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Role Quality Control in Clinical Biochemistry Laboratory.

Kalaiselvi VS, Ravisekar P*, Manjula Devi AJ, and Shanthi B.

Department of Biochemistry, Sree Balaji Medical College and Hospital, Bharath, University, Chromepet, Chennai-44, Tamil Nadu, India.

ABSTRACT

In the General practice, its not a simple process to examine the patient and giving him a prescription. Over many years there has been rapid extension in various branches of health care services. As a part of extensive process and increase of medical knowledge, the laboratory diagnosis has gained more importance in general practice. Especially in our country, we have been identified significant growth in laboratory services. By the quality control (QC) the laboratory can ensure that the results being given by the laboratory reliable to allow the decesion should be taken with confidence. Quality control is a study of those errors, which are responsible of laboratory and the procedures used to recognize and minimise them. The Internal quality control (IQC), External quality assessment (EQC), are the two different procedures complementary to each other. Internal quality control is based on monitoring the Biochemistry test procedure that is performed in the laboratory. It includes measurement on specially prepared materials and repeated measurements on routine specimens as well as statistical analysis day by day of date obtained from the test which has been routinely carried out. External quality assessment is the evaluation by an outside agency of the performance by a number of laboratories on specially supplied samples. Analysis of performance is retrospective. The objective is to achieve between lab and between method compatibility.

Keywords: Internal quality control (IQC),External quality assessment (EQC),Proficiency surveillance, Standardization.

Corresponding author

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INTRODUCTION

Quality control in the biochemistry laboratory is intended to ensure the reliability of the laboratory tests. The objective of quality assurance is to achieve reliable test results by Accuracy and Precision.

Accuracy refers to the closeness of the estimated value to that considered to be true. Accuracy can, as a rule, be checked only by the use of reference materials which have been assayed by reference methods. Precision refers to the responsibility of the result, but a test can be precise without being accurate. Precision can be controlled by replicate tests and by repeated tests on previously measured specimens. And the test result or value which we get should be closer to the previous one[1] .

Inaccuracy and/or imprecision occur as a result of using unreliable standards or reagents ,incorrect instrument calibration, or poor technique.eg consistently faulty dilution or the use of a method that gives a reaction that is incomplete or not specific for the test.

First of all, Edward Demming gave the idea about quality control. *According to him,* Improved quality=increased productivity at lower cost. This can be done by Eliminating rework, Save time, Save labour, Save material e.g. reagent, specimen etc, Patient care.

METHODS AND MATERIALS

Internal quality control

This is based on monitoring the Biochemistry test procedure that is performed in the laboratory. It includes measurement on specially prepared materials and repeated measurements on routine specimens as well as statistical analysis day by day of date obtained from the test which has been routinely carried out. There is thus continuous evaluation of the reliability of the work of the laboratory. Hence IQC primarily check the precision of lab work[3,7].

External quality assessment

This is the evaluation by an outside agency of the performance by a number of laboratories on specially supplied samples. Analysis of performance is retrospective. The objective is to achieve between lab and between method compatibility, but this doesn't guarantee accuracy unless the specimens have been assayed by a reference lab alongside a reference preparation of known value. Schemes are usually organized on a national or regional basis. Hence, EQA is mainly concerned with analytical part of the test[2].

Proficiency surveillance

This is concerned with various aspect of laboratory apart from analysis part i.e. this ensures adequate control of the pre and post analytical stages of test. It implies critical supervision of all the aspects of laboratory tests. Such as,Sample collection,Labeling, Delivering, Storage,Reading,Reporting,Establishment of normal reference values[4,5]. Maintenance and control of apparatus and instruments etc.

Standardization

This refers to both materials and reference methods.A material standard or reference preparation is used to calibrate analytic instruments and to assign a quantitative value to calibrators.A reference method is an exactly defined technique which provides sufficiently accurate and precise data for it to be used to assess the validity of other methods. The main international authority concerned with material standards are WHO and international council for standardization in hematology (ICSH). The material prepared by these authorities are international standards (international reference preparation)and are of primary standard. These international standards are not freely available and are not intended for routine use, but this serve as standards for assigning values to commercial standard which is of secondary standard.

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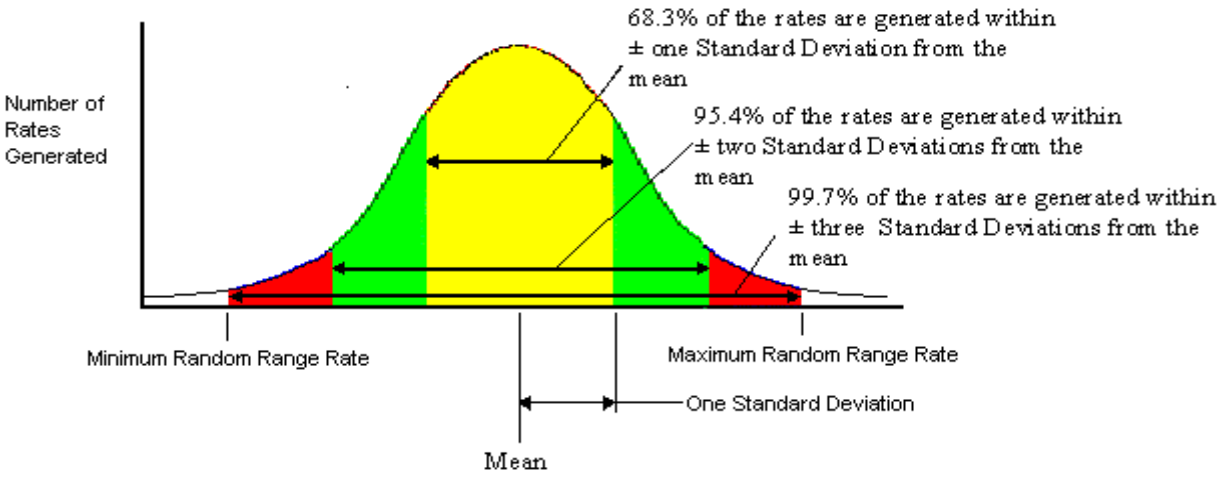
RESULTS

Standard deviation

If values are assigned to a same specimen a number of times by repeating the test, the dispersion of results around the mean will indicate the error of reproducibility. And deviation of values from the mean is called standard deviation. This gives an idea about precision (random error).95% of result should be with in ±2 SD. 99.7% of results should be with in ±3 SD. To determine SD, 10-20 identical tests are carried out on the same sample.



Gaussian distribution

It is a bell shaped curve resulting from events or data which occur symmetrically about the mean when frequency and data are plotted.

SD= *
Where,
X…test value
X*...Mean value
N... number of test
Extent of spread of measurement about mean is SD.

Shewart levey jenning chart

Runs or days are plotted on x axis.
Values obtained from analytic run are plotted on Y axis.

Samples of control specimens are included in every batch of patient's specimen. Mean and standard deviation are then established.

Satisfactory results are obtained only when Sequential results oscillate about the mean Less than 5% of results will fall outside of ±2 SD Error

If 2 or more results are on outside ±2 SD. Consecutive values may get increased or decreased. Consecutive values shouldn't on one side of mean[8].

DISCUSSION

Primary Goals –(1)To report out all correct data,(2)Not to report the incorrect patient values. *Error Detection*-To detect error before it leaves the lab.

Errors in quantitative system

There are two types of errors in quantitative system

1. Random error
2. Systematic error.

Random Error: This is the error in which there will be variation in test result /data on either side of mean. In other words the values obtained will be low as well as high to the mean value or true value.

This may be due to Slight variation in line voltage, lamp output or temperature,Slight variation in pipettors and dispensers. This error is measured by standard deviation (SD) and coefficient variation (CV).

Systemic Error

This is the error in which variation occurs in one direction away from the true value i.e. either value goes up or down. The difference between measured value and true value is called Bias Systemic errors are errors within the test system or methodology.

1. Assigned value to calibrators.
2. Reagent composition
3. Antibody specificity.

Components of error detection system

1. Patient identification, sample collection and handling.
2. Analytical method.
3. Instrument maintenance
4. Control material.-In build error detecting test, it is run as per the test and its value is known so helps to detect whether our test is correct or not.
5. Quality control monitoring.
6. Clerical.

Quality control material

It is a known sample whose range of values has been established prior to the test either by international authorities or by commercial firms. This control sample is inserted into the testing process, being exposed to the same condition as the patient sample and value is measured[6]. If the values of control material is with in the range then it is said that the test procedure of the error detectors.

CONCLUSION

This study explains QC techniques towards day-to-day monitoring of the reliability of Clinical Biochemistry laboratory performance. Application of these techniques will help reduce errors and give both the laboratory and the clinician confidence in the results. Through the sustained efforts of the ACBI, it will be certainly possible to encourage all Indian laboratories to implement QC as an integral part of laboratory practice.

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