

ORIGINAL RESEARCH

## Pre-Analytical errors in hematology

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### ABSTRACT

**Background:** Laboratory reports play major role in patient management. So, more importance should be given to the quality of laboratory reports. Hematology laboratory must ensure reliable test results with high degree of precision and accuracy. Even after so many advances, pre-analytical errors remain a challenge for hematology laboratory.

**Aims And Objectives:** The present study was undertaken with an objective to identify the major reasons of sample rejection in the pre-analytical phase and to do a root-cause-analysis of that reasons in order to improve the quality of laboratory services and proper patient care.

**Material And Methods:** All the samples received in the hematology laboratory of tertiary care teaching hospital, Ahmedabad during the period from January 2014 to August 2015 were included in the study. These samples are analyzed for pre-analytical errors such as clotted samples, hemolyzed samples, improper quantity of the samples, inadequate information in the requisition form, mismatch in test requested and sample collected, mismatch in sample label and information in requisition form.

**Results:** Out of 123228 samples, pre-analytical errors, as per above mentioned categories, were found in 5381(4.37%) samples. The most common pre-analytical error was clotted samples in 4173 (77.55%) samples, followed by Mismatch samples in 437 (8.12%) samples, Improper quantity in 405 (7.53%) samples, hemolyzed samples in 324 (6.02%) samples and inadequate information on requisition form in 07 (0.13%) samples.

**Conclusion:** Pre-analytical errors are frequent in the laboratories and can be corrected by regular root-cause-analysis of the involved reasons. Errors can be avoided by proper communication and co-ordination between laboratory and wards, awareness of correct phlebotomy technique, proper training and continuing medical education programs for laboratory and paramedical staff and knowledge of intervening factors that can influence laboratory results.

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## INTRODUCTION

Hematology is a discipline which covers a wide range of skills. It provides an indispensable base for proper diagnosis and management. Good practice of clinical medicine is governed by precise and accurate hematological reporting. An accurate result starts with a quality specimen. Improper results may be due to pre-analytical, analytical or post-analytical errors. Pre-analytical errors are one of the majority causes for inaccurate results in hematology. Controlling the pre-analytical variability in hematology testing is a critical factor for ensuring accurate results. By minimizing errors at pre-analytical phase, quality of analytical results can be improved.

Pre-analytical factors such as specimen collection, specimen handling, interfering substances and patient factors are common pre-analytical sources of inaccurate test results. Use of clinical laboratory test results, in diagnostic decision making has become an integral part of clinical medicine. More than 60-70% of the most important decisions on admission, discharge, and medication are based on laboratory test results <sup>[1]</sup>. With this high degree of influence, the reliability of laboratory testing and reporting is of utmost importance. Even though automation, standardization and technological advances have significantly improved the analytical reliability of laboratory tests, lab errors still do occur in the pre-analytical, analytical and post-analytical processes of the total testing process <sup>[1]</sup>.

Most errors in the venous blood testing process are Preanalytical, i.e. they occur before the sample reaches the laboratory <sup>[2-9]</sup>. Unlike the laboratory analysis, the pre-analytical phase involves several error-prone manual tasks not easily avoided with technological solutions <sup>[10]</sup>.

The different causes of rejection of samples in the pre-analytical phase have been classified as below :

- Clotted Samples.
- Hemolysed Samples.
- Improper Quantity of Samples.
- Inadequate information in the requisition form.
- Mismatch : Test Requested and sample collected.
- Mismatch : Sample label and information in Requisition Form.

One important source of preanalytical error is incorrect or incomplete information on the test request or on the test tube label <sup>[5,11]</sup>. Preanalytical errors are largely attributable to human mistakes <sup>[6,12]</sup> and the majority of these errors are preventable <sup>[2,4]</sup>. This is understandable, since the preanalytical phase involves much more human handling, compared to the analytical and post-analytical phases.

**Sample Collection:** Errors arising during sample collection and specimen handling are the most common type of preanalytical errors <sup>[12]</sup>. This handling can be the major uncertainty component for some analyses <sup>[10]</sup>. Even with a standardized procedure; venous blood sampling by different phlebotomists can have a higher variation than the laboratory precision <sup>[8]</sup>.

Sample collection phase starts with the phlebotomist picking up work orders from the lab receptionist and ends when she/he submits the patient samples to the analytic section of the lab for testing. It has been demonstrated that the most laboratory errors occur in this phase, primarily because of a lack of standardized protocols. The main reason or high prevalence of errors in this crucial step of the testing process is that it is currently difficult to monitor all pre-analytical variables (such as phlebotomy), which are not under direct laboratory control or

supervision<sup>[13]</sup>. The relative percentage of error in this phase is suggested to be as high as 84.5%<sup>[14,15]</sup>. There is a considerable difference between in and out patient departments, as reflected by the rather different error rates, which has been attributed to human factors related to skill in drawing blood and sheer volume of laboratory tests carried out for inpatients<sup>[14]</sup>. **Patient Identification:** Correct patient identification is one of the first steps in ensuring correct laboratory results. Improving the accuracy of patient identification is the highest priority for patient safety<sup>[16]</sup>.

Patient identification at venous blood sampling is an important source of error in blood transfusions, due to non-compliance with guidelines<sup>[17]</sup>. Mistakes in the patient identification procedure before venous blood sampling can be responsible for up to 25% of all preanalytical errors<sup>[12]</sup>.

Another common error involves a physician ordering laboratory tests on the wrong patient, either because the patient does not give his full name and identity, or because the physician makes mistakes while completing the order. Patient with identical names present a unique challenge to acute healthcare settings, a situation particular to the communities where most individual's names are not unique<sup>[18]</sup>.

**Inappropriate procedure for blood collection:** Among pre-analytical variables, inappropriate procedure for collection of venous blood accounts for 60% of the errors, highlighting the need for a more rigid and effective supervision of this pivotal and irreplaceable part of the diagnostic process<sup>[19]</sup>. Spurious variation of laboratory testing can arise if mixing of blood and additive is not done carefully<sup>[19]</sup>.

**Sample identification:** Labelling of test tubes, an equally important preanalytical step and a focal point for improvement of care<sup>[20]</sup>, should always be performed immediately before sample collection<sup>[21]</sup>. Frequency of misidentification in a stat laboratory might be as high as 8.8%<sup>[22]</sup>

**Sample submission to the lab:** Transport of samples to the laboratory can give rise to clinically important errors<sup>[2]</sup> if transport conditions are not optimized<sup>[23]</sup>.

## MATERIAL AND METHODS

All the samples received in the hematology laboratory of tertiary care teaching hospital, Ahmedabad during the period from January 2014 to August 2015 were included in the study. These samples are analyzed for pre-analytical errors such as clotted samples, hemolyzed samples, improper quantity of the samples, inadequate information in the requisition form, mismatch test requested and sample collected, mismatch sample label and information in requisition form. The findings are compared with other similar but independent studies carried out in different clinical laboratories. An attempt to identify the causes behind the major reasons of sample rejection in the Pre-analytic phase was made. This data has been presented and a quantitative analysis of the collected data was done. The data has been analyzed against various parameters like time, number of total samples handled etc. to identify possible correlations with any.

## RESULTS AND OBSERVATION

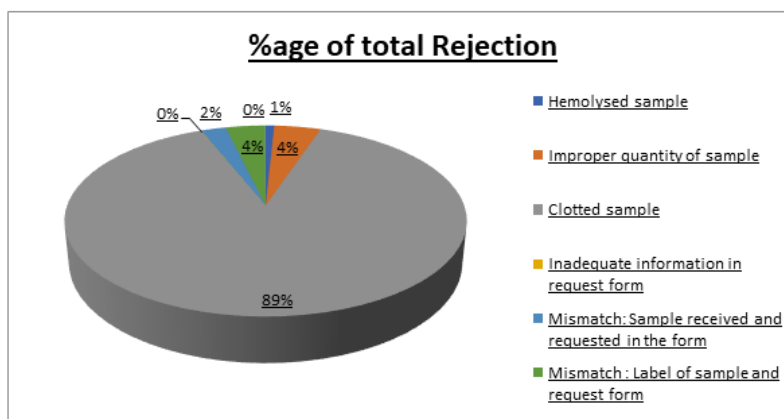
A total of 123228 samples were studied during the time period of January 2014 to August 2015. A quantitative analysis of the rejection data of this time period due to various reasons in the pre-analytical phase is done.

The data was analyzed in a more elaborate and extensive manner so as to reach to an inference regarding trends and inter-dependence of the errors on various aspects, parameters as well as manner of functioning of the laboratory in its day to day operation.

As already stated the errors are largely, if not in its entirety, human in the pre-analytical phase. Hence our approach of finding trends has been to identify when does the error maximizes, and which particular error is/are predominant and what are the possible factors of such human errors, for example larger sample size in that particular period, particular time of the year etc.

**Table 1: Percentage distribution of various reasons for rejection in the Pre-analytical stage-2014**

S/I No	Rejection Cause	Frequency	% of total Rejection
1	Hemolysed sample	22	0.81
2	Improper quantity of sample	119	4.38
3	Clotted sample	2408	88.66
4	Inadequate information in request form	1	0.04
5	Mismatch: Sample received and requested in the form	64	2.36
6	Mismatch: Label of sample and request form	101	3.71
7	Others	1	0.04



**Chart 1: Percentage distribution of various reasons for rejection in the Pre-analytical stage-2014**

Table 1 shows percentage distribution of various causes of rejection of samples during the pre-analytical phase in the year 2014. The total no of samples analyzed is **72015** and the total no of rejections have been **2716**. The data shows that the major reason for rejection in the pre-analytical phase is clotted samples (88.66%).

**Table 2: Percentage distribution of various reasons for rejection in the Pre-analytical stage-2015**

S/I No	Rejection Cause	Frequency	%age of total Rejection
1	Hemolysed sample	302	11.33
2	Improper quantity of sample	286	10.73
3	Clotted sample	1765	66.23
4	Inadequate information in request form	6	0.23
5	Mismatch: Sample received and requested in the form	270	10.13
6	Mismatch: Label of sample and request form	2	0.08
7	Others	34	1.28

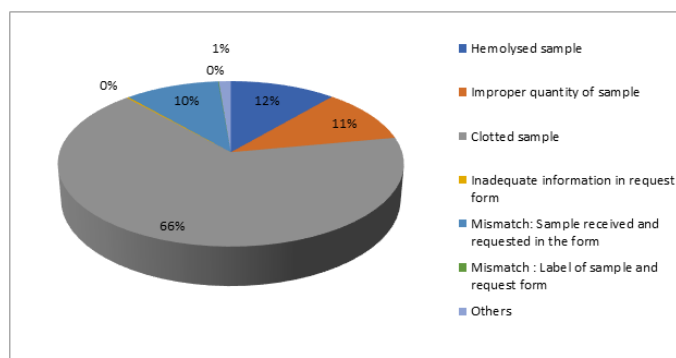
**Chart 2: Percentage distribution of various reasons for rejection in the Pre-analytical stage-2015**

Table 2 shows percentage distribution of various causes of rejection of samples during the pre-analytical phase in the year 2015 till the month of August. The total no of samples analyzed in this time period is **51213** and the total no of rejections have been **2665**. As observed in the previous year data, Clotted sample is the major reason for rejection (66.23%).

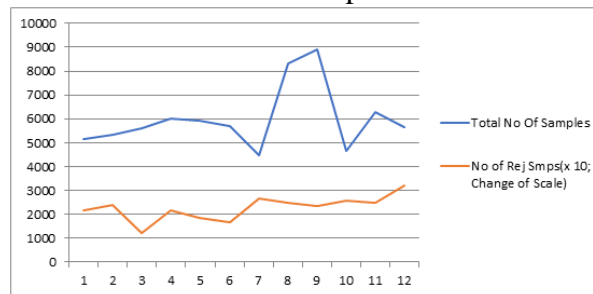
However, during this period, considerable number of cases of rejection due to improper quantity of samples, Hemolyzed samples and Mismatch between label of sample and request form etc. are also observed.

**Table 3: Monthwise distribution of rejection vs no of samples and percentage of rejection-2014**

Month	Total No Of Samples	No of Rejected Samples	% of Rejection	No of RejSmps (x 10; Change of Scale)
Jan	5159	215	4.17	2150
Feb	5342	240	4.49	2400
Mar	5594	120	2.15	1200
Apr	6015	215	3.57	2150
May	5909	184	3.11	1840
Jun	5713	166	2.91	1660
Jul	4458	267	5.99	2670
Aug	8300	247	2.98	2470
Sep	8927	235	2.63	2350
Oct	4655	259	5.56	2590
Nov	6278	249	3.97	2490
Dec	5665	319	5.63	3190
	<b>72015</b>	<b>2716</b>	<b>3.77</b>	

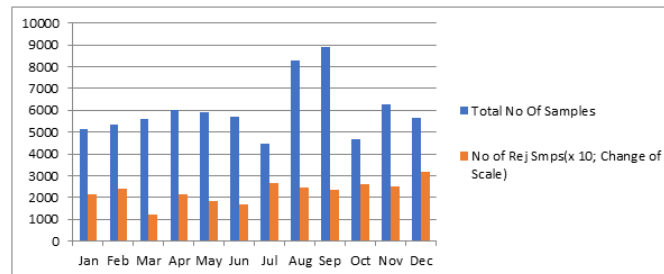
Table 3 shows the monthwise frequency of rejection due to various reasons against the total number of samples handled in that month. It also quantifies the total number of rejections as a percentage of the total no of samples that came for analysis in that particular month. The mean of percentage of rejection was found to be close to 3.8 percent of the total no of samples.

In the following line diagram and the histogram the absolute value of rejected samples has been multiplied by 10, that is change of scale has been done and plotted against the number of samples encountered in that particular instance. The line diagram tries to find out any linear correlation between the frequency of rejection with the total no of samples. The change of scale was done to facilitate a more meaningful diagrammatic interpretation of the correlation of the two parameters. It only tries to identify the presence of any correlation or the absence of the same between the two, i.e. frequency of rejection and total no of samples and doesn't call for any ambiguity regarding the absolute values of the said parameters whatsoever.

**Chart 3: Monthwise distribution of rejection(x 10)vs no of samples -2014**

The conclusion that can be drawn from the above line chart is that there is no direct linear correlation observed between the two, i.e. the frequency of rejection cannot be attributed to the

number of samples coming to the Lab for analysis. However a bigger sample size could have given us a more deterministic result.



**Chart 4: Monthwise distribution of No of samples and frequency of rejection( x10)-2014**

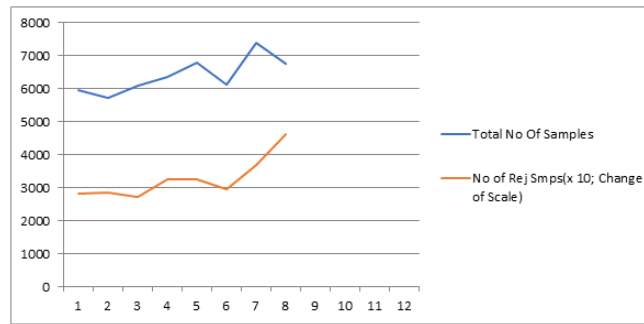
<b>Mean Sample Size/ Month</b>	<b>6001</b>
<b>Mean Rejection / Month</b>	<b>226</b>
<b>Mean %ge of Rejection</b>	<b>3.77</b>

Finally, for the year 2014, the mean sample size par month (6001), the mean rejection par month in absolute value (226) as well as percentage of the total no of samples par month (3.77%) in the pre-analytical phase was determined. The data can be a useful parameter for Quality control as well as performance assessment of a particular Lab over a certain specified time period when used in conjunction with other quality parameters.

**Table 4: Monthwise distribution of rejection vs no of samples and percentage of rejection-2015**

Month	Total No of Samples	No of Rejected Samples	% of Rejection	No of RejSmps(x 10; Change of Scale)
<b>Jan</b>	5944	281	4.73	2810
<b>Feb</b>	5724	285	4.98	2850
<b>Mar</b>	6093	271	4.45	2710
<b>Apr</b>	6362	327	5.14	3270
<b>May</b>	6804	375	5.51	3750
<b>Jun</b>	6140	295	4.80	2950
<b>Jul</b>	7396	369	4.99	3690
<b>Aug</b>	6750	462	6.84	4620
	<b>51213</b>	<b>2665</b>	<b>5.20</b>	

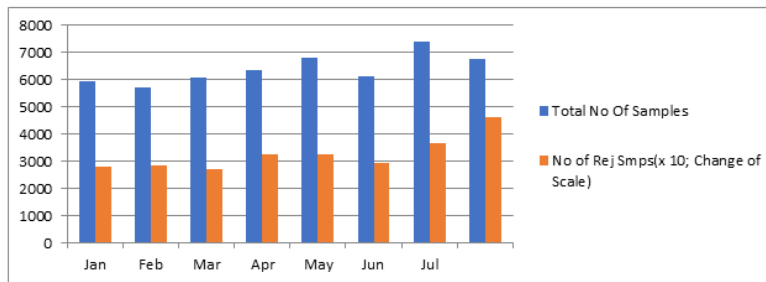
The same treatment was done to the data of the year 2015 up to the month of August for which data was available for analysis in Table 4 and subsequent line diagram and histogram.



**Chart 5: Monthwise distribution of rejection(x 10)vs no of samples -2015**

In the case of the year 2015 a certain degree of linear correlation between the frequency of rejection with the total no of samples was observed .

However it is maintained that a bigger sample size and data accumulation for a longer period of time could have given a more clear picture about the causal effect of sample size in pre-analytical rejection frequency , if any at all.



**Chart 6: Monthwise distribution of No of samples and frequency of rejection ( x 10)-2015**

<b>Mean Sample Size/ Month</b>	<b>6407.29</b>
<b>Mean Rejection / Month</b>	<b>327.14</b>
<b>Mean % of Rejection</b>	<b>5.11</b>

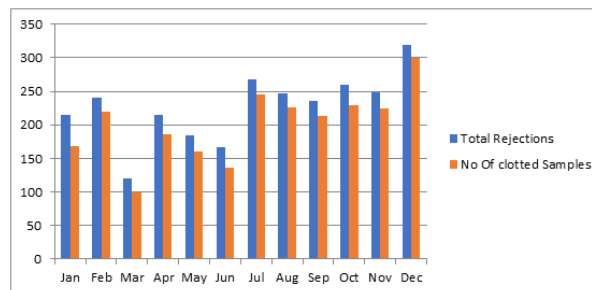
In the year 2015 a rise in the rejection percentage to the degree of almost 1.6 percentage points compared to the rejection frequency in the year 2014 was observed. However, since only eight month’s data were available, no conclusive remarks could be made regarding the relative performance of the particular Lab in the two periods. Nonetheless the observed trend can be a vital reason to re-examine the quality parameters maintained and followed by the Lab in order to reverse it in an effective manner.

Table 5 tries to gauge the contribution of clotted samples in the total no of rejection in a month wise basis. As already concluded in the earlier part of this study, clotted samples have the majority contribution, very often, to the degree of more than 90 percent of the total rejection in a regular basis.



**Table 5: Monthly distribution of rejections due to clotted samples and the percentage contribution of the said cause in total rejections - 2014**

Month	Total Samples	Total Rejections	No Of clotted Samples	% of Total Rejection
Jan	5159	215	168	78.14
Feb	5342	240	220	91.67
Mar	5594	120	100	83.33
Apr	6015	215	186	86.51
May	5909	184	160	86.96
Jun	5713	166	136	81.93
Jul	4458	267	245	91.76
Aug	8300	247	226	91.50
Sep	8927	235	213	90.64
Oct	4655	259	230	88.80
Nov	6278	249	224	89.96
Dec	5665	319	300	94.04
	<b>72015</b>	<b>2716</b>	<b>2408</b>	<b>88.66</b>

**Chart 7: Month wise distribution of total no of rejections clustered with rejections due to clotted samples -2014**

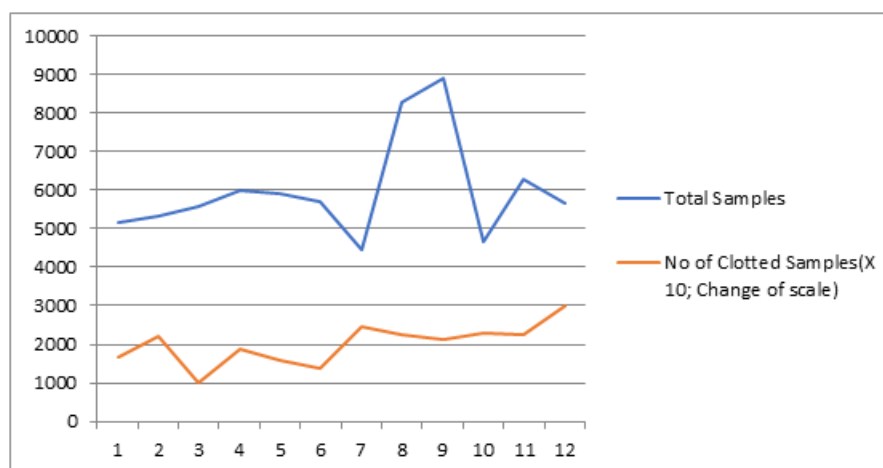
The immense influence or contribution of clotted samples in the total no of rejections is very evident from the above histogram.

Table 6 and the above line diagram again tries to identify linear correlation, if any, between rejections due to clotted samples and the actual no of samples which came to the Lab for analysis. As in the earlier case no linear correlation observed between the said parameters.

**Table 6 : Monthwise distribution of clotted samples against the total no of samples along with a change of scale -2014**

Month	Total Samples	No Of clotted Samples	No of Clotted Samples(X 10; Change of scale)
Jan	5159	168	1680
Feb	5342	220	2200
Mar	5594	100	1000

<b>Apr</b>	6015	186	1860
<b>May</b>	5909	160	1600
<b>Jun</b>	5713	136	1360
<b>Jul</b>	4458	245	2450
<b>Aug</b>	8300	226	2260
<b>Sep</b>	8927	213	2130
<b>Oct</b>	4655	230	2300
<b>Nov</b>	6278	224	2240
<b>Dec</b>	5665	300	3000

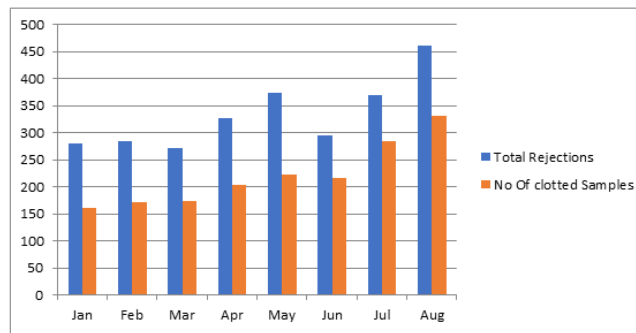


**Chart 8: Distribution of rejection due to clotted samples against no of samples handled (Change of scale of 10x on absolute no of clotted samples)-2014**

**Table 7: Monthly distribution of rejections due to clotted samples and the percentage contribution of the said cause in total rejections - 2015**

Month	Total Samples	Total Rejections	No Of clotted Samples	% of Total Rejection
<b>Jan</b>	5944	281	161	57.30
<b>Feb</b>	5724	285	171	60.00
<b>Mar</b>	6093	271	173	63.84
<b>Apr</b>	6362	327	203	62.08
<b>May</b>	6804	375	223	59.47
<b>Jun</b>	6140	295	217	73.56
<b>Jul</b>	7396	369	285	77.24
<b>Aug</b>	6750	462	332	71.86
	<b>51213</b>	<b>2665</b>	<b>1765</b>	<b>66.23</b>

Table 7 shows the distribution of rejection due to clotted samples par month against the total no of samples as well total no of rejections. It also shows the percentage contribution of rejections due to clotted samples in the total no of rejections.



**Chart 9: Month wise distribution of total no of rejections clustered with rejections due to clotted samples -2015**

From Table 7 as well as the subsequent histogram observe that although Clotted samples is still the major contributor in the total no of rejection per say however there is significant drop in relative percentage points while compared with the data of year 2014.

The improvement is to the degree of almost 22 percentage points which is major difference in all consideration.

On the other hand we observe a 2 percentage point rise in total no of rejections in this particular time period . i.e. the year 2015 in comparison to the year 2014.

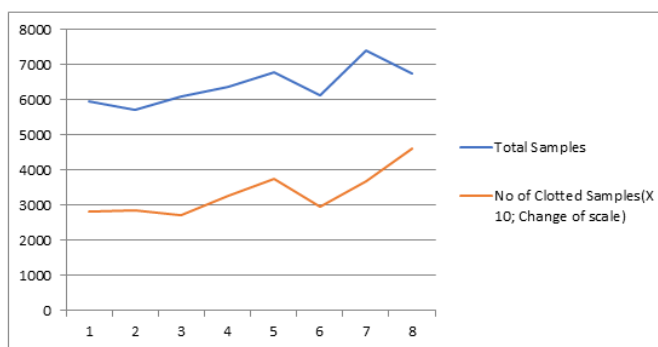
It is inferred that although the Lab under this study has been successful in minimising quite significantly the major contributor of rejection in the pre-analytical phase , i.e rejection due to clotted samples , rejection due to other reasons has risen to not only negate that effect but even to surpass it.

The attributes for such a behaviour of the rejection pattern in the pre-analytical phase needs to investigated and dealt with in an effective manner in order to maintain quality standards .

**Table 8 : Monthwise distribution of clotted samples against the total no of samples along with a change of scale -2015**

Month	Total Samples	No Of clotted Samples	No of Clotted Samples(X 10; Change of scale)
<b>Jan</b>	5944	281	2810
<b>Feb</b>	5724	285	2850
<b>Mar</b>	6093	271	2710
<b>Apr</b>	6362	327	3270
<b>May</b>	6804	375	3750
<b>Jun</b>	6140	295	2950
<b>Jul</b>	7396	369	3690
<b>Aug</b>	6750	462	4620

Table 8 shows the month wise distribution of rejection due to clotted samples against the total no of samples. In the following line diagram, we again try to find out any linear correlation between the two parameters. We have changed the scale for no of clotted samples to 10x in order to have better diagrammatic interpretation of the same.



**Chart 10: Distribution of rejection due to clotted samples against no of samples handled (Change of scale of 10x on absolute no of clotted samples)-2015**

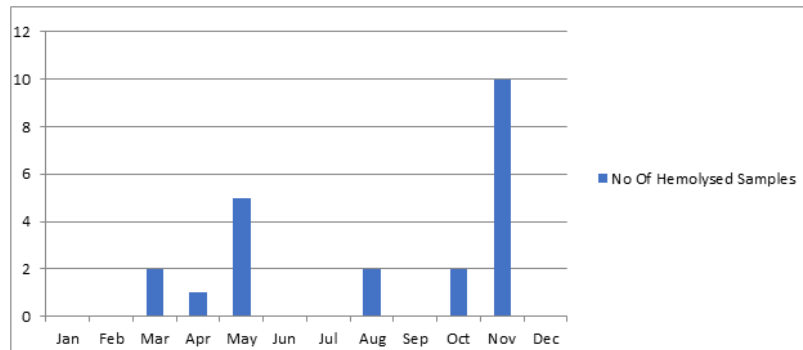
Here again , as in the case of total data for the year 2015, we find a comparable linear correlation between the two parameters. However the study maintains that much larger sample size is required to conclude casual relation between the two parameters.

In the following sections the contribution of various other pre-dominant reasons for sample rejection in the pre-analytical phase in the Lab has been studied.

Table 9 and the subsequent histogram shows the month wise frequency of rejections due to hemolysed samples. We observe that the occurrence of rejection due to hemolysed samples is rather insignificant in this particular time period i.e. less that 1 percent of the total rejection.

**Table 9: Month wise Frequency of rejections due to Hemolyzed sample - 2014**

Month	Total Samples	Total Rejections	No Of Hemolyzed Samples	% of Total Rejection
<b>Jan</b>	5159	215	0	0.00
<b>Feb</b>	5342	240	0	0.00
<b>Mar</b>	5594	120	2	1.67
<b>Apr</b>	6015	215	1	0.47
<b>May</b>	5909	184	5	2.72
<b>Jun</b>	5713	166	0	0.00
<b>Jul</b>	4458	267	0	0.00
<b>Aug</b>	8300	247	2	0.81
<b>Sep</b>	8927	235	0	0.00
<b>Oct</b>	4655	259	2	0.77
<b>Nov</b>	6278	249	10	37.04
<b>Dec</b>	5665	319	0	0.00
	<b>72015</b>	<b>2716</b>	<b>22</b>	<b>0.81</b>

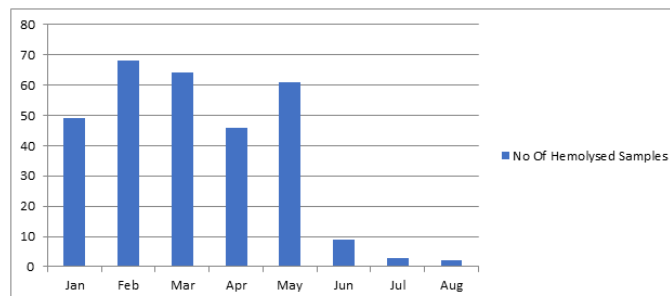


**Chart 11: Month wise Frequency of rejections due to Hemolyzed sample - 2014**

Table 10 and the following histogram shows the monthwise frequency of rejections due to hemolysed samples in the year 2015 up to the month of August. We observe a significant rise in rejections due to hemolysed samples compared to the year 2014. The percent increase in rejections due to hemolysed samples is more than 10 percent of the total rejections than the previous year. The process changes undertaken in between these two time periods , if any , needs to be reviewed and rectified .

**Table 10: Month wise Frequency of rejections due to Hemolyzed sample - 2015**

Month	Total Samples	Total Rejections	No Of Hemolyzed Samples	% of Total Rejection
<b>Jan</b>	5944	281	49	17.44
<b>Feb</b>	5724	285	68	23.86
<b>Mar</b>	6093	271	64	23.62
<b>Apr</b>	6362	327	46	14.07
<b>May</b>	6804	375	61	16.27
<b>Jun</b>	6140	295	9	3.05
<b>Jul</b>	7396	369	3	0.81
<b>Aug</b>	6750	462	2	0.43
	<b>51213</b>	<b>2665</b>	<b>302</b>	<b>11.33</b>

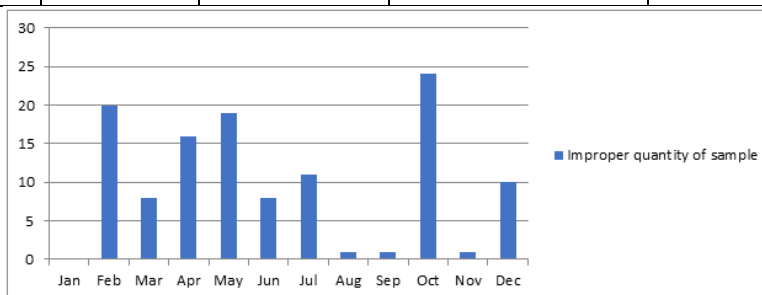


**Chart 12: Month wise Frequency of rejections due to Hemolyzed sample - 2015**

Table 11 and the subsequent histogram shows the month wise frequency of rejection of samples in the pre-analytical phase for improper quantity of sample collected by the phlebotomists.

**Table 11 : Month wise frequency of rejection due to improper quantity of sample – 2014**

Month	Total Samples	Total Rejections	Improper quantity of sample	% of Total Rejection
Jan	5159	215	0	0.00
Feb	5342	240	20	8.33
Mar	5594	120	8	6.67
Apr	6015	215	16	7.44
May	5909	184	19	10.33
Jun	5713	166	8	4.82
Jul	4458	267	11	4.12
Aug	8300	247	1	0.40
Sep	8927	235	1	0.43
Oct	4655	259	24	9.27
Nov	6278	249	1	3.70
Dec	5665	319	10	3.13
	<b>72015</b>	<b>2716</b>	<b>119</b>	<b>4.38</b>

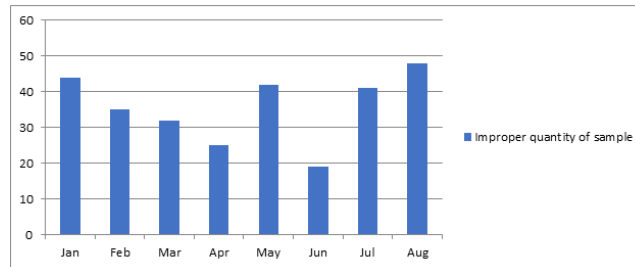


**Chart 13 : Month wise frequency of rejection due to improper quantity of sample – 2014**

Table 12 shows the month wise frequency of samples rejected due to improper quantity of samples in the year 2015 upto the month of August.

**Table 12 : Month wise frequency of rejection due to improper quantity of sample – 2015**

Month	Total Samples	Total Rejections	Improper quantity of sample	% of Total Rejection
Jan	5944	281	44	15.66
Feb	5724	285	35	12.28
Mar	6093	271	32	11.81
Apr	6362	327	25	7.65
May	6804	375	42	11.20
Jun	6140	295	19	6.44
Jul	7396	369	41	11.11
Aug	6750	462	48	10.39
	<b>51213</b>	<b>2665</b>	<b>286</b>	<b>10.73</b>



**Chart 14 : Month wise frequency of rejection due to improper quantity of sample – 2015**

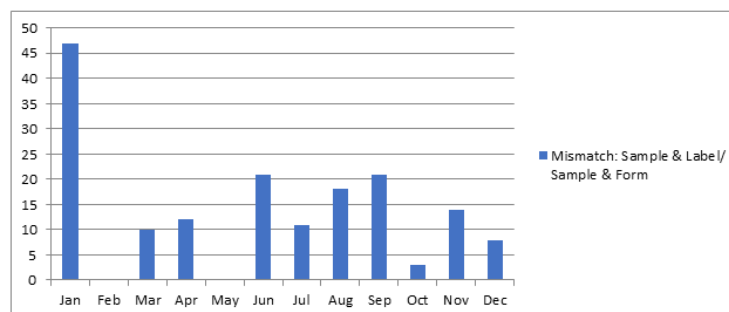
Here again we observe a rise in cases of rejection due to improper quantity of samples in the year 2015 as compared to the previous year.

Next the effect of mismatch of sample and the label or mismatch of sample and the actual sample required as per the requisition form i.e.as prescribed by the clinician is presented.

Table 13 shows the monthwise distribution of sample rejection due to mismatch of all sorts ,as explained earlier , in the year 2014.

**Table 13 : Month wise distribution of rejection due to mismatch – 2014**

Month	Total Samples	Total Rejections	Mismatch: Sample & Label/ Sample & Form	% of Total Rejection
<b>Jan</b>	5159	215	47	21.86
<b>Feb</b>	5342	240	0	0.00
<b>Mar</b>	5594	120	10	8.33
<b>Apr</b>	6015	215	12	5.58
<b>May</b>	5909	184	0	0.00
<b>Jun</b>	5713	166	21	12.65
<b>Jul</b>	4458	267	11	4.12
<b>Aug</b>	8300	247	18	7.29
<b>Sep</b>	8927	235	21	8.94
<b>Oct</b>	4655	259	3	1.16
<b>Nov</b>	6278	249	14	51.85
<b>Dec</b>	5665	319	8	2.51
	<b>72015</b>	<b>2716</b>	<b>165</b>	<b>6.08</b>



**Chart 15 : Month wise distribution of rejection due to mismatch – 2014**

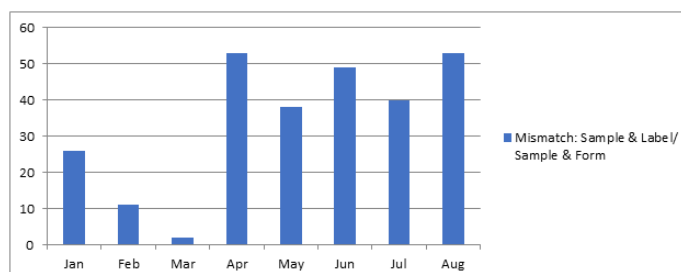
From the preceding data a more or less general trend in number of rejections due to mismatch in every month except in January was observed, when the absolute value goes up to a much higher value than the monthly average in the particular year.

This type of overshoot of certain value in a particular time frame over the average trend can be entirely random and offers no insight in general. However such overshoot calls for a review of the process and human resource involved in that particular time period to maintain desired quality standards.

Table 14 below shows the month wise frequency of rejection due to mismatch in the year 2015.

**Table 14 : Month wise distribution of rejection due to mismatch – 2015**

Month	Total Samples	Total Rejections	Mismatch: Sample & Label/ Sample & Form	% of Total Rejection
Jan	5944	281	26	9.25
Feb	5724	285	11	3.86
Mar	6093	271	2	0.74
Apr	6362	327	53	16.21
May	6804	375	38	10.13
Jun	6140	295	49	16.61
Jul	7396	369	40	10.84
Aug	6750	462	53	11.47
	<b>51213</b>	<b>2665</b>	<b>272</b>	<b>10.21</b>



**Chart 16 : Month wise distribution of rejection due to mismatch – 2015**

Table 15 & 16 shows the month wise distribution of sample rejection due to inadequate information in the requisition form regarding either patient identification or the particular test/analysis prescribed by the clinician in the year 2014 and 2015 respectively.

**Table 15 : Month wise frequency of rejection due to inadequate information in the requisition form- 2014**

Month	Total Samples	Total Rejections	Inadequate information in request form	% of Total Rejection
Jan	5159	215	0	0.00
Feb	5342	240	0	0.00
Mar	5594	120	0	0.00



<b>Apr</b>	6015	215	0	0.00
<b>May</b>	5909	184	0	0.00
<b>Jun</b>	5713	166	1	0.60
<b>Jul</b>	4458	267	0	0.00
<b>Aug</b>	8300	247	0	0.00
<b>Sep</b>	8927	235	0	0.00
<b>Oct</b>	4655	259	0	0.00
<b>Nov</b>	6278	249	0	0.00
<b>Dec</b>	5665	319	0	0.00
	<b>72015</b>	<b>2716</b>	<b>1</b>	<b>0.04</b>

**Table 16 : Month wise frequency of rejection due to inadequate information in the requisition form- 2015**

<b>Month</b>	<b>Total Samples</b>	<b>Total Rejections</b>	<b>Inadequate information in request form</b>	<b>% of Total Rejection</b>
<b>Jan</b>	5944	281	1	0.36
<b>Feb</b>	5724	285	0	0.00
<b>Mar</b>	6093	271	0	0.00
<b>Apr</b>	6362	327	0	0.00
<b>May</b>	6804	375	4	1.07
<b>Jun</b>	6140	295	1	0.34
<b>Jul</b>	7396	369	0	0.00
<b>Aug</b>	6750	462	0	0.00
	<b>51213</b>	<b>2665</b>	<b>6</b>	<b>0.23</b>

It is inferred from the data that rejection of samples for inadequate info is rather insignificant and can be treated as a rare exception in any case.

## **DISCUSSION**

In the earlier analysis, various possible errors and subsequent reasons for that in the stages of the pre-analytical phase were studied and discussed. The present study also tried to point out possible remedies by which the errors and rejection in this particular phase can be minimized.

In the next analysis section, the data collected from the laboratory over a period of 20 months were analyzed and presented in different ways so as to identify general trends of rejection due to various reasons.

From the analysis part it was concluded that clotted samples (77.55%) are the most common cause of rejection in preanalytical phase. Inappropriate sample volume (7.53%) being the second most common cause.

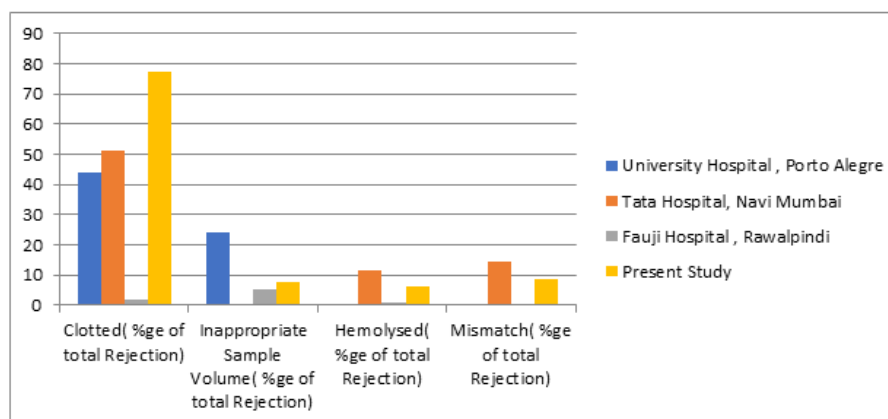
Now the findings of the present study will be compared with few other similar studies so as to validate the findings as well as to ascertain that this is indeed a general trend in all haematology laboratory or otherwise.

Three other studies has been considered and the data was compared with the findings of the present study. Table 17 and the following bar chart shows the contribution of different causes in

rejection of samples in the pre-analytical phase in four different studies done independently in four different laboratories.

**Table 17 : Comparison of causes of rejection in the Pre-analytical phase**

Study	Total Samples	Rejected Samples	Rejection Ratio (% rejected wrt sample size)	Clotted(% of total Rejection)	Inappropriate Sample Volume( % of total Rejection)	Hemolyse d( % of total Rejection)	Mismatch( % of total Rejection )
University Hospital , Porto Alegre,2012 <sup>[24]</sup>	77051	441	0.57	43.8	24	-	-
Tata Hospital, Navi Mumbai , 2012	32548	177	0.54	51.2	-	11.45	14.46
Fauji Hospital , Rawalpindi , 2010	33311	1006	3.02	1.8	5.4	1	0.1
Present Study, 2015	123228	5381	4.37	77.55	7.53	6.02	8.12



**Chart 17 : Comparison of causes of rejection in the Pre-analytical phase**

From the above table as well as the bar chart it is inferred that the general trend of reasons of sample rejection were similar in almost all the studies. In all four studies clotted samples is the major contributor in rejection of samples in the pre-analytic phase. However, the total rejection ratio is much more in case of the current study. Since the sample size under investigation is much

larger in case of the current study in comparison to the others the final data cannot be treated as a parameter of concrete and irrevocable conclusion. The sheer size of the samples coming for investigation and the huge number of staffs required to handle the same makes it much more difficult to maintain a low rejection ratio since the causes of rejection is almost entirely due to human errors in this phase and the level of competency of different people is bound to vary and more often than never frequency of errors has been found to be a function of work load as well. But it should be maintained that even in relative scale the rejection ratio is rather high, i.e. almost by 4 percentage points, which needs to be reviewed to achieve higher quality standards and better patient care.

## CONCLUSION

Pre-analytical errors are frequent in the laboratories and can be corrected by regular root-cause-analysis of the involved reasons. The most prevalent cause of sample rejection in the pre-analytical phase is clotting of samples. Other significant contributors are improper quantity of sample and hemolysed sample. The frequency of sample rejection is more or less random and no linear correlation was found whatsoever with either the volume of samples handled in that particular time period or the particular time of the year which we comprehended in view of the fact that the errors in this phase are mostly human errors.

Errors can be avoided by proper communication and co-ordination between laboratory and wards, awareness of correct phlebotomy technique, proper training and continuing medical education programs for laboratory and paramedical staff and knowledge of intervening factors that can influence laboratory results.

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