THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

MGIT CULTURE
Module 15: Quality assurance/quality indicators

Outline

- Definition of QA and QC
- QA plan in Pre-analytical phase
- QA plan in Analytical phase
- QA plan in Post Analytical phase
- Quality Indicator monitoring
- QC with laboratory data correlation
- Record keeping

Quality Assurance (QA)

Refers to a set of *systems* designed to continuously improve the reliability and efficiency of laboratory services.

This system includes quality control, external quality assessment, and quality improvement

Quality Control (QC)

Refers to the systematic internal monitoring of working practices, technical procedures, equipment and materials, including quality of reagents.

Quality assurance plan

Ensures the following are addressed

- General laboratory systems
- Pre-analytical Stage of testing
- Analytical stage of testing
- Post-analytical stage of testing

QC: General laboratory systems

- Laboratory arrangement
- Human resources (training health control)
- Laboratory equipment
- Collection and transport of specimens
- Handling of specimens
- Reagents and media
- Culture procedures
- Reporting of results

Laboratory arrangement

- Ensure that doors in the laboratory are always closed
- Work areas, equipment and supplies arranged for logical and efficient work flow
- Work areas should be clean
- Benches cleaned after each use with an appropriate disinfectant

Human Resource management

- Documented credentials for staff
- Orientation
- Training and competence assesment
- Sufficient staff to support workload
- Medical survielence

Pre-analytical systems

- Instructions to customers
  - Appropriate specimens
  - Collection, transport procedures
- Specimen reception
  - Documentation of specimen quality
  - Specimen rejection criteria
- Request forms
  - Filled with all the necessary information

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Analytical systems

- Standardized operating procedures (SOP)
  - Reviewed annually or more often as needed
  - Read ,understood and initialed by staff
- Equipment calibration
  - Thermometers
  - Pipettes
  - Timers

Analytical systems

- Quality control procedures and corrective actions
  - Test procedures
    - Microscopy
    - Processing and culture methods
    - Identification
  - Media and reagents
    - Sterility checks/performance characteristics
    - Labelling/storage (name, concentration, temperature)
    - Dated (received/prepared, in use, expired)
  - Equipment (also includes preventive maintenance)
    - Centrifuge
    - Incubator, water-baths, etc.
    - Safety cabinets
    - Refrigerators/freezers
    - Culture instruments

Analytical systems

Validation of new methods/procedures against the reference/gold standard for

- Sensitivity
- Specificity
- Positive predictive value
- Negative predictive value
- Turn-around time

Post-analytical systems

- Validation of test results
  - Review of results
- Routine monitoring of performance (performance indicators)
- Results audit
  - Monitoring of turn-around time for smear, culture, drug susceptibility results
  - Procedure for the delivery of timely positive results

Importance of performance indicators

- Establishes “normal” laboratory values/baseline for a given population or geographical region
- Identifies potential problems with pre-analytical, analytical and post-analytical phase of testing
- Lends credibility to laboratory results
- Ensures optimization of laboratory methods
- Identifies potential training needs

Approach to evaluating performance indicators

- Direct observation of microbiologists
- Review of the following
  - Laboratory Information System (LIMS)
  - AFB microscopy register
  - Culture worksheets
  - Final results
  - EQA or other PT results
  - Procedure manuals

Performance indicators

- Recovery rate of MTB
  - Percentage of MTB / total number of specimens
- Contamination rate

- Correlation between positive smears and positive cultures
- Percentage of negative smears resulting in positive cultures
- Turn-around time
- Proficiency testing performance (AFB microscopy, culture, drug susceptibility testing)

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Importance of monitoring MTB recovery rate

- Establishes a baseline for a given population or geographical area
- Assists in identifying potential false-positive or false-negative cultures (MTB)

Recovery rate of MTB

- Expectation: Population/geographical region/facility dependent/seasonal

- Increases may be due to:
  - Shift in patient population
  - Cross contamination/false positives
  - Contaminated reagents
  - Specimens contaminated during collection

- Decreases may be due to:
  - Shift in patient population
  - Problems with specimen quality
  - Problems with specimen processing or use of incompatible processing methods
  - Problems with equipment or media
  - Increase in contamination

Importance of monitoring contamination rates

- May reflect problems with pre-analytical phase of testing
- May reflect the technical proficiency of the laboratory
- May identify training needs (field and laboratory)
- Should ideally be stratified by media type

Contamination rate

- Expectation: 3–5% for solid media and specimens; 12% liquid medium

- Increases (>5% LJ; >12% liquid medium) may be due to:
  - Incomplete decontamination
  - Suboptimal reagents
  - Improper use of antibiotics (liquid)
  - Improper collection, storage or transport
  - Equipment (BSC, incubators, centrifuge)
  - Need for re-training staff
  - Changes in season

- Decreases (<3%) may be due to:
  - Harsh decontamination procedures
  - Stringent reagents

Importance of monitoring smear positivity rate, distribution of smear positivity grade, and smear and culture correlation

- Establishes a baseline for a given facility, population or geographical region
- Represents the type of specimens submitted (diagnostic vs follow-up)
- Identifies potential problems with microscopy
- Identifies potential problems with specimen processing or culture methods

Smear positivity rate

- Expectation: Population/geographical region/facility dependent

- Increases may be due to:
  - Shift in patient population
  - Cross contamination
  - Use of suboptimal slides
  - Use of contaminated or suboptimal reagents
  - Technical errors

- Decreases may be due to:
  - Shift in patient population
  - Suboptimal specimens submitted to the laboratory
  - Inadequate staining and evaluation of slides
  - Problems with equipment
  - Technical errors

Correlation between positive smear and positive culture

- Expectation: Majority
- Less than 95% may be due to:
  - Specimens submitted from patients on treatment (initial vs follow-up)
  - Reporting of false-positive smears
  - Excessive decontamination procedures
  - Stringent reagents
  - Problems with media
  - Problems with equipment
  - Excessive contamination

Proportion of smear negative/culture positives

- Expectation: Population/geographical region/facility dependent
- Increases may be due to:
  - Shift in patient population
  - Suboptimal staining reagents
  - Inadequate smear reading by staff
  - Reporting of false-positive cultures

Importance of monitoring turn-around time

- Critical to patient management
- Breaks the chain of transmission
- Ensures laboratory procedures are optimized
- Assists in identifying challenges with laboratory workflow algorithms, information systems and reporting systems

Turn-around time of results

- Expectation:
  - AFB smears: within 48 hours of specimen receipt of 80% of specimens
  - ID: laboratory/method dependent
  - DST: laboratory/method dependent

- Delays may be attributed to:
  - Batching specimens or isolates
  - Use of conventional ID and DST methods
  - Suboptimal use of technology
  - Use of National or other Reference Laboratory
  - Transport delays
  - Inadequate provision of supplies
  - Lack of communication between client and laboratory

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Limitations to monitoring performance

- Difficult to evaluate “real time” performance
  - Delays in specimen or isolate transport
  - Lengthy incubation periods
  - Conventional methods used for identification and susceptibility testing
- Human resource constraints
- Paper-based laboratory records
- Communication hurdles
- PT-bias

Summary

- A quality assurance programme consists of three components: quality control (QC), external quality assessment (EQA), and quality improvement (QI)
- Quality control should be practical and comprehensive
- Quality control is the responsibility of all laboratory personnel
- Monitoring performance helps to establish "normal" laboratory values, lends credibility to laboratory results, and helps to identify training needs among staff

Acknowledgement

References

- *Corrective and preventive action document. SANAS (South African National Accreditation System)*