.<sup>[12]</sup>

Post-analytical errors are mostly related to interpretation and transcription, patient mismatch etc. <sup>[1]</sup>

Most common errors are: -

- Wrong authentication,
- delayed results,
- issuing report to wrong person,
- Records entry errors or Transcript errors

In hematology laboratory the Post-analytical processes include confirming results, generating reports, and communicating them to clinicians in the form of printed reports or making oral communications about “alarm” and panic results. <sup>[13,14]</sup>

As per agency for healthcare research and quality estimates, 8th leading reason of death In the United states is, “medical errors” which is higher than motor vehicle accidents, cancer, and AIDS events per year. <sup>[15,16]</sup>

Even though automations, standardization and technical advance significantly improved the analytical accuracy of laboratory tests still we are struggling continuously with this situation. <sup>[11,17,1]</sup>

## **AIMS AND OBJECTIVE**

### **AIM:**

- Study of the errors in hematology laboratory in a tertiary care hospital.

### **OBJECTIVES:**

- To investigate for errors in hematology laboratory.
- To investigate for causes of errors in hematology laboratory.
- To investigate for cause of errors related to different hematological tests in hematology laboratory.

## **REVIEW OF LITERATURE**

Shukla DKB et al., in their study in Karad (India) in 2017, with 1, 21,470 samples found errors in 1431(1.18%) samples. Pre-analytical errors was noted in 1218(1.003%) tests followed by post-analytical in 213(0.17%) . Analytical error was not reported during the study period. The common reason being improper sample mixing and inadequate anticoagulant. <sup>[18]</sup>

Bhuyar BK et al., conducted prospective observational study in Karwar, for a period of 2 years , with total samples being 23680, 11414 being Indoor samples and 12266 being outdoor. They found preanalytical errors in 6.61% of Indoor samples and 3.69% of OPD samples. Hemolysed sample being the commonest preanalytical error both in OPD and

Indoor samples. Out of those 12266 samples received from outdoor investigations only 160 requisition forms were properly filled.<sup>[19]</sup>

In 2017, Arul P et al., with 118732 test samples (62,474 OPD and 56,258 IPD) in Southern India found pre-analytical errors in 513 samples (0.43%), Inadequate samples (0.2%) being the commonest errors followed by clotted samples (0.12%). Both misidentifications (wrong labeled vials or incorrectly filled forms) and wrong chosen vials constituted 0.07%. A hemolyzed sample was seen in 0.03%, Diluted samples accounted for 0.02% .

Alpdemir M et al; found errors with respect to different phases as 81.7%, 1.7%, and 16.6%, respectively., with total error frequency as 0.73% during 1-year period. Clotted sample was observed as the most frequent reason for such problems. In the analytical phase the most common error was unacceptable performance in EQA (78.5%).<sup>[20-28]</sup>

## **METHODOLOGY:-**

**TYPE OF STUDY:-**Observational study

**LABORATORY:-**Hematology laboratory

**STUDY LOCATION:** - TeerthankerMahaveer Hospital and Research center

**STUDY DURATION:-**six months from 1<sup>st</sup> January 2019 to 30 June 2019.

**INCLUSION CRITERIA:-**All the blood samples received during the study period.

**SAMPLE SIZE:-** minimum 383 sample.

Sample size was calculated using the formula:-

Total sample size

$$S.S = \frac{Z^2_{\alpha/2} P Q}{E^2}$$

**P:** prevalence rate %

**Q:** (100-p) %

**E:** error

**Z<sup>2</sup><sub>α/2</sub>:** Standard normal variant

Here

$$P = 47.05\%^{[1]}$$

$$Q = (100-47.05\%)$$

$$E = 5\%$$

$$Z^2_{\alpha/2} = 1.96 \text{ at } 5\% \text{ type error}$$

$$S.S = (1.96)^2 \times 47.05 (100-47.05) / (5)^2$$

$$= 382.822$$

=383 (minimum sample size)

### PATIENT PREPARATION (FOR OPD SAMPLES)

Collection site is cleaned with alcohol in a centrifugal manner as prescribed by standard operating procedure of laboratory. Before venipuncture, alcohol is allowed to evaporate in order to ensure avoid contamination of specimen with alcohol, which can lead to hemolysis.

- By using vacutainer tube collection the following sequence of drawing a blood is follow:  
-

TEST	ANTICOAGULANTS
Blood culture	Blood culture bottle
PT & APTT	Sodium citrate
CBC,ESR	EDTA
LFT, KFT	Plain vial
Blood sugar	Sodium fluoride

### SAMPLE RECEIVING ( FOR IPD SAMPLES)

- Completeness of requisition slip is checked and matched with that of labeling on sample.
- Quality of sample is checked with respect to the
  - quantity of sample in vacutainer
  - any evidence of hemolysis
  - any evidence of clotted sample
- appropriate order of draw must be maintained if sample is to be collected in multiple vials fir different tests.
- The vacutainer must be properly filled as recommended mixed carefully.
- Different samples have their individual special handling requirements which must be followed .

### OBSEVATIONAL STUDY SEEN IN THREE STAGES:-

- Pre-analytical
- Analytical
- Post- analytical
  - Laboratory request forms of indoor samples were screened for :
    - Patient Information:
      - (a) Name
      - (b) Age
      - (c) Sex
      - (d) CR NO.
      - (e) Location
    - IPD/OPD no.
    - Sample Information:

(a) Nature of the sample (b) Date and Time of collection.

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**DEPARTMENT OF PATHOLOGY**

Patient's name.....Age/sex.....Date.....  
Ref.byDr.....ProvisionalDiagnosis.....  
CR. No.....OPD/IPD No.....Ward.....

Investigation Required for Hematology

<b>Routine Tests</b>
HB
TLC
DLC
ESR
H-1(HB,TLC,DLC)
H-2 (HB,TLC,DLC,ESR)
Complete blood count
Platelet Count
Peripheral Blood Smear
Absolute Eosinophil Count
BT
CT
PCV
Total RBC
RBC Indices
1-MCV
2-MCH
3-MCHC
RDW
MPV
Reticulocyte count
Blood group & Rh typing
<b>SPECIAL TESTS</b>
Prothrombin Time
APTT
Clot Retraction Time
D. Dimer (FDP)
G6PD

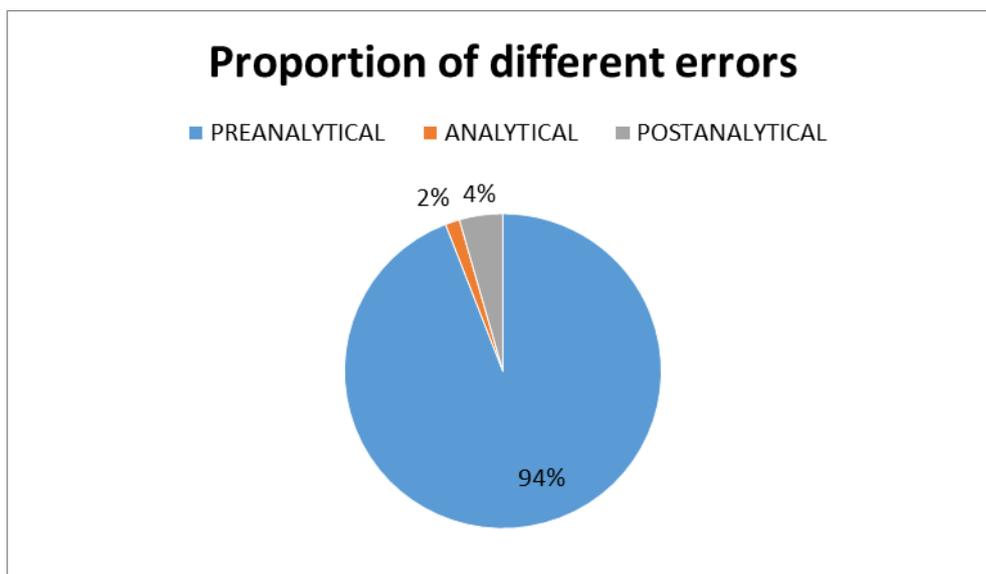
Sickling Test
LE Cell
FetalHemoglobin
Osmotic Fragility Test (O.F.T)
Direct Coombs Test
Indirect Coombs Test

**RESULT**

During the study period of six months, total 304,358 tests were analyzed which included samples from outpatient department (OPD) and inpatient department (IPD), 529 errors were detected in hematology laboratory. These errors were further categorized as Pre-analytical, Analytical and Post-analytical. The Pre-analytical errors constituted maximum number of errors i.e.in 501samples (94.7% of total errors) which constituted major chunk of errors which is close to 0.16%, which was followed by post analytical errors which was found in 17cases (3.21% of total errors) with frequency of 0.0036% ;Analytical errors were detected in least number of cases i.e.11reports (2.07% of total errors) [table 1 &2]

**Table: 1 proportion of different errors out of total errors**

PREANALYTICAL	ANALYTICAL	POSTANALYTICAL
94.7%	2.07%	3.27%



**Table: -2 Distribution of errors into different categories with relative frequency of error**

OPD/IPD				
s. no	Tests	Total Tests	Errors	Errors percentage= (Error/total tests X100 )
1	Pre-analytical	304,358	501	0.16%
2	Analytical		11	.0036%
3	Post analytical		17	.0055%

Total tests were categorized into OPD and IPD department. Tests ordered for was mainly for CBC, ESR, PT, APTT and hemoglobin. Tests ordered for other hematological investigations which constituted minor proportion of cases were excluded from study.

**Table: 3 Distribution of errors for various tests in pre-analytical phase**

s. no	Tests	OPD			IPD		
		Tests	Errors	Errors percentage= (Error/total tests X100 )	Tests	Errors	Errors percentage= (Error/total tests X100 )
1	CBC	80,037	189	.23%	195,129	164	0.084%
2	ESR	7,495	10	0.13%	3,090	08	0.25%
3	PT APTT	520	19	3.65%	6,774	94	1.38%
4	Hemoglobin	7,939	07	0.08%	3,374	10	0.29%
5	Total	95,991	225	0.23%	208,367	276	0.13%

Further the errors were categorized into various reasons for the same which were Clotted samples, Haemolysed samples, Quantity insufficient, Improper requisition form, Short sample, Without labeling, Wrong labeling, Wrong sample in vial, Sample overflow.

Improper requisition form constituted majority approximately two third followed by insufficient quantity which constituted approximately one fifth of all pre-analytical errors in OPD samples. Clotted sample was found in approximately 5% of errors found in OPD samples.

More than half (**55.4%**) of errors in IPD was due to clotted sample, improper requisition form constituted approximately 20% followed by insufficient sample quantity (**10.97%**),

**Table: 4Distribution of various causes of errors in CBC samples and their frequency.**

Errors in CBC	
OPD	IPD

Type of error	Total samples	Errors	Percentage	Total samples	Errors	Percentage
Quantity not sufficient	189	36	19.0%	164	18	10.97%
Wrong labeling		03	1.58%		08	4.87%
Clotted sample		09	4.76%		91	55.4%
Improper requisition form		130	68.7%		29	17.6%
Haemolysed sample		00	00%		01	0.6%
Wrong CR no.,		05	2.64%		06	3.64%
Wrong sample		00	00%		09	5.48%
Short sample		06	3.17%		01	0.6%
Sample overflow		00	00%		05	3.04%

As already shown in table-3 majority of requests for coagulation tests were received from IPD(6,774), test from OPD was even lesser than 10% of that asked from IPD, when we look into the %age of error amongst IPD samples it was 1.38% close to one third that \of OPD, majority of these were due to clotted sample( 2/3rd of IPD and 1/3rd of OPD samples) most likely due to inappropriate method of sample collection. Second commonest cause of error was incomplete requisition form. [table 5]

**Table: 5**Distribution of various causes of errors in coagulation samples and their frequency.

Errors in coagulation samples						
OPD			IPD			
Type of error	Total samples	Errors	Percentage	Total samples	Errors	Percentage
Quantity not sufficient	19	01	5.26%	94	02	2.1%
Wrong labeling		01	5.26%%		00	00%
Clotted sample		07	36.8%		58	61.7%
Improper requisition form		05	26.3%		01	1.06%
Haemolysed		00	00%		10	10.6%

sample					
Wrong CR no.,	00	00%		04	4.25%
Without labeling	00	00%		01	1.06%
Wrong sample	02	10.52%		04	4.25%
Short sample	01	5.26%		06	6.38%
Sample overflow	02	10.52%		08	8.51%

As seen in table 3 tests asked for ESR was from OPD was double that of IPD and number of error was almost equal thus making error frequency from OPD double that of IPD. Major reason for the reason was found to be insufficient sample quantity in equally OPD and IPD samples.

(Table): 6Distribution of various causes of errors in ESR samples and their frequency  
Errors in ESR samples

Type of error	OPD			IPD		
	Total samples	Errors	Percentage	Total samples	Errors	Percentage
Quantity not sufficient	10	07	1.10%	08	04	50%
Improper requisition form		02	33.3%		01	12.5%
Haemolysed sample		00	00%		01	12.5%
short sample		01	0.1%		00	00%
Clotted sample		00	00		02	25%

Looking into the most frequent reason of error in hemoglobin estimation was incomplete requisition form in OPD sample whereas in IPD major reason was clotted sample which was found to be unfit for estimation with automated hematology analyzer.

Table 7: Distribution of various causes of errors in hemoglobin estimation samples and their frequency

Type of error	OPD			IPD		
	Total samples	Errors	Percentage	Total samples	Errors	Percentage

Wrong labeling		02	28.5%		00	00%
Clotted sample		00	00%		06	60%
Improper requisition form	07	05	71.4%	10	00	00%
Wrong CR no.,		00	00%		02	20%
Wrong sample		00	00%		02	20%

**ANALYTICAL FINDINGS:-**

Of the total 11 analytical error out of 304,358 tests performed four was found in CBC estimation all was later found to be due to auto agglutination which was resolved on incubation of the sample at three different temperatures i.e. at room temperature, refrigerator and body temperature. Three errors were seen in ESR estimation due to various technical errors. Four errors were seen in coagulation sample.

**Table:7 Distribution cases with analytical error and their frequency**

s. no	Tests	Tests	Errors	Errors percentage= (Error/total tests X100 )	Type of error
1	CBC	275,166	04	.001%	Auto agglutination
2	ESR	10,585	03	0.02%	Technical error
3s	PT APTT	7,294	04	0.05%	Reading raised
4	HB	11,313	00	00%	

➤ **POST-ANALYTICAL FINDING:-**

Most common test showing analytical error was CBC which was 13 out of 275,166 tests performed major reason being typing error, Misplaced reports, mainly.

**Table:8 Distribution cases of post-analytical error and their percentage**

s. no	Tests	Tests	Errors	Errors percentage= (Error/total tests X100 )
1	CBC	275,166	13	0.004%
2	HB	11,313	01	.008%

3	PT APTT	7,294	03	0.04%
4	ESR	10,585	00	00%

## DISCUSSION:-

Several studies have been conducted to investigate errors involved in their system, here we prospectively conducted an observational study over a period of six months in hematology laboratory, comprising of total 304,358 tests which included samples from outpatient department (OPD) and inpatient department (IPD), and we found error frequency to be 0.17% (529 errors) which is slightly lesser than half compared to observation by **VikramNarang et al**<sup>[103]</sup>(0.38%) who conducted the study over a period of one year with a higher sample size (1.5 times that of ours), **Arul P et al**<sup>[20]</sup> found error frequency to be slightly higher (0.43%) than even by **VikramNarang et al** but they had a sample size half that of ours over a study period of one year. With almost similar sample size as that by **Arul P et al**<sup>[26]</sup>; **Viscuso, D. G. I et al**<sup>[27]</sup>; **Dhirajkumar B. Shukla et al**<sup>[18]</sup> found error frequency to be three times.

On comparing our study which is conducted in hematology laboratory, with the findings of similar studies being conducted based in clinical laboratories which was not only restricted to hematological investigations, conducted by **Alpdmir M et al**,<sup>[28]</sup> **Toshniwal P et al**<sup>[29]</sup>, **Mehdi, H. E et al**<sup>[30]</sup>; **Bhuyar BK et al**,<sup>[19]</sup> and **Kapoor S et al**,<sup>[31]</sup> with sample size of 15,320, 23680, 649,001 and 46,404 respectively with study period, is similar to the study done by **Alpdmir M** (1.7%) the post-analytical error which was found in 17 cases with frequency of ( 3.27%) was lesser compared to **Toshniwal** (14.49%) and **Alpdmir M et al**(16.6%).

We found error frequency in OPD to be almost twice (0.55%) as compared to that from IPD (0.25%) which is strikingly reversed when compared with the study conducted by **Upreti S et al.**, **Arul p et al.** and **Sadiq F** which varies from 6 months to two years, Our study encountered significantly lesser frequency of error when compared with study done by them except for by **Alpdmir M et al. (0.73%)** whose study was somehow comparable but still significantly high.

The pre-analytical errors constituted maximum number of errors i.e.in 501 samples (94.7% of total errors), which was followed by post analytical errors , 17 cases (3.21% of total errors) with frequency of 0.0036%; Analytical errors were detected in least number of cases i.e.11 reports (2.07% of total errors) , these findings are similar to the study conducted by **Tadesse h et al.(75%)**,<sup>[32]</sup> **Alpdmir M et al. (81.7%)**, and **Dhirajkumar B. Shukla et al (85%)** which was followed by analytical error which was detected in least number of cases i.e. 11 reports (2.07% of the total error set al. most of these errors . This can be due to strikingly higher errors in IPD when compared to OPD in post analytical errors, which is mostly not considered in most of the studies carried out.

The reason for higher percentage of pre-analytical errors in all the studies are mostly related to inadequate training and awareness of Nurses and paramedical staff while collecting samples.

In the analytical phase, all errors was due to Auto agglutination (total=11) which comprises of only 2% of errors in our study which is similar to the study conducted by **Sakyi AS et al**<sup>[33]</sup>; **García, E et al**<sup>[34]</sup> with a total number of 589,510 tests whose percentage of analytical error was 2.2%(210 out of 9176 errors) with majority of cause for them being malfunction of instrument. The reason for difference in error is due the setup of both laboratories. Ours being hematology laboratory whereas their being biochemical laboratory.

The Post-analytical findings we observed, accounted for 3.27% (17 error) of all the errors, typing error being the most common cause with error frequency of 0.004%..**Shukla DKB et al. and Toshniwal p et al.** found 15% (213 errors) and 14.49% (1244 errors) in this phase with error frequency being significantly higher in both the studies than that of our study. Most common cause in study conducted by Shukla DKB et al. was Delayed dispatch and by Toshniwal p et al. as Delay in reporting

## CONCLUSION

Errors in hematology laboratory which is classified as Pre-analytical, analytical, and post-analytical errors remain the biggest limitation to laboratory service and it thus has impact on healthcare management and cost involved. Majority of reasons involved behind analytical errors is within the scope of laboratory and thus can be reduced to a great extent by training of laboratory staff, participation in quality system and regular monitoring of equipment's. We found analytical error to be close to 2% most of which were related to auto clumps which can be resolved by incubation at body temperature most of the time as these are cold auto agglutinins which poses analytical problem, especially in winters. We found Post analytical error also to be insignificant (3.2%), most of which was due to wrong entry of results, such errors can also be avoided and minimized by close and frequent monitoring of laboratory reports. Pre analytical error remains cornerstone of any laboratory since majority of steps which are reasons behind these errors remains out of direct control of laboratory. Our study also showed similar trend with pre-analytical errors being the major chunk of errors, top reasons behind this being the inadequate documentation of clinical information and inadequate sample volume leading to clots micro clots and hemolysis of sample mainly for tests involving blood counts, ESR and coagulation studies. Both the steps are usually out of direct supervision of laboratory as sample is usually collected by nurses and paramedical staff in wards or OPD. Optimum utilization of vacutainer system with evacuation tubes, application of bar coding of samples along with regular training of personnel involved in sample collection can reduce such type of errors to a great extent.

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## ABBREVIATIONS

**OPD** :Outpatient departments

**IPD** :Inpatient departments

**CBC** :Complete blood counts

**PT** :Pro-thrombin time

**APTT** :Activated partial thromboplastin time

**HB**:Haemoglobin

**ESR** :Erythrocyte sedimentation rate

