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# QUALITY CONTROL IN MICROBIOLOGY

## 13.1 INTRODUCTION

**Quality:** Quality means meeting the pre-determined requirements of users for a particular substance or service.

**ISO:** International standard Organization

The ISO is one of the leading International Bodies that has brought together International Community in developing uniform standards for quality in manufacturing and service sectors.



## OBJECTIVES

After reading this lesson, you will be able to:

- describe terms related to Quality Assurance
- enlist the phases of Quality assurance
- describe the phases of quality Assurance
- appreciate the benefits of quality assurance program

**Quality** includes the following

**Total Quality Management (TQM)**

**Continuous Quality Improvement (CQI)**

**Quality Assurance (QA)**

**Notes**

**TQM** evolved as an activity to improve patient care by having the laboratory monitor its work to detect deficiency and subsequently correct them.

**CQI** and **PI** seek to improve patient care by placing the emphasis on not mistakes in the first place.

**QA** is associated with the three phases of quality assurance

**Pre- analytical**

Analytical

**Post –analytical**

**Pre-analytical**

**Specimen collection:** The material must be from the **actual site** of infection. It should be properly collected with minimum chances of contamination. It should be collected in a adequate sized sterile container.e.g. In case of tonsillitis the throat swab should be taken from the inflamed peri-tonsillar fossae. Pus should be collected from the inflamed area near the margins of the abscess and should not be collected from the centre of the abscess where the dead and necrotic material is likely to be there.

**Optimal time** of Collection of sample must be established to provide the best chance of recovering the causative micro-organism from the specimen. E.g. In typhoid fever the blood culture is recommended to be done in the first week of fever. The WIDAL test should be done in the end of second week of fever. The specimen should be collected before the administration of any antibiotic. If the patient is on antibiotics then the specimen should be collected before the next dose of antibiotic is administered.

A **sufficient quantity** of the specimen should be collected to perform the tests required. E.g. 5-10 ml of blood should be collected in the blood culture bottle.

**Appropriate collection devices and specimen containers** should be used for the collection of specimen. All containers used for collection of culture specimen should be sterile. The handling of the containers, while collection of the specimen, should also be such that the sterility of the container is maintained at all times.

**Labeling** of the specimen should be proper to ensure there is no mixing up of specimen.

**Proper selection of culture media** should be made to ensure that the pathogenic organisms are isolated from the specimen. Fastidious organisms like Streptococci and Meningococci may require blood agar and chocolate agar to be used for isolation.

Specimen should also be collected for direct microscopy and proper smears should be made.



Notes

**Specimen transportation:** The primary objective of the transport of diagnostic specimen, whether within the hospital, from the clinic or externally by mail, or transportation to a distant reference laboratory, is to maintain the sample in as near its original state as possible. If prolonged delay is expected before the specimen can be processed, it is generally preferable to freeze the specimen at  $-70^{\circ}\text{C}$ . Freezing at  $-20^{\circ}\text{C}$  may be used for many specimens if the period of storage is brief. Storage should not be in a frost free refrigerator.

**Transport media:** Some transport media's are available for microbiology specimen e.g. Stuart's media, Cary-Blair media.

**Specimen receipt and Preliminary observations:** Initial observation and handling of specimen should be performed carefully. While handling the specimen universal safety precautions should be observed at all times. Personal protective equipment like gloves and masks should be worn whenever necessary.

The acceptance of specimens includes the following:-

Documentation of essential data in a log book

Visual examination of the specimen for adequacy. Samples which do not meet the acceptance criteria should be rejected. It is always a good idea to define the rejection criteria. For example saliva is rejected when sputum sample is supposed to be collected. A well formed stool is not the proper sample for hanging drop preparation to look for darting motility of suspected *Vibrio cholera* bacteria.

### Analytical

Analytical phase includes the following:-

- (a) **Training of the staff:** The quality system is only as good as the staff who actually work with it. No matter how good the quality system is on paper, if the theory cannot be translated into practice, quality cannot be achieved. Training of the staff is essential to achieve the goals of the quality system. The training must include an understanding of the importance of quality. Post training support is also essential to ensure continued competence of the staff.
- (b) **Microscopic examination of specimen:** The microscopic examination of the clinical specimen is done to assess the presence of pathogenic bacteria, neutrophils etc. It may also be used to assess the suitability of the specimen for acceptance or rejection.
- (c) **Processing of specimen:** The proper processing of microbiology specimen includes the proper selection of culture media, maintaining the optimal



Notes

temperature and atmosphere of incubation and proper characterization of the isolated pathogen by appropriate biochemical reactions and antibiotic sensitivity testing.

- (d) **Monitoring and evaluation:** The laboratory management must develop and implement quality indicators to systematically monitor and evaluate laboratory’s contribution to the patient care. Assessment of quality through audits (Internal or External) is a must. The laboratory must participate in an External quality assurance program. It is also possible to do inter – laboratory comparisons of test results. Internal quality is also essential to evaluate the technician competence and the performance of automated equipments.

**Post - analytical**

- a) **Reporting of results:** Reports of microbiology culture results should be issued as soon as useful information becomes available. Each laboratory must establish those results that will be considered “Urgent” or “critical”. In addition some results may be considered as important but not necessarily urgent. For example when a pathogenic bacteria is observed in the direct microscopy examination of cerebro spinal fluid then this is to be considered as a critical result. The detection of metachromatic granules in a Gram positive bacilli on Albert’s stain is suggestive of *Corynebacterium diphtheria* and hence is considered as a critical result.
- b) **Analysis of results:** It is incumbent on the laboratory director to provide feedback to the clinician on some parameters of laboratory performance. Studies on the Turn around time (TAT) and anti microbial susceptibility patterns is helpful to the clinicians.

**Benefits of Quality assurance programs** include the following

- Production of quality products and reliable services.
- Motivation factor for the staff to work better.
- Creation of good reputation for the laboratory.
- Prevention of legal suits and associated complications



**INTEXT QUESTIONS 13.1**

1. Meeting pre-determined requirement of users is .....
2. Uniform standards of quality is developed by .....
3. Phases of quality assurance program are ....., ..... and .....
4. Training of staff is part of ..... phase of quality assurance program.



### WHAT YOU HAVE LEARNT

- Quality is meeting pre-determined requirements of user for a particular device.
- International standard organization, develops uniform standards for quality in manufacturing and service sectors.
- Quality Assurance has three phases namely pre-analytical, Analytical and post-analytical.
- Pre-analytical phase involves activities during specimen collection, of time of collection, quantity, collection devices and containers, Labelling of specimen, selection of culture media, transportation of specimen and transport media used.
- Analytical phase includes training of staff, microscopic examination of specimen, processing of specimen, monitoring and evaluation of laboratories.
- Post analytical phase includes reporting of results and analysis of results.
- Main benefit of Quality assurance program is to provide quality products and reliable services.



Notes



### TERMINAL QUESTIONS

1. Define quality.
2. Describe briefly the phases of Quality Assurance.
3. Enlist the benefits of Quality Assurance Program.



### ANSWERS TO INTEXT QUESTIONS

1. Quality
2. International Standard Organisation (ISO)
3. Pre-analytical, Analytical and post-analytical
4. Analytical