International Journal of Advanced Research in Engineering and Technology (IJARET)
Volume 6, Issue 10, Oct 2015, pp. 147-153, Article ID: IJARET_06_10_021
Available online at
http://www.iaeme.com/IJARET/issues.asp?JType=IJARET&VType=6&IType=10
ISSN Print: 0976-6480 and ISSN Online: 0976-6499

QUALITY CONTROL METHODS FOR GOOD LABORATORY PRACTICE IN CLINICAL LABORATORY

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ABSTRACT

Quality Control in the clinical laboratory is a system designed to increase the probability that each result reported by the laboratory is valid and can be used with confidence by the physician at making a diagnostic or therapeutic decision. Quality control (QC) procedures function by detecting analytical errors. The general method existed is not preferable for the assessment of quality control as per the guidelines given by World Health Organisation (WHO). Keeping these points in view the present study was carried out on Quality assessment of the laboratory results of blood urea, thyroid hormone, blood glucose and uric acid levels measurements, obtained from different, departments at New Horizon college of engineering, Bangalore, India. The quality assessment of the different molecules was done by means of the statistical methods Mean (x^-), Standard deviation (s), Coefficient of variation (CV) and the Standard deviation index (SDI) asper the WHO suggestions, and assess the quality of the results by means of general and specific assessment methods like internal quality control (ICQ) and external quality assessment (EQA). 10 samples for duplicate test and 11 samples for replicate test (As per WHO suggestions) were studied for blood urea, thyroid hormone, glucose level and uric acid levels measurements respectively. Biostatistical analysis of present study agrees with the statistical analysis recommended by WHO.

Key words: Internal quality control (IQC), External quality assessment (EQA), Good Laboratory Practice (GLP), WHO Statistical procedure, Standard Deviation (SD) and Coefficient of Variation (CV).

Cite this Article: R.S.Upendra, Jyoti Kishen Kumar, Veeresh.V, Shubha.B, and Savitha.N Quality Control Methods for Good Laboratory Practice in Clinical Laboratory. *International Journal of Advanced Research in Engineering and Technology*, **6**(10), 2015, pp. 147-153.
http://www.iaeme.com/IJARET/issues.asp?JType=IJARET&VType=6&IType=10

1. INTRODUCTION

Quality assurance aims at ensuring for both laboratory staff and clinicians. The results from a clinical laboratory will only be considered reliable if stringent quality control procedures are Adopted [1]. Before forwarding results to the clinician the laboratory must satisfy itself that the procedures adopted for analysis are reliable and the results are quality controlled. Objectives of WHO-improve laboratory performance, promote establishment of national quality assurance programmers, promote laboratory standards at country level to achieve comparability of results, to assist in setting up laboratory network for disease surveillance [2]. Internal quality control (IQC), is concerned essentially with precision (or) reproducibility of laboratory results on a daily basis, whilst external quality assessment (EQA) concerned with inter laboratory or inter method or inter instrument harmony [3]. EQA can be used to obtain a correct value for an analysis. For the analytical part of quality assurance programme it should be emphasized that the application of Good Laboratory Practice (GLP) is essential element [4, 5]. Factors influencing the analytical results which are not under the control of the laboratory biological factors i.e. Age; Sex, Biorhythm, Nutrition, Physical state, Genetic Factors; technical factors such as conditions of sampling, sampling techniques; medication [6,].

2. MATERIAL AND METHODS

2.1. Internal Quality Control: Statistical analysis

2.1.1. The duplicate tests

On patient specimens are easiest procedure to carry out, every specimen should be tested in duplicate. About 10 consecutive blood samples are collected and subjected for detection of Urea & Thyroid hormone (T4) in duplicate at Biochemistry and Immunology laboratory (Table.1). Standard deviation is calculated for duplicate test results: [7,9,10, 11].

$$SD= \sqrt{\sum d^2/ 2n} \quad (1)$$

Where, d2 = difference between duplicates squared, N = number of specimens tested in Duplicate.

Table.1 Consecutive measurements of Urea and Thyroid hormone (T4 (nmol/l), in duplicate

No. of Specimen	Urea in blood		T4 in blood	
	1st count	2nd count	1st count	2nd count
1	26	28	125.48	121.60
2	25	25	194.05	194.05
3	25	22	131.61	131.09
4	42	48	106.42	111.33
5	24	25	112.60	113.89
6	16	17	110.91	107.22
7	14	17	131.61	127.99
8	16	18	89.7	113.03
9	23	24	91.30	89.68
10	23	27	92.62	96.32

2.2. Replicate tests on patient specimen

Replicate measurements on single specimen shall define the error of reproducibility and is a method for evaluating technical excellence and instrument which are unstable (WHO/LAB/98.4). A repeated measurement on suitable control material for detection of both glucose and uric acid levels in the blood sample as per WHO recommendations was discussed in Table.2. The analysis was done at the Immunology and Biochemistry laboratory, for replicate testing eleven identical tests on one sample (control material (Lytrol P), was carried as discussed in Table 2. Then the results of blood glucose level and uric acid were subjected to the control charts, by calculating the difference from mean for each measurement [12,13].

$$SD= \sqrt{\sum d^2/ n-1} \quad (2)$$

Where $\sum d^2$= sum of square differences. Calculate CV= 100SD/mean%.

The desirable level of precision should be such that errors caused by the measurement Procedure do not significantly affect clinical interpretation of the data.

Table 2 The measurements of glucose level and uric acid by using control material (Lytrol P).

slno	(Glucose) Lytrol P	(Uric acid) Lytrol P
1	183	9.7
2	176	10.4
3	189	10.2
4	197	10.1
5	197	10.4
6	207	10.2
7	198	10.5
8	194	10.3
9	198	10.3
10	199	10.3
11	194	10.4

2.3. Control chart

This uses the mean and SD obtained from the control material (lysate or preserved blood) as its basis originally devised for industrial purposes was applied To clinical laboratories by Levey and Jennings, (WHO/LAB/98.4.) [7,14]. Present study calculated the Mean, SD and +/- 2SD from the previous results obtained by the replicate tests on glucose levels and uric acid levels, then the result of control material for each test glucose level and uric acid level was recorded daily (Table 3), to estimate the error on the control chart [7,14]. The measurement of glucose levels for twelve days and for the uric acid levels eight days was discussed in Table 3.

Table 3 Daily estimated control material for sugar and uric acid (Lytrol P)

Days	1	2	3	4	5	6	7	8	9	10	11	12
Sugar	187	184	178	192	173	184	193	202	191	183	195	176
Uric acid	10.9	9.2	9.5	11	10.7	10.5	11	10.5	--	--	--	--

3. RESULTS & DISCUSSION

3.1. Internal Quality Control: Statistical analysis

3.1.1. The duplicate tests

Statistical results of duplicate tests clearly explain none of the duplicate test should be differ from each other by more than 2 standard deviation as calculated. This method was used to identify random errors. If the test is always wrongly performed than the standard deviation should be more than 2, and shall not be sensitivity to individual errors [13, 15, 16]. Estimated the calculation for the detection of urea by duplicate test was discussed in Table 4 & 5.

Table 4 The final results of statistical analysis calculated for urea and T4

Statistical Results	$\sum d^2 =$	$\sum d^2/2n$	$\sqrt{\sum d^2/2n}$	SD =	2SD =
Tests					
Urea	81	4.05	2.01	2.01	4.02
T4 in blood	120	6.50	3.49	5.55	11.10

Table 5 The laboratory results obtained by duplicate test from haematology department

Duplicate test no	Hgb		WBCs		RBCs	
	First count	Second count	First count	Second count	First count	Second count
1.	11.9	11.8	4.3	4.5	4.8	4.8
2.	13.0	13.1	6.6	6.4	4.7	4.7
3.	8.8	8.8	6.1	5.3	2.8	2.8
4.	13.3	13.1	4.4	4.1	4.5	4.5
5.	12.3	12.2	3.4	3.7	4.0	4.0
6.	12.6	13.1	5.2	5.3	4.3	4.4
7.	14.1	14.7	4.3	4.0	5.1	4.9
8.	13.5	13.6	9.0	8.5	4.9	4.9
9.	11.4	11.2	4.8	4.9	4.9	4.9
10.	8.8	9.1	7.7	7.1	4.1	4.0
11.	12.4	12.0	7.2	7.0	4.1	4.3
12.	13.4	13.6	6.1	6.2	4.6	4.5
13.	11.3	11.1	5.8	6.0	4.0	3.8

Statistical Analysis-

$\sum d^2$	1.06	0.23	0.15
SD = $\sqrt{\sum d^2 / 2n}$	0.2	0.09	1.97
2SD	0.4	0.19	3.95

None of the duplicate tests should be differ from each other by more than 2SD as calculated. [8,10,12]. Based on the above calculation the final results for urea test and T4 test indicates that in urea tests the specimen 4 is unsatisfactory and must be repeated; $d^2 = 06$ and $d^2 = 36$, the SD and 2SD shown in, Table 5. In case of T4, the test 8 shows that $d^2 = 23.33$ and $d^2 = 544.24$, SD and 2SD shown in, Table 4 should also be repeated. This indicates if the test is always performed wrongly the SD will wide and will not be sensitive to individual errors. These results agree with the statistical analysis recommended by WHO, since this procedures were contrast and can be easily done at any intermediate and peripheral laboratories.

3.2. Replicate tests on patient specimen

Replicate tests calculates the Mean, SD and +/- 2SD, for sugar and uric acid based on the data collected from Table 6.The daily results of control Material as shown in the Table 7.

Table 6 The measurement of glucose level and uric acid, control material (Lytrol P).

Test	**(Sugar) Lytrol P**		**(Uric acid) Lytrol P**	
Values no	**Replicate**	**Daily**	**Replicate**	**Daily**
1	183	187	9.7	10.9
2	176	184	10.4	9.2
3	189	178	10.2	9.5
4	197	192	10.1	11.0
5	197	173	10.4	10.7
6	207	184	10.2	10.5
7	198	193	10.5	11.0
8	194	202	10.3	10.5
9	198	191	10.3	10.5
10	199	183	10.3	10.5
11	194	195	10.4	10.5

Table 7 Interpretation of statistical results on arithmetic graph paper

Statistical Results	**Mean**	**SD =**	**+2SD =**	**-2SD**
Tests				
Sugar	193.81	8.44	210.7	176.92
Uric acid	10.25	0.21	10.67	9.82

After calibrate the vertical scale in appropriate units and the horizontal scale in days. The Fig. 1 and Fig. 2 was the reflect of the explanation of WHO notes, a spot is made on arithmetical graph paper with the results of analyse on the vertical scale

against the date of measurement on horizontal scale. The diagram gives an immediate overview of quality of laboratory measurements. This will interpret about, improper function of the analytical system, analytical material, quality of the reagents, quality of control material and application of analytic system, suggested by WHO. Based on these factors present study daily reported the IQC (Fig. 1). When the test is in control all the measurements on successive sample will approximate the established mean, with only minor divisions which will oscillate above the line of the mean. The chart suggested fault in technique, instrument, pipette or reagent due to the distributions of data in arrangement in different position, in the first, second, third and fourth day, the value was outside +/- 2SD – indicating that the analytical system applied was out of order [17].

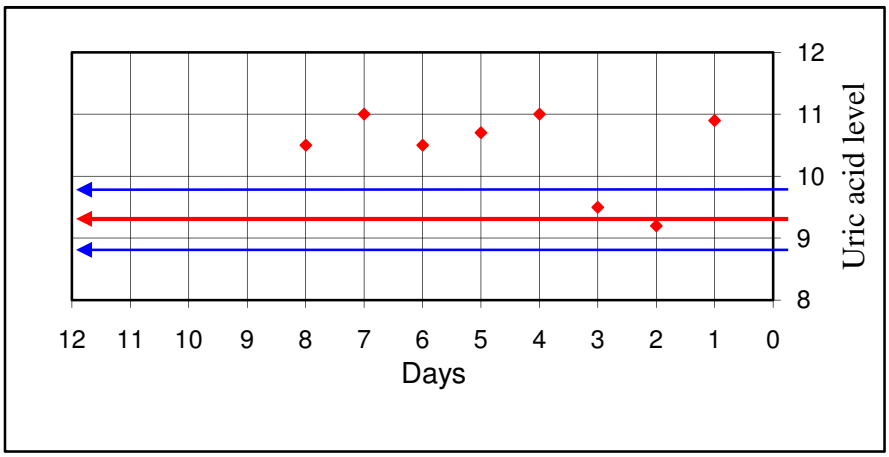

Figure 1 Control chart for uric acid

The distribution of value as in fifth day indicating the analytic system is out of order Fig. 2. The results were close and equally distributed around the mean value indicating day 3rd; 10th and 12th show GLP, these value reflect the problems to be solved related to analytic system. Loss of control had occurred due to a systematic error (Fig.1 due to the faulty reagent. When the reagent was replaced, control was Re-established as shown in the Fig .1 & 2.

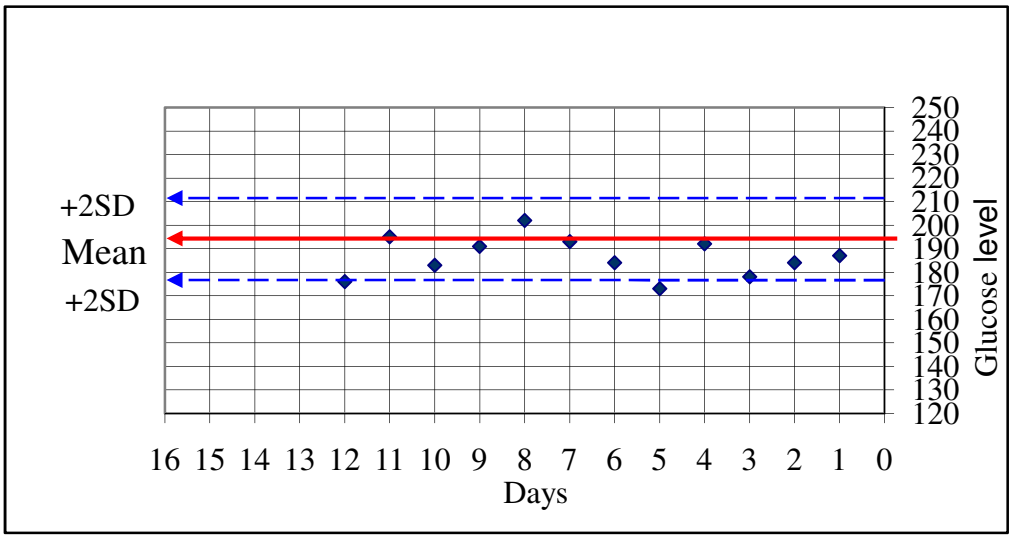

Figure 2 Control chart for sugar

CONCLUSION

Final recommendation that can be easily used the statistical analysis to be in position to know the errors, and can be handled and solved, the procedures are explained by WHO for many Times, the technicians should try to understand and search for all the documents related to the IQC - It is essential to be in a position to insure that your work place (laboratory) results Are under the programme recommended by WHO as medical statistic analysis procedures are Important for intermediate and peripheral laboratories. Results of our biostatistical analysis agree with the statistical analysis recommended by WHO, So this procedures well contrast and can be easily done at any intermediate and Peripheral laboratories. For activation the QC of Medical Laboratory Results Statistical Analysis should be forced. Medical statistic analysis procedures are emphasizing Good Laboratory Practice (GLP), which is essential element reflect the trust in laboratory results.

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