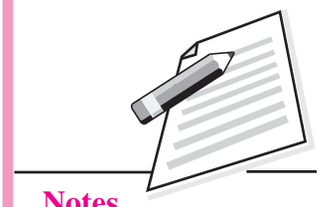

26

LABORATORY QUALITY MANAGEMENT

26.1 INTRODUCTION

Have ever accompanied your family members to nearby market for buying vegetables? Have you noticed how many customers lift few vegetables and either press or break it into two? For example, to know whether a lady's finger is supposed to be good if it is found to be firm while breaking off its tail. Many vegetables and fruits such as brinjal, apples etc. are supposed to be good if they are felt as firm but not hard at our hands. So what exactly is the customer doing by checking one or two vegetable or fruit? And is it sufficient if they check just one or two randomly? Why don't they touch and check each and every piece? Well, what they are doing is they are doing a quality check. And yes, most often if a random piece is good then mostly the whole bunch is usually almost good. Similarly, in a laboratory set up if you want to know whether the tests that are being done are of good standard or not you have to run a quality check. And this is slightly different from random checking of vegetables. It is a methodical process with certain rules and regulations which is known as **Quality control**. Besides the process, laboratory quality control has to be managed following regularity and policies. This is otherwise known as **Laboratory quality management**.

Fig. 26.1

Notes

OBJECTIVES

After reading this lesson, you will be able to:

- define quality control, accuracy and precision
- define laboratory quality management
- differentiate between precision and accuracy

26.2 QUALITY MANAGEMENTCONTENT

The main objective laboratory quality management is to

(a) Identify errors,

(b) Decrease errors

(c) Correct the root cause of errors

(d) Increase the efficiency of the lab

by regular checking of the analytical process at each step sticking to quality control material or calibration material (internal and external), before releasing the patients' reports .

So what is basically quality control?

Quality control otherwise known as QC is a measure of precision.

Precision means how often the measurement system produces **the same result** again and again over time and under different operating conditions.

As we are discussing precision you must also know what accuracy is. Accuracy is how often the measurement system produces **the correct result** over time and under different operating conditions.

For example according to internal quality control (level 2; secondary standard) of the laboratory, the value of creatinine is 2 mg/dl in the quality control material. If your laboratory measurement system measures this for 6 times by instrument A and 5 times by instrument B.

Instrument A produced results as:

(a) 4.1

(b) 4.2

(c) 4.1

(d) 4

(e) 4.1

(f) 4.1

And Instrument B produced results as:

(a) 4

(b) 0.9

(c) 2.1

(d) 2

(e) 1.9

(f) 2

Then your Instrument A is precise but not accurate. Why? This is so because, it 4 out of 6 times produced result close to 4. So it is always producing values close to one result. But it was supposed to produce result close to 2! Serum creatinine normal range is roughly 0.5 to 1.1 mg/dl in females and 0.6 to 1.2 mg/dl in males. And our level 2; secondary standard which corresponds to higher level standard, value should be close to 2. So it is not accurate and this type of inaccurate results will make laboratory reports unreliable.

On the other hand, Instrument B is accurate but not precise. Why? This is so because, 4 out of 6 times, it produced result close to 2. So it is always producing values close to standard value. But it also produces result far away from that is 0.9 and 4. So it is good for the laboratory to produce accurate result 3 times out of 5. But also in 2 cases out of 6 if value is so far from correct value, laboratory cannot be sure whether it's the right value or one of its precision errors.

For extra information on standards and internal quality control refer chapter on Primary and Secondary standards.

INTEXT QUESTIONS 26.1

1. The main objective laboratory quality management is to decrease errors
2. Accuracy means how often the measurement system produces the same result
3. Precision means how often the measurement system produces the correct result

26.3 LABORATORY QUALITY MANAGEMENT

The management of quality in a laboratory follows an order which works in a cycle. The various parts are

(a) The goal and objectives set by the management to maintain quality in laboratory

(b) To provide initial requirements such as instruments, calibration materials, trained manpower, a competent lab manager etc.

(c) To set the quality control processes

(d) To do quality assessment at required interval and identify error

(e) To take steps to eliminate error and also to improve quality

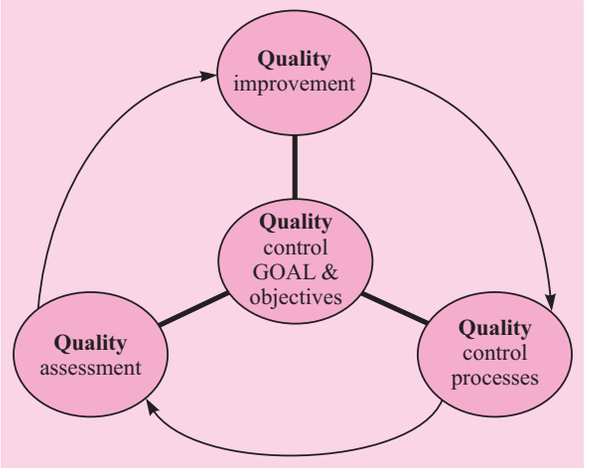

Fig. 26.2 : The management of quality in a laboratory

INTEXT QUESTIONS 26.2

1. Arrange the followings in order.
   (a) Set the quality control processes
   (b) Provide initial requirements
   (c) Take steps to eliminate error
   (d) Perform the quality assessment at required interval
   (e) Set your goals and objectives

26.4 SETTING OF GOAL AND OBJECTIVES FOR QC

This depends from laboratory to laboratory. This depends on the vision of management and facilities provided. The objectives for QC is guided by the keeping the following points in mind

- To set the analytical error limit
- To set the critical range for analytes to make medical decisions

So we should understand the types of errors that can occur in a laboratory. Basically all types of errors associated with analysis and final reporting of a patient's sample can be broadly divided into 3 categories.

1. Pre-analytical error
2. Analytical error
3. Post analytical error

26.4.1 Pre-analytical error

It consists of all errors that occur before the patient's sample reaches laboratory.

One should be aware that most of the errors (around 75%) come under this group. Therefore, even though being a laboratory personnel we are responsible for analytical error, we should not ignore pre-analytical error. Laboratory personnel **must be aware** of all types of pre-analytical error and be concerned with it. Because if we can decrease pre analytical error then the total load of analysis by us will also decrease. It means automatically the percentage of correct reports generated by our laboratory also will increase. Apart from that it will save the time, money and our energy spent on processing of wrong sample. This in turn will improve patient care service by laboratory. Some of the common preanalytrical errors are described below.

(a) Order the test:

- Inappropriate test: Thyroid hormones should not be ordered within 2 weeks of starting therapy
- Wrong patient identification: It can happen if clinician does not verify the patient his/her name and other details
- Handwriting not readable etc: One of the most common error laboratory personnel have to deal with! For example if FBS (Fasting blood sugar) is not written properly can look like RBS (Random blood sugar). So a value of 130 for FBS (should be <126mg/dL) that should have drawn attention for RBS (should be <140mg/dL) would go unnoticed.

(b) Sample collection

- Wrong patient identification: It can happen if clinician does not verify the patient his/her name and other details before collecting sample
- Wrong tube: Blood sample for serum should not be collected in anticoagulated tubes
- Inappropriate volume collected: First the phlebotomist should calculate the total amount of sample needed. This is done by adding the amount of sample needed for each test ordered. In this way sample collected would neither be wasted nor be less for any test.

- Inappropriate sample collected: For example if sample is hemolyzed due to incorrect way of collection, it should not be sent for potassium estimation.
- Collection at wrong time: Sample for cortisol should always be collected before 8am.
- Delayed transport: Delay in transport can decrease the value of sugar in blood sample at 7% rate. This happens because sugar gets utilized by RBC and WBC.

If the laboratory personnel identify pre-analytical error, sample should be rejected.

INTEXT QUESTIONS 26.3

(Being an efficient lab personnel, do you agree or not with the following statements. Answer with yes or no)

1. The clinicians are so busy. They need not write the diagnosis or patients name on requisition form
2. We should not fuss over simple mistakes like writing FBS which looks like RBS
3. Clinicians and nurses are directly dealing with patients and not by us who are sitting in laboratory. They can never make mistake in identifying their on patient
4. If a patient who has come from far distance, for giving blood for serum cortisol at 12 pm I should not feel pity. I should tell him to come again next day
5. I do not have a serum tube but there are enough heparinized tube with me. It is alright if I collect in serum tube, later on I can transfer into a heparinized tube

26.4.2 Analytical error

Most common analytical errors are

- Faulty calibration of instrument or errors not corrected in instrument
- Interfering substance in sample
- Sample mix up **(very dangerous and can lead to legal problems)** etc

The errors that occur while analyzing samples can be decreased by using standard equipments such as:

- Using standard quality of water
- Calibrating the pipettes, glasswares etc

- Maintaining the instrument within their proper working condition etc
- Checking the quality of analysis (most important) by comparing the values with quality control materials (external and internal QC material).

The QC sample has to be stable, should be divided into different vials. So we can analyzes the same QC sample from time to time. Either it has to be bought from laboratories supplying secondary standards as lyophilized powder for internal calibration. It can also be prepared by pooling of sera and storing kept in different aliquots at -20 degree for repeated use. The most common method for comparing the laboratory value observed for true value of standard is by drawing control charts or by statistics.

Laboratory quality control material is run at the beginning of each shift or preferably in the morning and in the evening, also, after an instrument is serviced, or when a new reagent box is opened etc and of course whenever patient results seem inappropriate.

The easiest chart is **Levey Jenings chart**. This chart is named after its inventors Sir Levey and Sir Jennings in 1950. later it was improved by Henry and Segalove. Here, the days are plotted in X-axis and observed values for standard are plotted on Y-axis. The mean and one standard deviation (1SD), two standard deviation (2SD), and three standard deviation (3SD) limits are plotted on the Y-axis. Comparing the pattern of plotted points gives the simple way to detect the

- Increased random error
- Any shifts in the trends of calibration

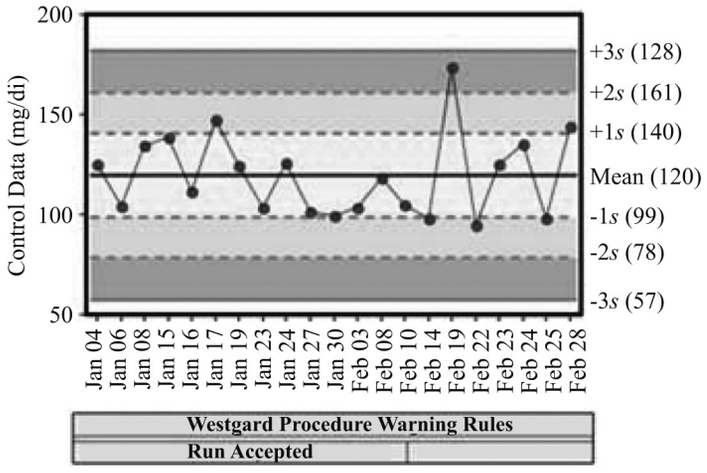

Fig. 26.3: Levey-Jennings chart/Graph

In order to draw a Levey Jenings chart, the QC material has to be analyzed for 20 consecutive days. Then calculate its mean and standard deviation. Now draw the points on the y axis on a graph sheet with no of days in X axis. Now join the

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points. Next draw the mean as a line parallel to X axis. Next draw the lines on both sides of mean for range of ± 1SD then ± 2SD. Likewise, ± 3SD then ±42SD also can be drawn. However, the **control limit is taken as mean ± 2SD range**.

If any observed value falls out of this mean ± 2SD range, on any day, all laboratory procedure has to be stopped, error has to be corrected. Till then patient report should not be given out.

Shewhart chart on the other hand is a statistical process. Here, the short term estimate of sigma is used unlike Levey-Jennings chart where long term estimate of sigma (standard deviation) is used.

There is a **Westgard multirule procedure** which helps us decide which observed values for QC material is to be rejected. For example,

- If one control value exceeds ± 1SD then it's a warning.
- If one control value exceeds ± 3SD; or if one value exceeds + 2 SD and the other – 2SD then these are **random errors**, so test should be rejected. Go for error detection. Withhold patients' results.
- If 2 consecutive values exceed ± 2SD; or 4 consecutive values exceed ± 1SD then these are **systematic errors**, so test should be rejected. Go for error detection. Withhold patients' results.

And so on…..

Here we should know what a random error is. It is an error that occurred by chance. For example, sudden loss of power leading to decreased incubation temperature. So this would affect test run only at that time and not to any other test. So error happens randomly.

So what is a systematic error? It is an error that is occurring systematically to all tests. For example: use of a faulty pipette. So, an incorrect volume of sample or reagent will be equally added to all tests. So error happens systematically.

INTEXT QUESTIONS 26.4

1. The pipetting error is a type of ..... error
2. Sample mix up is an analysis error which can lead to ..... problems
3. Westgard rule is for ..... of a test.
4. Levey Jennings chart is drawn after minimum ..... days.

26.4.3 Post analytical error

Most common post-analytical errors are

- Wrong patient identification so wrong reporting
- Transcription error (wrong entry, writing not clear)
- Delayed reporting
- Previous values not available for comparison etc.

You should also know that delayed reporting is a post analytical error. Still the lab is held responsible for it because laboratory personnel are responsible for its reporting.

The laboratory is controlled by a laboratory manager who is the link between lab technicians and the management. The laboratory manager is responsible for satisfying customers' quality requirements and also to meet the regulations set by the management as well.

In any organization, the people working behind the machines are most important and not the machine itself. Therefore, irrespective of the quality of instruments and other facilities provided quality in laboratory can be maintained to its best possible standard by the dedication of laboratory personnel. Therefore, a positive attitude among all laboratory personnel, respect for each other and a sincere desire to solve problems will improve the over all quality of the laboratory service.

WHAT HAVE YOU LEARNT

- As the laboratory deals with patients' samples based on which medical decisions aret taken it is important to run a quality check and control of quality. The laboratory has to manage control of quality by certain rules in order to decrease pre analytical, analytical and post analytical errors which can occur at random or systemically. For error detection labs rely on various statistical methos or graphs such as Levey Jennings chart with Westgard's rules etc. after error detection the source of error has to be removed, till then no patient report should be given out.

TERMINAL QUESTIONS

1. What are the steps for management of laboratory quality?
2. Discuss various types of pre analytical errors

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3. Describe Levey Jennigs chart and role of Westgard's rules in it.
4. Describe various types of errors that can be detected by Levey Jennigs chart.

ANSWERS TO INTEXT QUESTIONS

26.1

1. True
2. False
3. True

26.2

(e) Set your goal and objectives
(b) Provide initial requirements
(a) Set the quality control processes
(d) Perform the quality assessment at required interval
(c) Take steps to eliminate error

26.3

1. No
2. No
3. No
4. Yes
5. No