Review: Quality Control Approaches in Clinical Laboratories

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Abstract- Lately, researchers are firmly believing that quality control is one of the key requirements to provide reliable and accurate data recording and measurements for patients tests and treatment plan.

Method: Referring to some significant different resources, precise information of the quality control and standard test procedures were provided. In addition to that statistical analysis of processed data was used to evaluate, monitoring and improve performance. Based on obtained data from mean value, standard deviation, Levey-Jennings chart and Westgard rules.

Conclusion: Convenient maintenance and periodic calibration of laboratory equipment's is a very significant part of the entire QC system. As well as, QC improves the efficiency and traceability to the overall output and decreasing the cost of running.

Index Terms- Laboratory Quality Control, mean value, standard deviation, Levey-Jennings chart, Westgard rules.

I. INTRODUCTION

Quality control in the medical laboratory is a statistical procedures used to monitor and evaluate the analytical process that produces measurement and results of patient's tests. Good Laboratory Practices (GLP) is a ceremonial foundation that was created by the American Food and Drug Administration (FDA) in 1978. This formal regulation has a world-wide impact. Indeed, in 1981, the Organization for Economic Co-operation and Development (OECD) produced the GLP principles that become internationally standards for the quality control measurements and calibrations for the various equipment, machines and tests [1]. However, researchers do not confined quality control to only laboratory operations, but they insist that quality control must be involved in all decisions, i.e., concerning with the quality of the product. In fact, quality control deals firmly with systems that accept or rejects any activity or parameter that might affect the quality of the product and thus prevent quality deficiency [2].

In general, during the design stages of a clinical laboratory, there are some principles that should be taken into account, such as the suitability of construction materials and ventilation. Moreover, the laboratory should be supplied with regular amounts of water of appropriate quality, as this water will be used in cleaning as well as testing purposes. In addition, the laboratory should be provided with separate air handling units for biological, microbiological and radioisotopes testing areas [3]. One of the most important points that should be considered when installing a quality control laboratory is the division of it into separate sections. For example, the microbiology section should have special arrangements such as airlocks and laminar air flow work station.

On the other hand, diagnostic tests in medical laboratory could be quantitative (a number) or qualitative (positive or negative) or semi-quantitative (limited to a few different values). Therefore, QC play a significant role for patient's outcomes during diagnosis and treatment. It is ensure and validate whether the laboratory devices are operating within pre-defined specifications and accuracy, inferring that patient test results are reliable for decision making and treatment planning.

Commonly ,normal practiced routine controlled procedures are used to define quality control process in clinical laboratory. These rules include the following points according to (Taylor et al. 2018) [4]:

1- The instruments in the laboratory and the laboratory itself should be cleaned daily.
2- All the instruments in the laboratory should be validated as well as checked and the results should be recorded carefully.
3- The samples arrived at the laboratory should be registered in an incoming registration section.
4- Humidity and temperature inside the laboratory should be recorded daily.
5- Log books should be filled for every instrument used inside the laboratory correctly and carefully.
6- Any fault in any instrument inside the laboratory should be immediately reported to the quality control manager, so that an action will be taken immediately to overcome this fault

However, quality control is a wide field of research, there are some terms that are associated with this field and it is very important to distinguish between these terms, such as verification, validation, calibration and qualification. Indeed, verification is one the quality control processes. This process is used to estimate whether a system, product or service associated with quality control is respond to rules, conditions and specifications implied by the standards. Another term associated with quality control is the validation [5]. Validation is a quality assurance process. Validation process core is establishing an evidence that performs high degree of assurance that the product

will meet in an advance stage its intended rules. Calibration is another term associated with the quality control. It is a set of operations demonstrates the relationship between values specified by an instrument and the corresponding known values of reference standards. Finally, qualification is the primary responsibility of the quality control managers. In this process, the staff ensure that the products meet both quality and efficiency standards set by the company.

II. Methodology

Quality control is reported in the graphical, chart and statistical analysis of process data for the purposes of evaluating, monitoring, and improving clinical laboratory test performance. Therefore, QC statistics data for each results performed by laboratory medical device can be calculated from the QC database obtaining by test control materials at specific control level. These obtained data represents the behavior of test results at specific concentration. The most common statistical formulas used in laboratory are the mean value [$\bar{x}$] and the standard deviation [s].

The mean or the average value of the control material at specific level reflect the best estimation of analyst true value. The calculation of mean value for controller at specific level can be obtain by adding all results of controller material in the data set then divided by the total number of data set for the controller at specific level, according to the following formula:

$$[\bar{x}] = \sum Xn/n$$

Where, Xn : is the result value of controller at specific level

n : is the total number of test value for controller at specific level.

During the running of controller at specific levels it is important to note the accepted range of controllers. For example Level 1 (Normal Controller) for Potassium test is between (3.7 to 4.3) mmol/L. while the accepted ranges for level II (Abnormal Controller) is (6.7 to 7.3) mmol/L. the below table shows the daily obtained data for QC controller for Potassium test compared to patient results during the first week of November.

QC Test	Level I Normal Control Range 3.7 – 4.3 mmol/L	Level II Abnormal Control Range 6.7 – 7.3 mmol/L	Patient Results
1 November	4.0	7.0	4.2, 4.0, 3.8, 5.0, 5.8, 4.2
2 November	4.1	7.0	3.8, 4.4, 4.6, 3.9, 4.8, 4.4
3 November	4.0	6.9	4.4, 3.9, 3.7, 4.7
4 November	4.2	7.1	4.7, 5.6, 4.2, 3.7, 4.3
5 November	4.1	7.0	4.2, 4.3, 4.1, 4.3
6 November	4.1	7.0	4.6, 4.4, 5.5, 3.8, 3.2
7 November	4.2	8.0	2.8, 4.6, 4.2, 3.2, 3.9, 4.1

Table 1: QC value for Potassium Test using Level I and Level II Controllers.

Standard deviation is a statistical value which quantify the relation for numerical values of QC and represent how are these values close together. Also, the term precision is commonly used interchangeably with standard deviation. As well as, the term imprecision express how numerical QC values far apart from each other. Significantly, the standard deviation values are used to monitor ongoing day to day performance of medical laboratory devices. For example, if the calculated standard deviation goes from previous value such as 0.08 mmol/L to 0.16 mmol/L, indicating that there is a critical loss of precision. Which reflects a malfunction of system used to obtained test results.

The standard deviation can be calculated according to the following equation:

$$S = \sqrt{\sum (Xn - \bar{X})^2/(n-1)}$$

The standard deviation is calculated from the same data used to calculate the mean at specific level of controller. Providing an important estimate for results consistency and repeatability. The good result reflect a trend of low standard deviation and low imprecision. While inconsistent results high standard deviation and high imprecision as shown in below figure.

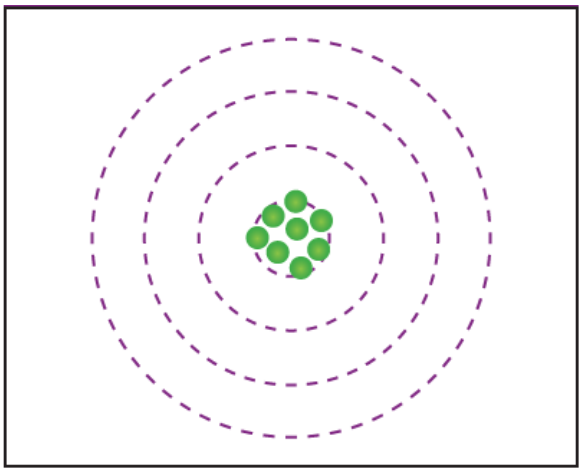

Figure 1: Low standard deviation and low imprecision

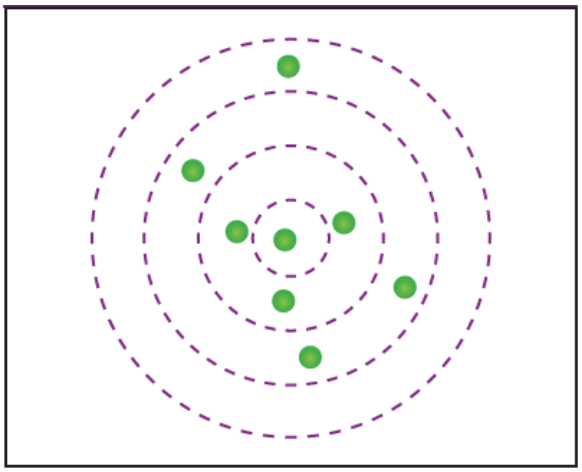

Figure 2: High standard deviation and high imprecision

After a test has been set up and standardized using a controllers at specifics levels. The simplest way to keep track and monitor of these results is to build up certain type of QC graphs usually known as Levey-Jennings Chart. Standard deviation and mean value are the basic input for Levey-Jennings Chart which is useful for monitoring run-to-run or day-to-day distribution of quality control values. Actually, Levey-Jennings chart illustrates the value of standard deviation and mean value of specific controller against days, months or the run number as shown in below figure.

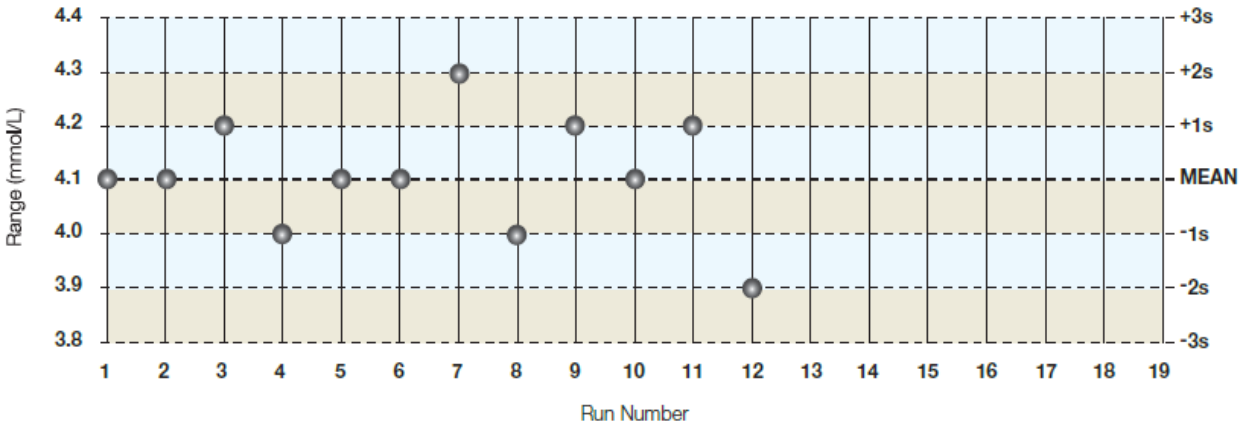

Figure 3: Levey-Jennings chart for Potassium Test using Normal Controller (Level 1).

Another way to express the QC for specific controller can be achieved by using normal distribution curve. Figure 4 shows the distribution of all QC value obtained by the test around the mean value. It is useful to estimate the accuracy and precision of the medical laboratory device under certain specification.

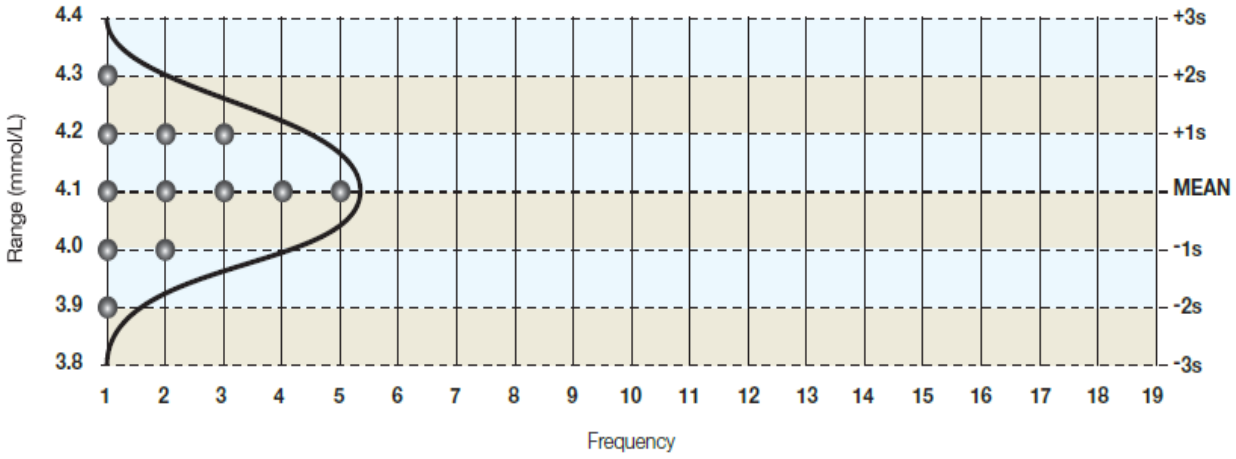

Figure 4: Relative Distribution of QC Values for Potassium Test using Normal Controller (Level 1).

However, Good Laboratory Practices (GLP) requires to document the assayed QC materials and the QC results to ensure optimal monitoring of analytical tests. Levey-Jennings and normal distribution chart have a great potential to summarized the data of QC tests and identify the test type, the medical laboratory device, units, operator who performed the test, and the total results of quality controller at each level.

III. Discussion

During performing QC tests, it is possible to obtain some type of systematic errors, which are evidenced by the change of mean value or standard deviation values. These systematic errors could be demonstrated in gradual trend of QC values which reflect loss of reliability or could be unexpected shift in QC values which reflect sudden and dramatic positive or negative change in test system. Also, random errors may occur during QC tests. Random errors can be defined as any positive or negative deviation between obtained results and accepted result. For any QC test, there are accepted and non-accepted range of results values. In general, QC for clinical laboratories use the value of standard deviation to define the accepted range for QC values. The criteria of (± 2) of standard deviation is usually used to limit the accepted rang for QC test. Which means that, when the obtained results of QC test falls between (± 2) of standard deviation, this produce 95.5% of the measurement is correct and only 4.5% of measurement fall outside the unaccepted limit.

To define specific performance limits Westgard rules are usually used for QC tests in clinical laboratories including two types of rules; warring rules that trigger a review of test procedures, calibration of laboratory equipment, controller material and reagents performance when systematic error is detected, and the obtained QC results goes out the limit of (± 2) of standard deviation. While the mandatory rules states that the results should be rejected when the obtained QC value exceed the standard deviation by (±3), or when the obtained results are fall in the same side of mean.

Consequently, the most significant benefit of applying quality control tests for clinical laboratories procedures is to predict malfunction and problems before it actually happened, then a corrective procedure should be taken to the tested system**.** In addition to that, QC has many objectives to improve the performance of medical laboratories, including the following main points.

1- Reduce errors made by instruments and technicians, and this will improve quality and productivity in advance stages.
2- Create more efficient teamwork.
3- Reinforce job involvement and participation.
4- Increase the motivation associated with employees.
5- Influence the capability of problem-solving efficiently.
6- Promote communication inside the organization and between the technicians.
7- Promote a consistent manager-worker relationship.
8- Develop a greater safety awareness.
9- Encourage cost reduction either in reagents or in samples.

Obtaining these objectives will be with the great benefits for the organization. Not only this, understanding of quality and cost leads to a new significant of relationship between these two concepts, which is “Improving in quality lead to reduction in costs” according to Parvin et al. 2017 [6]. Figure 5 illustrates this relationship.

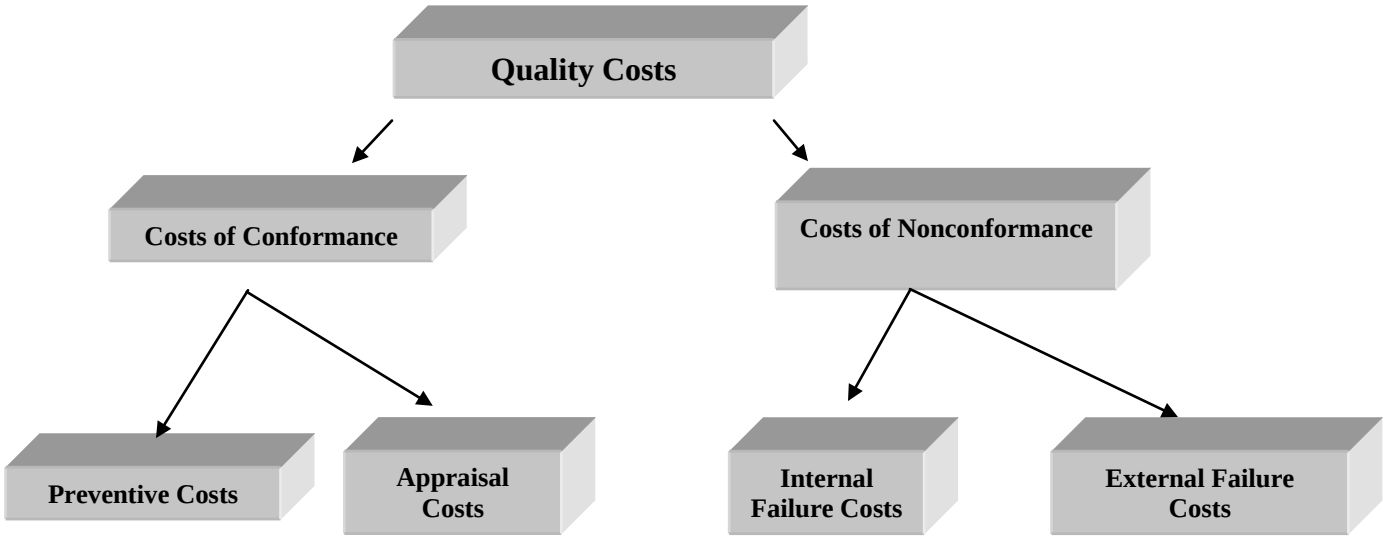

Figure 5: Relationship between Quality and Costs

The main relation between QC and cost prevention can be accomplished by training staffs who perform their responsibility and tasks in correct way according to specified standards and have the ability to educate new staff member on QC procedures. On the other hand, this will reduce the cost of quality testing which is known as appraisal cost. As well as, internal and external failures will dramatically reduced by ensuring that the quality control criteria is applied to the complete system of clinical laboratory.

IV. Conclusions

Quality control implementation is a novel process with different stages, started from the decision of management for clinical laboratory, selecting an appropriate standards, collecting information and defending the responsibilities. However, QC requires a lot of energy, time and specific regulation. All invested time and cost will potentially return in term of increased quality, confidence and reliability in test results for patients, and improvement of system's procedures. Leading to higher efficiency and traceability to the overall output for the complete system. In addition to that, QC chart and statistical process provides an effective monitoring and documentation for all parameters and results obtained by the QC process. Levey-Jennings Chart and Westgard rules are useful to determined the accepted range of test results and ensure that laboratory process and equipment meet the requirement of quality control criteria.

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