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Original Article

QUALITY CONTROL IN BIOCHEMISTRY LABORATORY

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ABSTRACT

Thanks to plethora of lab investigation lots of others in pipeline, the diagnosis of even rare diseases has been possible. This have severed the patient and humanity as a whole. To get the maximum advantage it is duty of the medical personal to make it has precise and accurate as possible. For this we have to raise the quality of laboratory results as well refining the skills. For any investigation three steps are important such as pre-analytical analytical and post past analytical. Out of this most common and easy to taggle pre-analytical step because it includes the factor which can be sorted out even before going to this next step in the laboratory. The post analytical error can affect after the analytical part is complete. The analytical error is dependent upon the functioning of the equipment's and the specialist working on this are specially trained. All the three phases can be controlled under quality control (IQC &EQC) which is further of two type internal quality control (IQC)and external quality control (ECQ). The interpretation of quality control data is done with the help of both graphical and statistical tools. Quality control data is most commonly visualized with the help of Quality Control (QC) charts which include Levey-Jennings (LJ) Charts and Westgard Rules. Both are useful in detecting trends or shifts observed from the average target value[4] THE EQC dependence upon the proficiency testing on the other hand IQC is perform daily in the laboratory using controls with known value, whereas EQC depends upon the involvement of the lab in an external quality assessment scheme (EQAS) which make the result of the test competent.

Aims and objective: they include

1. To remove the frequency of prominent error in all the three phases.
2. dealing efficiently with samples coming at a brisk rate in emergency and multispecialty.
3. to include the quality indicator to over this error.

The scheme was to find the frequency of all the errors during two years. This was an observational study in tertiary care centers. The path of the samples was followed from sample collection to the result of investigation. During this periods deficiency in caring out the sample was ensured.

Results: total rate of error measure in our lab is 10% out of which pre-analytical is 4.4% and analytical is 2.4% and post analytical is 3.2%.

INTRODUCTION

QC or Quality control plays decisive factor in maintaining notable standard of lab. reputation. The results become a hall mark of that infrastructure. They highlight deficiencies ang help at three steps. These are taken in three steps which are before the sample is processed (Pre analytical), during the process of analysis (Analytical) and up to disbursement of reports to the patients (Post analytical). It also plays a good role is calibrating accurately the upcoming apparatus in the lab. Both internal and external quality controls have made dent in making the results precise and accurate which can later help in getting accreditation from NABL & NABH.[2]. There are a number of potential errors which can affect the quality of the clinical laboratory results. These errors can occur in pre-analytical, analytical and post-analytical phases. There are a number of fallacies which can occur when the sample is collected from the patient till it is transported to the laboratory for analysis. These are explained as follows:

Pre-analytical Errors

1. Credentials of the patient: There should be accurate particulars such as name, gender, age, ward, including patient' sposture, exercise, diet, medical history, pregnancy, H/O any type of drug taken for any illness.

2. Wrong technique of taking sample of drug: e.g., inadvertently take in blood from vein when it is required from the arteries kike in ABG.

3.Advances in use of specific type of vacutainer fore. g., vacutainer containing sodium citrate is used in place of sodium fluoride for analysis of plasma glucose.

4. Quantity of the sample insufficient: An insufficient quantity of sample cannot be enough for processing all the tests which have been requested by the clinician.

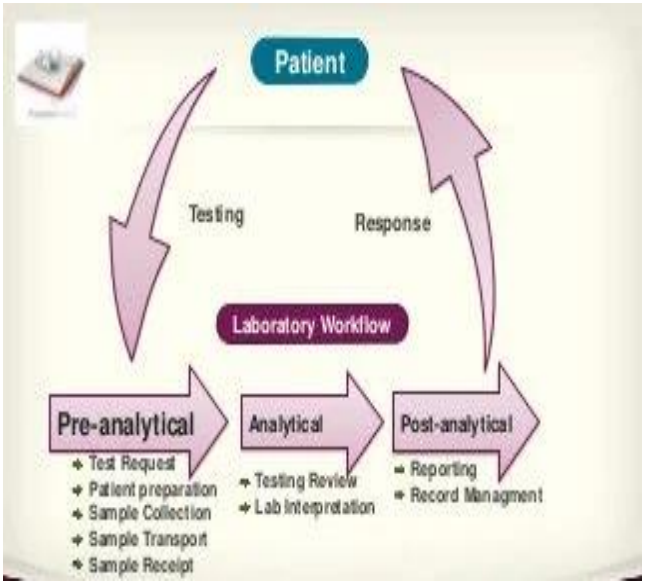
4. Vigorous shaking of sample makes the blood sample hemolyzed which can't be processed for tests like enzymes, serum electrolytes.

5. Lack of facilities required for storage of samples which can hemolyze the sample if not stored at required temperature For overnight If a sample has not been properly stored or a blood sample has been left overnight before being sent to the laboratory, it will become hemolyzed, heat and exposure to light can change the actual value of many analytes in routine clinical chemistry such as photo-degradation of bilirubin by light exposure.

2.2. **Analytical Phase**

The analytical phase begins from the time when the patient's specimen is ready for major analytical errors which may affect the quality of the results obtained which may include analysis, pre-treatment, reagent volume, sample and reagent mixing, incubation, reaction timing, and calculations. Glassware like pipettes, test tubes etc., which may not have cleaned and calibrated. The quality of distilled water, reconstitution and other processes, it is important that all the steps should be followed as per manufacturers guidelines. During the analytical step, the quality of lab. investigations can be held with the help of Internal quality as well as external quality controls. Analytical errors are seen after the use of improperly processed Distilled Water, expired reagents and controls and calibrators, blockade in aspiration system of reagents and samples [1]. The personals in the lab maintaining EQAS, finding trends, may take time to be accurate., unacceptable results should be treated at war footing level and no stone should be unturned to maintain IQC & EQC.

Post-Analytical Step: It deals with the reporting of investigations after going through analytical phase keeping in mind the units, calculation, and other technical information so that the doctor can easily make out the message. Most of causes of errors should be legibly written and technically perfect 3. These small things in the clinical Lab can remove analytical errors which can distort the accuracy, precision, sensitivity, specificity and reproducibility and repeatability of the analytical methods [1].



Accuracy

Accuracy refers to the degree of agreement between a measured value and its 'true' value. It is generally measured by direct comparison to a referred value, control, EQ sample or calculating the refer serum. 3.

Precision

Precision refers to the reproducibility or the closeness of the measured level. Precision is quantitatively expressed as Standard Deviation (SD) or more precisely as Coefficient of Variation (CV) of the results in a set of replicate measurements. Hence good precision means least CV. An ideal laboratory should endeavor to get ideal precision and accuracy.

Specificity: It is the ability of a method to measure whole amount of component required. A lack of specificity could lead to a falsely elevated result where the test is measuring components other than the analyte of interest.

Sensitivity: Efficiency of the system to measure small amounts of an analyte that has been measure. It will affect precision and accuracy, when strive to measure bottom levels which may give the clinical sense.

Repeatability: It is the difference between successive measurement that have been perform on the same sample under similar condition (e.g., same analyzer, same user, same laboratory, same methods, and same reagent lot) within in a very short time[6].

4. **Statistics in quality control:** since the management of the disease depends upon lab results so these should be reliable and accurate. The laboratory finding should be summarized so as to monitor the performance like quality control.[3] This statistic is nominated by their center spread and shake.

Distribution: This should be Gaussian distribution which forms the basis of statistical control. This is a biaxial bell-shaped diagram (X/Y) in which X-axis shows the values of a variable's observation and Y-axis shows the frequency of each value. This curve indicates 68% of values that will fall under the 1SD from the mean value and 95% would be expected to fall within 2SD and 99.7% would be expected to fall within 3SD.

Mean ($\bar{x}$): arithmetic average of a group of values and is determined by summing the values and dividing by the number of values.

$\bar{x} = (\Sigma xi) / n$

Where; $\bar{x}$ = mean, Σ = add up, xi = all of the values, n = number

Median Value (M):it represents the center of the distribution. It is often used with skewed data.

Mode Value (Mo):it is the value with the highest frequency and is used to describe the data with two centers (bimodal).Measure of Spread of the Data around the Mean

Standard Deviation(SD): it is the measure of dispersion of a group of values around the mean. It is derived from the curve of normal distribution and is used to assess precision[2].

$$\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$$

s = standard deviation, $\bar{x}$ = mean, Σ = add up, xi = all of the values, n = number

Coefficient of variation (CV): is defined as the ratio of standard deviation to the mean and is expressed as percentage. It is another measure of percentage of imprecision[5].

CV = (S/) X 100

Where; CV = coefficient of variation, s = standard deviation, $\bar{x}$ = mean

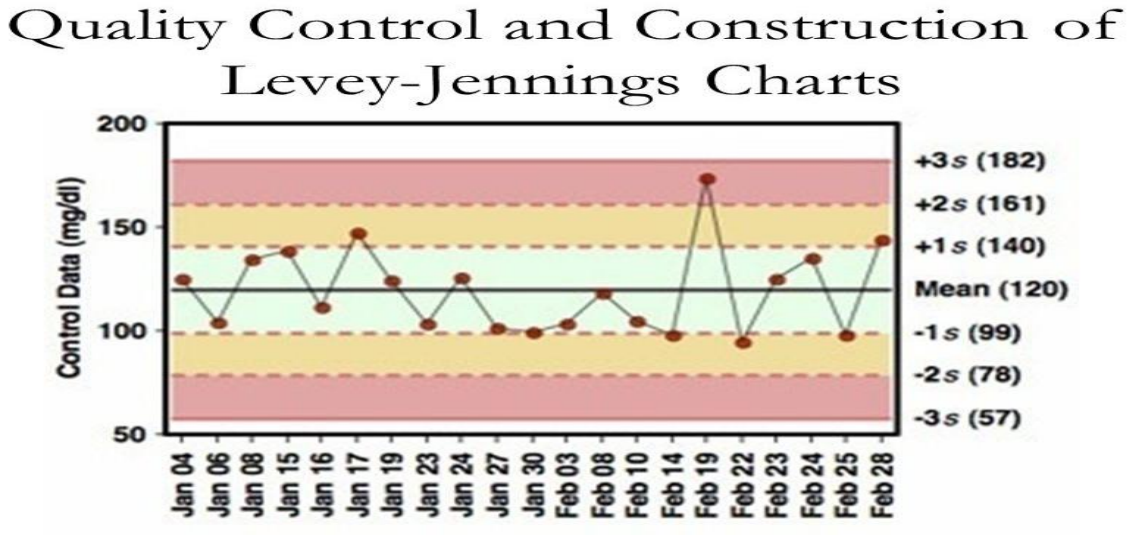
Standard Deviation Index: It is the difference between individual value subtracted from the group mean divided by the SD of the group also known as Z- statistic. It is used for peer-group comparison.

Quality Control in Laboratory:

1. **Internal quality control:** it is performed every day. In those we use reagents, equipment and glass wear. It should be done with 2 QC levels for each analyte. This signifies the precision.
2. **External quality control:** EQAS is performed as a test for the method. it involves the participation of the lab with samples for analysis on monthly basis. This should be replica of the procedure done with this analyte. Results are reported to the outside agency running EQAS (External Quality Assessment Scheme). They then provide a report for the participating lab based on mean coefficient of variation and standard deviation index of the lab[1].

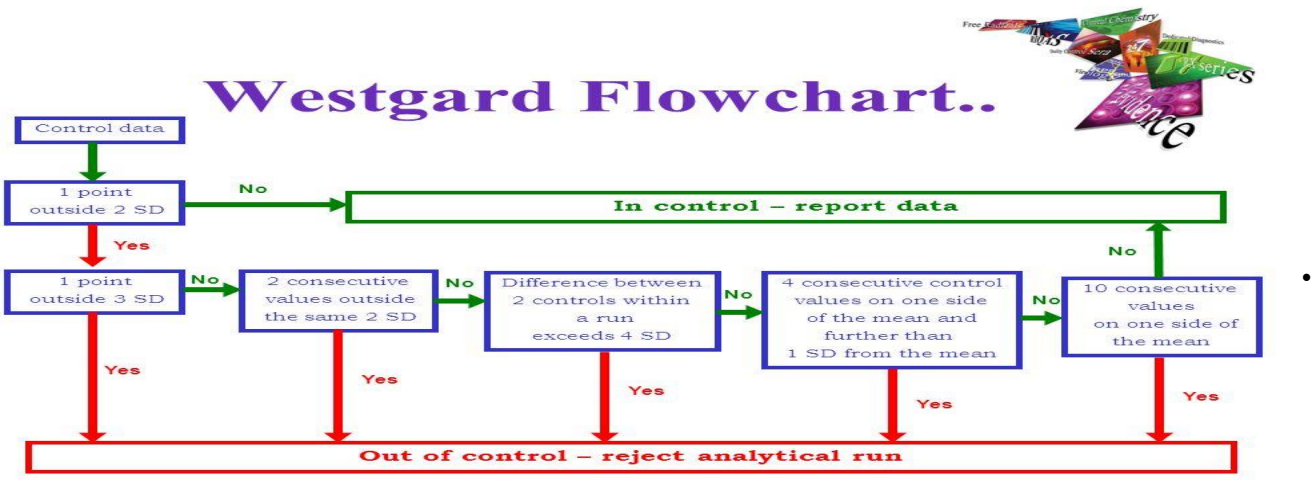
QC Charts: they are used to verify the old prior QC results with in a particular range diagrammatically.

L-J CHARTS:



It is a graphical method for displaying the values of controls. Controls values are plotted v/s days of the month which is indicated on the X axis and value of control as mean±1SD and mean±2SD and mean±3SD

are indicated on the Y axis. Deviation is grater than mean±2SD this is indication for rejecting the run.



WESTGARD RULE:

These rules tell us about deciding the fate of the run and helps in improving the quality control. These are defined as follows:

• Westgard 2_{2S} rule: It is violated when 2 consecutive control values for the same level fall or both controls in the same run outside the mean±2SD. This run has to be rejected.

• Westgard 4_{1S} rule: It is violated if four consecutive control values exceed the same limit (mean + 1SD) and this may indicate the need to perform instrument maintenance or reagent calibration.

• Westgard 1_{3S} rule: It is violated when either of the two control values fall outside mean +3SD. The assay run is rejected when a single control value exceeds the mean plus 3SD or mean minus 3SD.

• Westgard 4_S rule: It is violated when one control value exceeds the mean by +2SD and the other control value exceeds the mean by -2SD. The range between the two results will therefore exceed 4SD hence the run is rejected.

Westgard 10x rule: This rule is violated when the last 10 consecutive control values are on the same side of the mean or target value. So, the run has to be rejected.

CORRECTIVE ACTION AND PREVENTIVE ACTION (CAPA)

Corrective action is that action which should be used to stop the occurrence of non-conformities. Preventive action is that which should give the opportunity to prevent potential nonconformities. Corrective action has to be taken when there is a problem. If a problem does not exist, preventive action has to be taken. Once the run is rejected on the basis of quality control results, the problem is to be solved by taking corrective action, so that results become accurate. Corrective action starts with the root cause analysis which forms the most important part of corrective action. The root cause analysis should be done by the laboratory staff familiar with the problem. The results of the corrective action taken need to be recorded and monitoring should be done to verify the completion of actions taken and also to see its effectiveness. The corrective and preventive action process includes following steps [7]:

a. Reviewing and defining the problem or non-conformity.

b. Finding the cause of problem.

c. Develop an action plan to correct the problem and prevent the recurrence.

implementing the plan.

e. Evaluating the effectiveness of the correction in preventing the problem.

Clinical Audit of the Laboratory: In addition to participating in external quality assessment schemes, laboratories are also subject to clinical audit. This is a systemic and critical assessment of the general performance of the laboratory against its own declared standards and procedures and against nationally agreed standards. In the context of analytical procedures, the audit evaluates the laboratory performance in terms of the appropriateness of the use of the tests offered by the laboratory, the clinical interpretations of the results and the procedures that operate for the receipt, analysis and reporting of the test samples. The objective of the audit is to ensure that the patient receives the best possible care and support in a cost-effective way. The audit is normally undertaken by Junior Doctors, Lab. & its staff & assessors from the agency. Clinical audit is carried out for benefit of the Lab. and Its staff.

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