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Study of Multiple Internal Quality Control Tools in A Haematology Laboratory of A Tertiary Care Hospital

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Abstract

Background: Internal quality control is monitoring the procedure to ensure continual evaluation of the reliability of daily work of the laboratory. This ensures continual validation of the reliability of the results produced by the laboratory, before the release of reports. It includes repeated measurement on routine samples using the control samples along with daily statistical analysis of data. Several methods are available for the analysis of laboratory quality control data like Levey Jennings chart (Westgard Rules for interpretation), Cumulative sum chart and Average of Normals chart. Laboratory testing is a complex activity, each involving a series of process steps, every one of which can result in an error. The classification of errors is based on the time they appeared in laboratory practice namely pre-analytical, analytical and post analytical stage. In the present study, we have compared Westgard rules, cumulative sum and average of normals in early identification of laboratory errors.

Aim: To study usefulness of Westgard rules, cumulative sum and average of normal, as tools for internal quality control and to compare the three tools in early identification of laboratory errors.

Material and Methods: Total 900 data points (quality control values or events), pertaining to each of the haematological parameters haemoglobin, total leucocyte count, platelet, mean corpuscular haemoglobin concentration and Prothrombin Time were analysed. Prothrombin time was analysed on Erba Semi Automatic ECL 105 single channel coagulation analyser and rest parameters were analysed on fully automated 5 part analyser XT-4000i. For statistical analysis of data, Levey Jennings chart and Cumulative sum chart were used for haemoglobin, total leucocyte count and platelets. Westgard rules were used for interpretation of Levey Jennings charts. Average of normals chart was

used for statistical analysis of mean corpuscular haemoglobin concentration parameter.

Results

a) Out of 900 data points analysed, 35 out-of-limit events were recorded on Levey Jennings chart, of these 13 were detected by Cumulative sum chart and none by Average of normals chart

b) Levey Jennings chart picked up all systematic and random errors while Cumulative sum picked up all 3 systematic and only 10 random errors. No out-of-limit events were detected by Average of normals chart.

c) All the 3 systematic errors were picked up by Cumulative sum chart earlier than LJ chart while 4 random errors were detected earlier by LJ chart.

d) Root cause analysis for each of out-of-limit situations was done and most common cause was found to be material (reagent and control).

Conclusion: In the present study we have found that Levey Jennings chart is more efficient with respect to Cumulative sum chart in detecting random errors. Cumulative sum chart detects systematic errors earlier than LJ chart. We recommend use of more than one internal quality control tool for statistical analysis of data.

Keywords: Internal Quality Control, Levey Jennings Chart, Westgard Rules, Cumulative Sum Chart, Average of Normal Chart.

Introduction

Laboratory services have a great influence on clinical decision making: 60–70% of the most important decisions on admission, discharge, and medication are based on laboratory test results.[1]

Laboratory testing is a complex activity, consisting of a series of interrelated processes, each involving a series of process steps, every one of which can result in an error. [3]

In order to ensure quality patient care, measures must be taken for monitoring and control at each step from collection of blood specimens, through the actual processing and analysis, to reporting of the results.

The classification of errors is based on the time they appeared in laboratory practice namely pre-analytical, analytical and post analytical stage.[5] The preanalytical phase includes all the processes occurring before the sample is being processed in the laboratory.[6] Lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, make up 93% of the errors currently encountered within the entire diagnostic process.[7]

Analytical phase starts when the patient specimen is prepared in the laboratory for testing and it ends when the test result is interpreted and verified by the technician in the laboratory.[8] Common analytical errors are due to expired reagent, expired control, failure in sampling by analyser, failed aspiration by analyser and more. Analytical errors are divided into random errors and systematic errors. The analytical errors can be detected by statistical quality control methods.

Post-analytical phase refers to transmission of data from analyzers to the LIS, validation of results and delivery of the results to physicians. Common post analytical errors include wrong matching between sample and laboratory's file, transcription error, delay in delivering and loss of results. [5]

Internal quality control monitors the performance of the test procedures in the laboratories on daily basis. It includes measurements on specially prepared control materials, repeated measurements on patients' samples and statistical analysis of data. This ensures continual

validation of the reliability of the results produced by the laboratory, before the release of reports.[10]

Walter Shewhart suggested statistical techniques and designed control charts to decrease the variability due to random errors. Stanley Levey and Elmer Jennings adapted Shewhart's control chart for chemical analyses in the medical laboratory. This was called "Levey-Jennings chart" and is even now the primary quality control tool for automated analyzers. Before its invention, precision was ensured in many laboratories by double measurements.[9] Levey-Jennings chart and Westgard rules detect random and systematic errors.[5]

In 1950s, E. Page invented the "cumulative sum chart" (Cusum chart). This is a specialized diagram adapted for the detection of small systematic errors which cannot be detected by the Shewhart chart.

Robert Hoffmann and Michael Waid published the opinion that the arithmetic average of normal test results produced by biochemical analyses can be used to detect systematic errors. This method was named "average of normals" (AON) and was based on the principle that the average value of normal test results from successive days should lie within specific limits. If limits are exceeded, it detects a systematic error.[9]

Materials and Methods

Study Site: Study was conducted in the Department of Pathology, Hindu Rao Hospital, Delhi-110007.

Study Design: Analytical-cross sectional study.

Sample Size: 900 control runs

Methodology: The haematology section of the hospital receives samples from both out-patients and in-patient departments. The section is currently having five part Sysmex XT-4000*i* (Sysmex Corporation, Japan) which was used for analysis of Hb, PLT and TLC two times a day. PT was analysed twice a day on Erba Semi-Automatic ECL 105 single channel coagulation analyser (Erba manheim, UK). Commercial control material for internal quality control, were used for this study (Sysmex Coporation, Japan).

The result of control run was analyzed using Westgard rules and Cusum method simultaneously.

Levey Jennings chart (LJ chart)

All out-of-limit events in LJ chart were interpreted using Westgard rules and corrective as well as preventive measures were taken. On LJ chart, mean was marked on Y axis as a horizontal line. Control limits were marked at ± 1SD, ±2SD and ± 3SD and runs were plotted on X axis. Following Westgard rules were followed for error detection:

12S: refers to the control rule commonly used with a Levey-Jennings chart, in which control limits are set as the mean ± 2SD. This rule is used as a warning rule in present study, to trigger careful inspection of the control data by other rejection rules.

13S: reject run when 1 control measurement exceeds the mean ±3 SD. This is considered as random error in present study.

22S: reject run when 2 consecutive control measurements exceed the same mean +2 SD control limit or the same mean -2SD control limit. It is considered as random error in present study.

R4S: reject when 1 control measurement in a group exceeds the mean + 2 SD control limit and another consecutive exceeds the mean -2 SD control limit.

41S: reject run when 4 consecutive control measurements exceed the same mean +1 SD or the same mean -1 SD control limit.

8x: reject when 8 consecutive control measurements are on one side of the mean.

10x: reject when 10 consecutive control measurements are on one side of the mean.

Cumulative sum chart (Cusum)

For CUSUM control chart application we cumulated the upper and lower standardized deviations as shown in equation 1. The standardized deviations were modified by a factor k= 0.5, and upper and lower cumulative sums were calculated as shown in equation 2 and 3. Following method was used to plot CUSUM chart. 1. Standardized deviation zi was calculated using the formula:

$$z_i = \frac{x_i - \bar{x}}{SD}$$ [Equation 1]

Where, xi is the value of control material obtained in a particular run, $\bar{x}$ is laboratory mean and SD is standard deviation of the control material.

Upper cumulative sum (SH) and lower cumulative sum (SL) was calculated as

SH= max [0, (zi - k) + SH -1] [Equation 2]

SL = – max [0, (–zi-k) + SL – 1] [Equation 3]

Where, SH-1 was upper cumulative of previous value

SL-1 was lower cumulative of previous value

Upper and lower reference limits in the present study were set as +4 and -4 respectively. For situations where SH < 0 and SL > 1, their values were reset to 0.

Average of normals (AON)

Average of normal was calculated daily and any out-of-limit situations were noted. Hematology analyzers use another average of normals method, the Bull's algorithm. In Bull's algorithm a moving average is calculated instead of a mean value. Bull's moving average is symbolized as $\bar{X}$B. It is calculated by the formula:

$\bar{X}$Bi = (2-r) $\bar{X}$B,i-1+rd [Equation 4]

The constant r defines the percentage of the participation of the previous Bull's moving average to the calculation of the current one. The value of r = 0.4 therefore Bull's moving average participate to the calculation of the current moving average with a percentage of 40%. In contrary to AON method Bull's algorithm uses all the patient values not only the normal ones. Bull's algorithm detects only systematic errors and it has its own control chart and its own rules. If Bull's algorithm is used for the quality control of erythrocyte indexes the control limits of Bull's chart are $\bar{X}$B ± 3%. The range ± 3% comes from the biological variation of the erythrocyte indexes which is almost 1%. The erythrocyte index we have used is mean corpuscular haemoglobin concentration: MCHC= (Hb (g/dL))/ (Hct (%)) 100

Root Cause Analysis

Root cause analysis will be performed for each out-of-limit situation using fish bone chart. Errors detected were classified according to the phase in which they appeared namely pre-analytical (figure 3), analytical (figure 4), post-analytical (figure 5). Preventive and corrective actions were taken according to the cause analyzed.

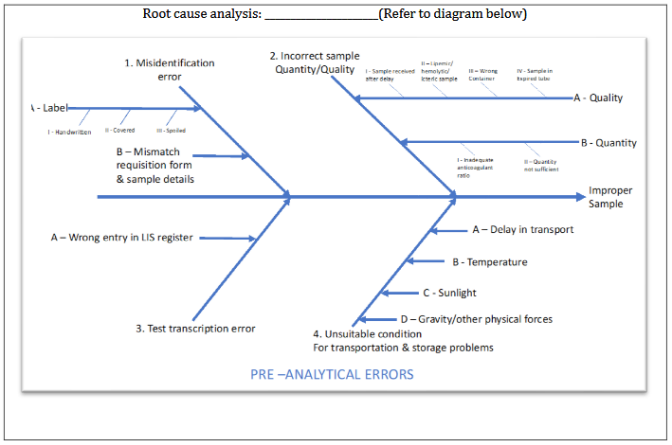

Figure 1: Fish bone chart for Pre-analytical errors

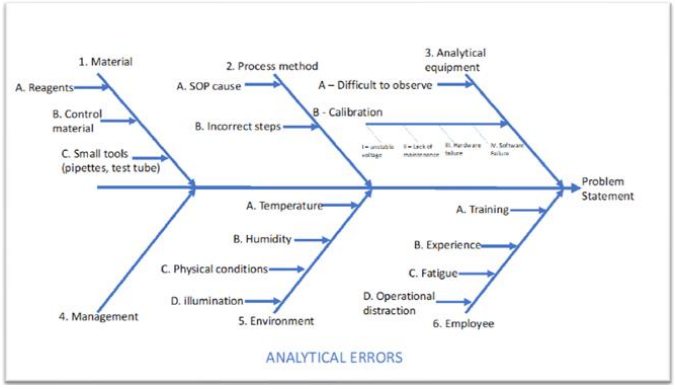

Figure 2: Fish bone chart for analytical errors

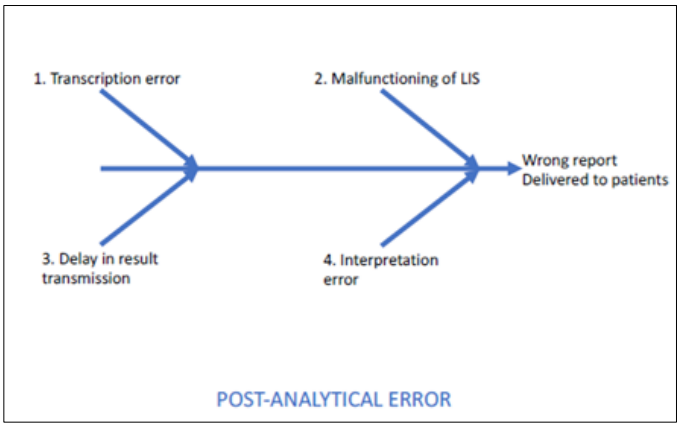

Figure 3: Fish bone chart for Post-analytical errors

Statistical Analysis

The control data was entered into Microsoft Excel file and further analysis was done using Python (version 3.6) language through Jupyter notebook software.

The LJ chart, Cusum chart and AON chart were prepared as described in Materials and Methods section.

To find the association between large random error and equipment related cause, chi-square test was used. A *p*-value of less than 0.05 was considered as statistically significant.

Results

Number of Errors

A total of 900 data points (quality control values or events) each of hemoglobin (Hb), platelets (PLT), total leucocyte count (TLC) and prothrombin time (PT) were analysed during the study period. On analysis of data, we found that out of 900 data points analysed, 35 events (3.88% of total runs) showed either warning or out-of-control situation according to Westgard rules and out of these 35 events, 13 were also picked up by Cusum chart. AON chart, using MCHC data, did not pick up any warning or out-of-control situation.

Table 1: Number and percentage of errors associated with each haematological parameter

Haematological parameter (analyte)	Total runs	Number of errors	Percentage error out of total runs (n=900)	Percentage error out of total errors (n=35)
Hb	900	3	0.33%	8.57%
TLC	900	12	1.33%	34.28%
PLT	900	10	1.11%	28.57%
PT	900	10	1.11%	28.57%
Total		35		

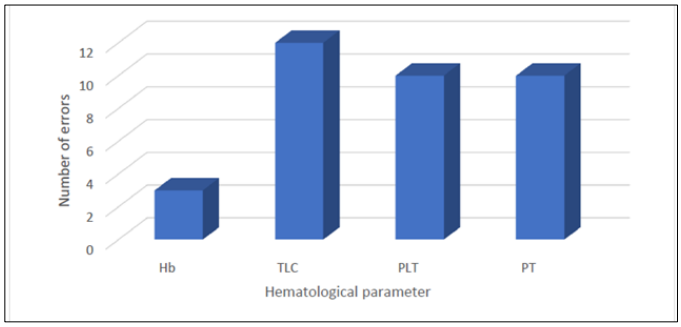

Figure 4: Bar diagram representing number of errors in each haematological parameters

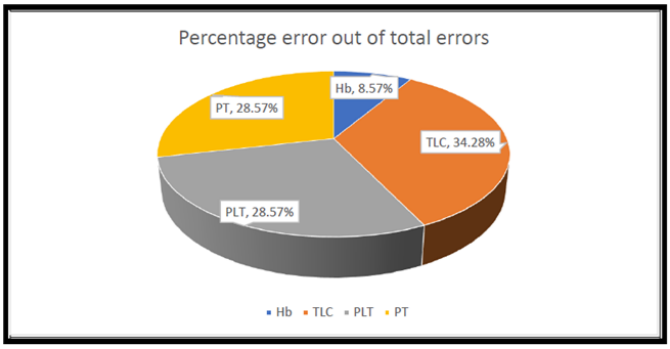

Figure 5: Pie diagram representing percentage error out of total errors associated with each haematological parameter

Westgard Rules Violation

Out of 35 events which had shown warning or out-of-control situations, 32 were random errors and 3 were systematic errors. Among 32 random errors, 14 events

were depicted as warning as these violated 12S Westgard rule while 14 events violated 13S Westgard rule, one event violated 22S and one violated 13S followed by 12S Westgard rules. A total of 3 systematic errors which violated 41S (2 events) and 10X (1 event) Westgard rules, were recorded.

Table 2: Number and percentage of type of Westgard rules violated

		Number of instances of Westgard rule violation	Percentage out of total runs (n=900)	Percentage out of total errors (n=35)
Westgard rules violated	1_{2S}	15	1.66%	42.85%
	1_{3S}	15	1.66%	42.85%
	2_{2S}	1	0.11%	2.85%
	4_{1S}	2	0.22%	5.71%
	10_{X}	1	0.11%	2.85%
	1_{3S} followed by 1_{2S}	1	0.11%	2.85%
Total instances		35		

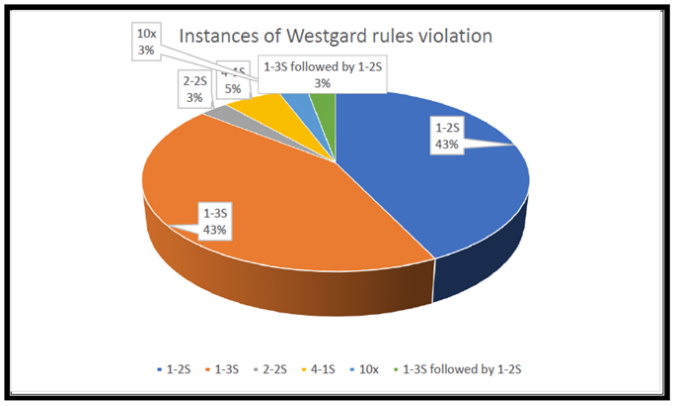

Figure 6: Pie chart demonstrating instances of westgard rules violation

Cusum chart violation

Out of 900 data points analysed for hematological parameterts, Cusum chart recorded a total of 13 out of limit events. Out of these 13 events, 3 were systematic errors while 10 were random errors which were also picked up by LJ chart.

Cusum chart of out of limit events were compared to Westgard rule violation detected by LJ chart with respect to time lag (Table 3). When LJ chart detected the event early, lag period was considered as positive whereas if Cusum chart had detected the deviation early, lag period was considered to be negative in present study, as shown in table 3. Cusum picked up out-of-limit events earlier with respect to LJ chart, on three instances all of which were systematic errors.

Table 3: Comaparative table of deviations noted by Cusum chart and LJ chart in terms of date

S.no.	Analyte	Cusum chart deviation date	LJ chart deviation date	Westgard rule violated	Lag in LJ chart (day/days)
1	PT	18/11	17/11	1_{3S}	+1
2	PT	28/01	30/01	4_{1S}	-2
3	PT	13/08	12/08	2_{2S}	+1
4	PT	25/09	25/09	1_{3S}	0
5	PT	02/02	01/02	1_{3S}	0
6	Hb	28/10	28/10	1_{3S}	0
7	Hb	01/02	31/01	1_{3S}	+1
8	TLC	04/07	04/07	1_{3S}	0
9	TLC	21/08	21/08	1_{3S}	0
10	TLC	23/12	22/12	1_{3S} followed by 1_{2S}	+1
11	PLT	07/02	07/02	1_{3S}	0
12	PLT	05/05	06/05	10_{X}	-1
13	PLT	02/09	03/09	4_{1S}	-1

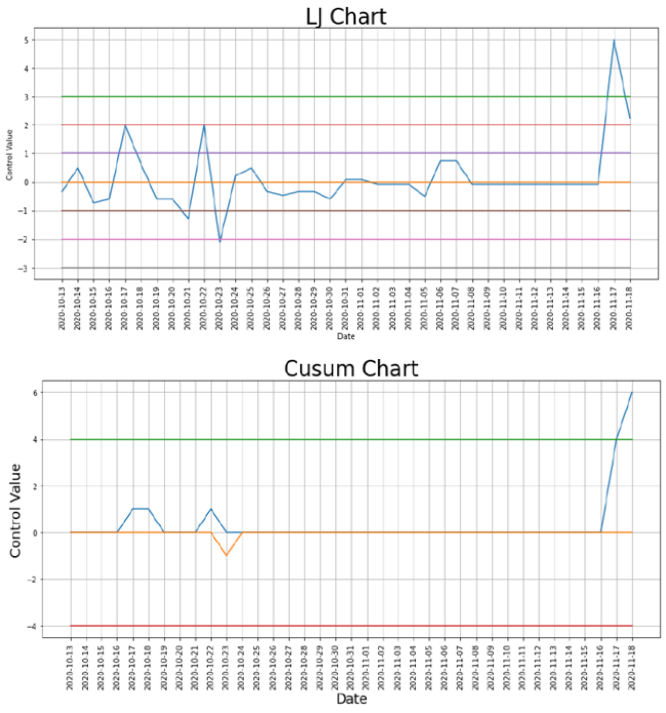

Figure 7: LJ chart of PT showing 13S deviation on 17/11/20 and corresponding Cusum chart showing out-of-limit event on 18/11/20

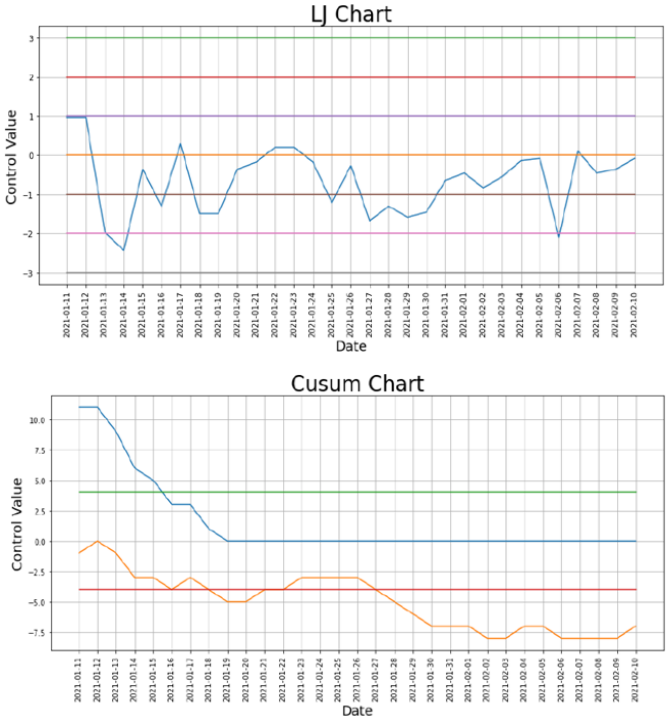

Figure 8: LJ chart of PT showing 41S error on 30/01 and corresponding Cusum chart showing out-of-limit event on 28/01

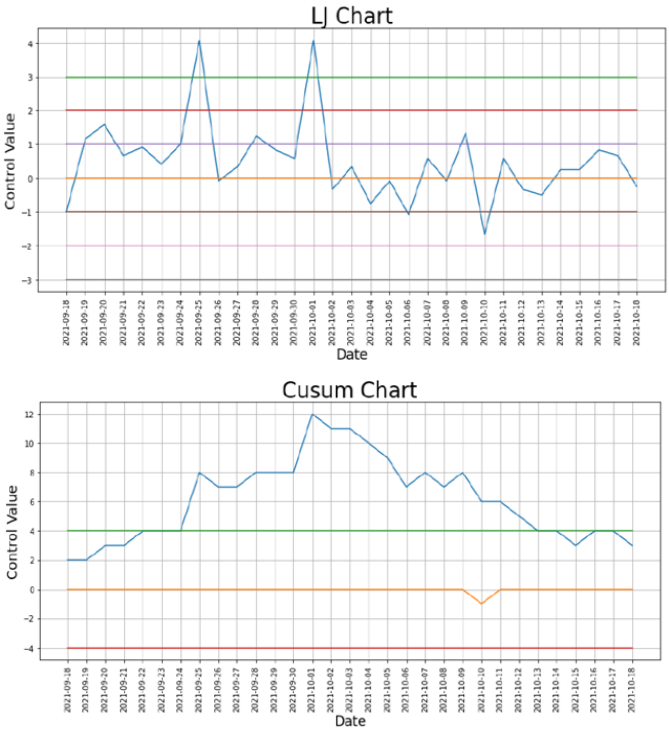

Figure 9: LJ chart of PT showing 13Serror on 25/09 and corresponding Cusum chart showing out-of-limit event on 25/09

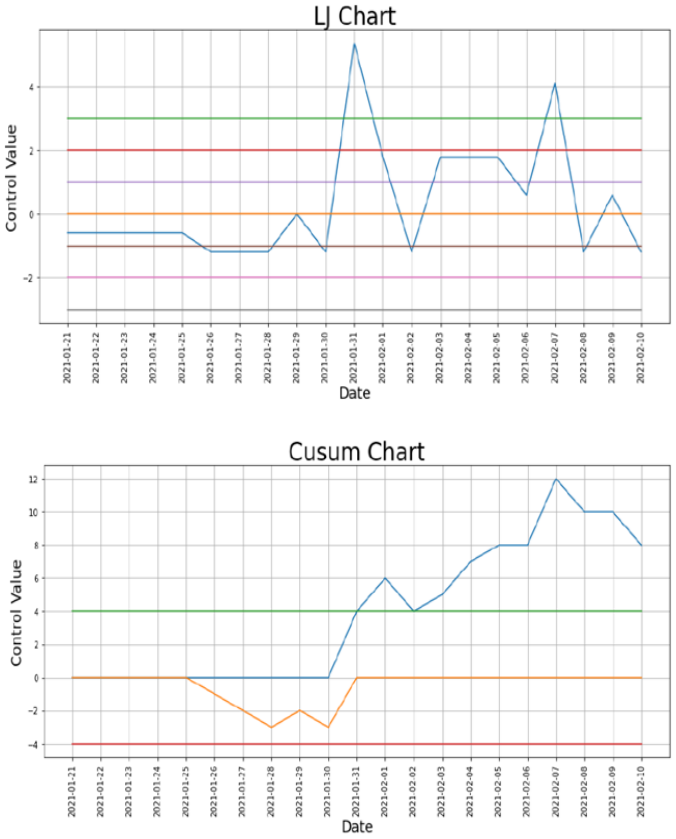

Figure 10: LJ chart of Hb showing 13S error on 31/01and corresponding Cusum chart showing out-of-limit event on 01/02

Average of Normals (AON)

Average of normals chart, which was initially designed for red cell indices, in present study the AON chart of MCHC parameter was analysed. Out of 900 data points analysed, no out of limit events were found.

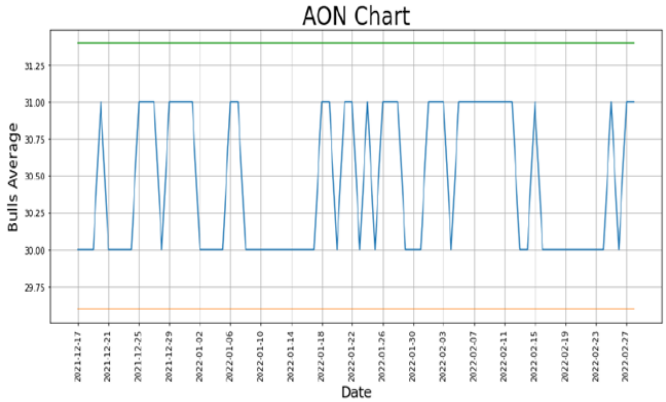

Figure 11: Graph of average of normals showing all the values within control limits

Root Cause Analysis

Quality control is applicable to all the three phases of laboratory operation 1) the pre-analytical phase, 2) the analytical phase and 3) the post-analytical phase. The pre-analytical phase is related to sample collection, transport, accession and processing. The analytical phase is related to actually carrying out the test (material, process method, analytical equipment, temperature etc.) and the activities that follow (transmission of results, storage/disposal of samples, maintenance of test data etc.) comprise the post-analytical part. In our study, a total of 35 events were recorded as warning or out-of-control situations. Root cause analysis was done for each of these 35 events which led to the conclusion that 33 errors occurred in analytical phase and 2 occurred in post analytical phase. Two post analytical errors were due to transcription error while the causes of analytical errors are mentioned in the following table (table 3).

Majority of the analytical errors (18 in number) were due to reagent or control material related issues (54.54% of analytical errors) which comprised of both random and systematic errors, maximum (8 in number) being random error which violated 12S Westgard rule. Second most common cause of analytical error was equipment related problems (24.24% of analytical errors) which led to violation of 12S (2 events) and 13S (6 events) Westgard rules. Other causes included operator's lack of intensive training (9.095), high ambient temperature (6.06%) and incorrect procedure (6.06%).

Table 4: Root cause analysis of total analytical errors

	Root cause	Frequency of Westgard rules violation		Number of analytical errors	Percentage out of total analytical errors (n=33)
	Reagent	1_{2S}	3	11	33.33%
Material related		1_{3S}	4		
		4_{1S}	2		
		10x	1		
		2_{2S}	1		
	Control material	1_{2S}	5	7	21.21%
		1_{3S}	2		
Equipment related		1_{2S}	2	8	24.24%
		1_{3S}	6		
Method related	Incorrect steps	1_{2S}	1	2	6.06%
		1_{3S}	1		
Environment related	Temperature	1_{2S}	1	2	6.06%
		1_{2S}	1		
Employee related	Training	1_{2S}	1	1	3.03%
	Experience	1_{2S}	1	2	6.06%
		1_{3S}	1		
Total analytical errors				33	

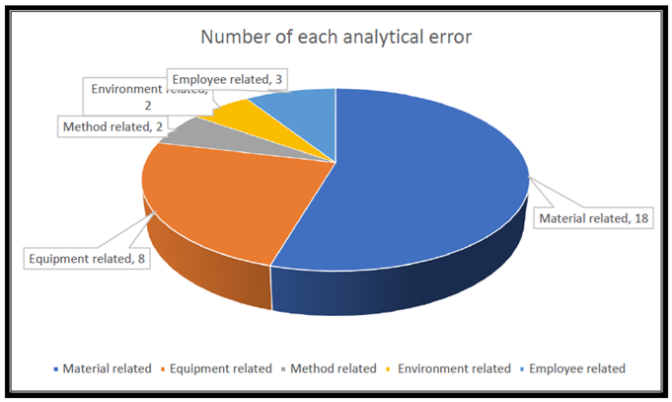

Figure 12: Number of each analytical error

Chi-square chart for euipment related errors

In present study, out of 33 analytical errors detected, equipment related causes were 8, which made upto 24.2% of total analytical errors. Among total 8 equipment related errors, 6 violations of 13S rule and 2 violations of 12S rule of Westgard were noted.

Table 5: Association between type of error and euipment as a cause

Chi square statistic is 4.5877. The p-value is 0.032201. Significant at *p* less than 0.05.

	Others	1_{3S}	Total
Equipment error present	2	6	8
Equipment error absent	17	8	25
Total	19	14	33

Discussion

Application of quality control measures in a testing laboratory facilitates validation of test results by increasing accuracy and precision. Monitoring day-to-

day performance of assays helps in increasing the probability of detecting out-of-limit situations at the earliest. Different methods like LJ chart, Cusum chart and AON chart have been in used since long. All these methods demonstrate warning or out-of-limit situations in control runs, but there is a paucity of literature about their comparative efficacy in error detection. In the present study, we aimed to explore this lacuna in literature. Data was recorded on LJ charts, Cusum charts and AON chart which provide a useful tool for visual monitoring and statistical analysis of results.

We have recorded a total of 35 violations in Westgard rule out of 900 runs in present study, which forms 3.88% of total runs. A study in clinical virology laboratory has recorded 3.3% violations in Westgard rules on running internal quality control samples which was comparable to our results. The authors highlighted batch to batch variation in the serological assays by inclusion of IQC samples. They have recommended the use of data obtained with assay controls to set the acceptable limits for testing of anonymous samples under quality assessment schemes.[21] Another study had recorded a total of 11 violations in Westgard rules out of 540 runs accounting for 2.03% of total runs which is also similar to the results obtained in present study. [22]

Levey-Jennings chart and Westgard rules detect both random and systematic errors.5 Random errors have an unpredictable occurrence in both magnitude and direction. Systematic errors create a predictable bias in results of the test. In this study total 35 errors were detected in which 32 were random errors and 3 were systematic errors according to Westgard rules.

In this study, we plotted LJ charts to graphically monitor if the control values were falling within or out of range. Mean was marked on Y axis as a horizontal line. Control limits were marked at ± 1SD, ±2SD and ± 3SD and runs were plotted on X axis. LJ chart picked up all 35 errors, both random and systemtic.

Among total 35 errors, 15 events violated 12S Westgard rule. Westgard rule 12S denotes warning rule to trigger careful inspection of control data by other rejection rules. It constituted 1.66% of total runs and 42.85% of total errors. Another 15 events violated 13S Westgard rule, which formed 1.66% of total runs and 42.85% of total errors. Two events violated the 4X Westgard rule and one event each violated 22S, 10X and 13S followed by 12S Westgard rule. Dubey et al.[22] showed similar findings using LJ charts for illustrating the performance of internal quality control samples on 180 runs each for HBsAg, anti HCV and anti-HIV ELISA. For HBsAg ELISA, violation of warning rule (12S) was indicated in two runs (1.11%). For anti-HCV ELISA quality control testing, violation of 13S rule formed 1.11% of total runs.[22] Another study conducted by Waterhouse et al.[23] aimed to assess the impact of several microsatellite analytical parameters in the quantification of hematopoietic chimerism after allogeneic hematopoietic stem cell transplantation and to analyze it through the application of internal quality control procedures. They used LJ chart for quality control evaluation and had shown that out of total 55 consecutive runs, 2 events showed 12S deviation according to Westgard rules, which accounted for 3.63% of total runs. Also, one event of 22S rule violation was detected in their study using LJ chart.[23]

In present study out of 900 runs, 33 errors were analytical errors which formed 3.66% of total runs. Another similar study conducted by Goswami et al.[24] detected errors in 954 blood samples, where total analytical analytical errors formed 0.1% of total runs.

Even though both these studies were conducted in hospitals catering similar population and had comparable sample size, our study detected higher (3.66%) analytical errors.[24]

In a CUSUM chart, by summing the deviation from the process target, positive and negative deviations will tend to cancel each other out and the cusum plot will run horizontally when the system is stable. If there is beginning of change in system average, the plot will move increasingly upwards or downwards. This deviation will become apparent quickly and there is rapid response which is the feature of cusum charts and their use.[15]

As mentioned earlier, in present study, total 35 errors were recorded by LJ chart while out of these 35 errors only 13 errors were documented by Cusum chart. LJ chart detected violation of 13S Westgard rule one day earlier than Cusum chart, on two separate occasions in PT and Hb parameters. Violation of Westgard rule 22S in PT parameter and 13S followed by 12S in TLC were picked up a day earlier by LJ chart with Westgard rules. Therefore it suggests that random errors have a greater chance to be picked up early by Westgard rules. Cusum chart detected 4 consecutive out-of-limit events more than +1SD for PT parameter, two days before LJ chart could. In PLT parameter, out of limit events which happened on 4 consecutive days (violated 41S Westgard rule) as well as on 10 consecutive days (violated 10X Westgard rule), were detected one day earlier by cusum as compared to LJ chart. Thus systematic errors were picked up earlier by Cusum chart as compared to LJ chart in this study. This is in line with the findings of previous studies by Westgard et al.25 They proposed that Cusum chart is more sensitive for the detection of systematic shift and drifts. In an study, author pointed out that a basic Shewhart control chart like LJ chart can have a possibility of false alarm at each sampling point. Cusum chart accumulate information over time and so these are not affected easily by metrics of false alarm. This sensitivity is advantageous for processes needing precise control.[26] In another publication, it was mentioned that athough Cusum is usually of interest for detecting systematic errors, it also detects random error. They have discussed improved detection of systematic errors by combined shewart-cusum chart.17 In an study on internal quality control in haematology laboratory, out of total errors, nine random errors were picked up by LJ chart but missed by Cusum while 22 instances of systematic errors were only picked by CUSUM method. These findings are similar to our study.[27]

Consistent with these findings of present study is the study conducted by Nightingale, M. J et al.28 NHS Blood and Transplant Southampton UK, compared the use of conventional Shewhart chart and CUSUM chart in quality monitoring of blood components and assessed the sensitivity and specificity of a range of techniques for variable and attribute (proportion non-conforming) data. According to them, CUSUM charts perform better than the shewart chart in detecting small persistent shifts from the mean. They also proposed that CUSUM was more sensitive in detecting small changes more quickly than shewart chart. Their recommendation was to apply shewart or CUSUM to detect shifts of 2SD or more in the mean or SD for parameters that require detection of a significant shift within 5 days.[28]

Sampson ML16 used Cusum with logistic regression (CSLR) method to predict the testing errors and they proposed that Cusum is rapid and sensitive method for the detection of laboratory errors.[16]

Cusum provide rapid analysis and identification of trends in a series of data. A study done by Chang and McLean at Department of Trauma & Orthopaedics, Dumfries and Galloway Royal Infirmary, UK. Twenty consecutive patients dressing was done. Cusum chart was used to assess the dressing with regards to skin blistering. At an acceptable level of performance the curve would oscillate about the horizontal axis and the overall trend therefore said to be flat. In case of unacceptable performance, the cusum slopes upward. They recommended the use of cusum technique in the early evaluation of a clinical procedure before its implementation.[15]

Yadav et al.[27] conducted a study in a tertiary care hospital for internal quality. They analysed 1825 data points out of which total of 31 events showed error. All the random errors were picked up LJ chart while all the systematic errors were picked up by Cusum chart. It was concluded that in comparison to Westgard rules, CUSUM is more sensitive for detection of systematic error (bias) while random errors have a greater chance to be detected early by Westgard rules.[27] These findings are in concordance with findings in present study.

Hoffman et al.[18] gave their opinion that the arithmetic average of normal test results produced by biochemical analyses can be used to detect systematic errors, it was named as average of normals. In our study average of normals was applied for MCHC parameter. Out of 900 data points analysed, AON could not detect any out-of-limit events.

Clinical and Laboratory Standards Institute has advised that the common practice of repeating control measurements should be avoided, instead should investigate the problem, identify its cause, and take corrective actions when control results are out-of-limit. Root cause analysis of each error was done in our study inorder to discern the cause and correct it accordingly.

LJ chart is used as a tool for monitoring error and eventually correction of the underlying cause. This has also been stated by Westgard under statistical quality control procedures that doing SQC right also involves analysis of controls in each analytical run on a daily basis, interpretation of the control results, followed by appropriate actions and concluding with documentation of the actions taken.[29] Similar methodology has been used in quality control monitoring of serological samples by some authors, which included error detection by LJ chart and undertaking and documenting corrective actions accordingly.[22]

In our study, root cause of each error was investigated and corrective as well as preventive actions were taken to reduce the propability of future errors. The most common causes were material related which included reagent material (31.42%) followed by control material (21.21%) problems. Most commonly reagent and control materials were deteriorated due to improper storage which led to significant difference in previous values. To prevent recurrences, we performed relevant modifications in our standard operating procedures and conveyed the same to the operators.

Other reasons for reagent related errors included improper reconstitution and usage without confirming expiry date. Technical staff were sesitized about the same. Second major cause of errors were due to instances of equipment glitches (22.85%) due to interrupted electric supply and problems pertaining to software and hardware of hematology analysers. Most of the out-of-limit events (6 in number) were of 13S type. Equipment related causes were significantly associated with large random error (13S). For solving this,

everytime there occurred a problem with analyser, engineer was called and it was repaired. Next in the row were causes related to employee training and experience (8.57%). Same control measurements done by senior well experienced technical staff gave correct value on occasions which gave deranged values when done by trainee. These were minimized by proper training of personnel, strict adherence to standard operating procedures (SOPs) and by careful supervision of the process. Added to these, high ambient temperatures during summer led to 5.71% of total causes. Due to high temperature, sometimes required standard temperature for hematology analysers' functioning could not be met leading to error. Appropriate actions were taken by department for maintaining required temperature.

Control sample and reagent related causes contributed to most (54.54%) of the analytical errors while equipment related issues contributed to 24.24 % of analytical errors in our study. A cross sectional study was conducted by Tadesse et al.8 at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia with the objective of determining the magnitude of type of errors in a hematology tests. They analysed 2606 hematological samples over four months. Overall 742 hematology laboratory errors were detected which were due to pre-analytical, analytical and post-analytical errors. It was documented that majority (42.8%) of the analytical errors were due to improper reagent storage and second most common cause was equipment failure because of electric interruption.[8] This finding is consistent with present study.

Conclusion

In the present study we have found that LJ chart is more efficient with respect to Cusum chart in detecting random errors. Cusum chart detects systematic errors earlier than LJ chart. We recommend use of more than one internal quality control tool for statistical analysis of data.

Abbreviations

AON: Average of Normals

Cusum: Cumulative Sum

Hb: Haemoglobin

IQC: Internal Quality Control

LIS: Laboratory Information System

LJ chart: Levey- ennings chart

PLT: Platelet count

PT: Prothrombin Time

SD: Standard Deviation

SQC: Statistical Quality Control

TLC: Total Leucocyte Count

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