THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Training on EQA and National TB Laboratory Network

Module 1: Overview of EQA

(Date)

Uganda Supranational Reference Laboratory

Content Outline

- What is EQA?
- Benefits of EQA
- Types of EQA methods
- Management of EQA

External Quality Assessment (EQA)

- **A system for objectively checking the laboratory's performance using an external agency or facility**
- Ensures customers (physicians, patients and health authorities) that the laboratory can produce reliable results
- An indispensable part of a laboratory quality management system

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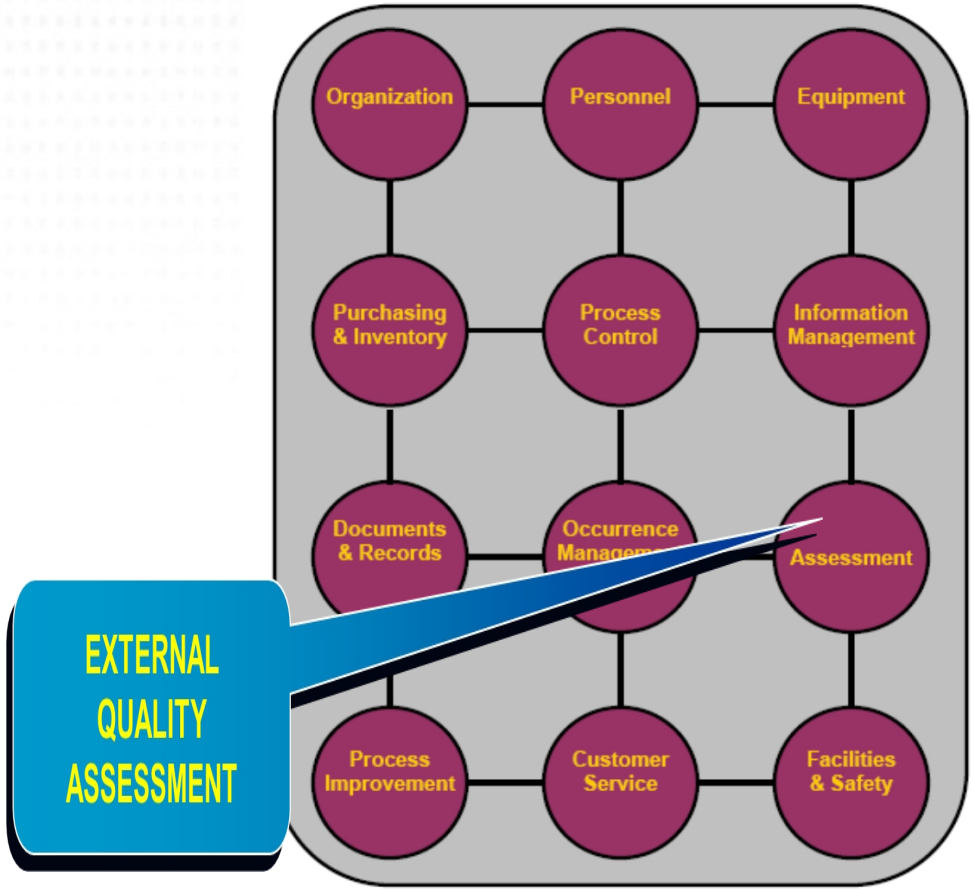
EQA BENEFITS

- allows comparison of performance and results among different test sites;
- provides early warning for systematic problems associated with kits or operations;
- provides objective evidence of testing quality;
- indicates areas that need improvement;
- identifies training needs.

The Quality System

Quality System Essentials (QSE)

Set of coordinated activities that function as building blocks for quality management



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ISO 15189:2012 Requirements Regarding EQA

- The laboratory shall participate in interlaboratory comparisons such as an EQA programme appropriate to the examination and interpretation of examination results.
- The lab management shall monitor the results of EQA and participate in the implementation of corrective actions when predetermined criteria are not fulfilled.

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Methods of EQA

- Proficiency testing- External Provider sends samples for testing to laboratories and results are analysed, compared and reported to the laboratories.
- Rechecking- Slide read /samples tested are rechecked by a higher Level lab.
- On-sites evaluation- external evaluation of laboratory on site using a standard checklist.

PROFICIENCY TESTING

- Laboratories receive samples from a PT Provider. The provider may be an organization (non-profit or for profit) formed specifically to provide PT or reference laboratories.
- Samples are provided at regular intervals

PROFICIENCY TESTING

- Laboratories will test PT samples and return results to the PT provider. Results are evaluated, analysed and laboratories are provided with feedback about their performance.
- Participants use this feedback to take corrective actions for improvement where necessary

Panel Testing

ADVANTAGES	DISADVANTAGES:
• Low workload for a peripheral center • Improves laboratory credibility • Rapid response countrywide possible • Use of stained and unstained smears can help to identify the source of a problem • May lead to identification of faulty	• Does not measure routine performance • High workload for NRL

Panel Testing: Indications for Use

- Minimal first step for EQA with limited resources
- Rapid assessment of gross deficiencies
- Evaluates proficiency of laboratory technicians prior to and following training
- A tool during problem-oriented supervision

Rechecking

- This method is commonly used for AFB smear microscopy; Slides that were read by the peripheral laboratory are rechecked by a higher level laboratory.
- Slides for rechecking must be collected randomly to allow for the accuracy of the original result to be evaluated.

Rechecking

- Rechecking must be based upon statistical consideration e.g. the most commonly used LQAS method
- When discrepancies occur there should be procedures in place to resolve them.
- The outcome of rechecking must be analysed for effectiveness with timely feedback and corrective measure initiated for labs identified with errors.

Blinded Rechecking

ADVANTAGES	DISADVANTAGES
• Low workload for a peripheral laboratory • Motivates to improve daily performance • Reflects reality of routine performance	• Higher workload for a higher level center • Needs close adherence to elaborated procedures • Can not be used with very low positivity rates

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Blinded Rechecking: Indication for use

- The best method for evaluating lab performance
- Countrywide coverage
- Ongoing and permanent

On-site Evaluation

- provides information for internal process improvement
- assists the laboratory in collection information for planning and implementation of training, monitoring and corrective actions.

On-Site Supervision

ADVANTAGES	DISADVANTAGES
• Direct personal contact • Motivating to staff • Observation of actual work • Identifies causes of errors • Permits verification of equipment quality and function	• Usually poor coverage • Labor intensive • Costly • Needs very good supervisors

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On-site Supervision

Indications for use

- Complementary to rechecking and panel testing for constructive feedback and problem solving
- Implementation and monitoring of quality improvement measures
- Data collection and flow of information among laboratory levels

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Situational Analysis: How to Identify the Most Feasible EQA method(s) For a Country? (I)

COUNTRY A:

- Populous; vast territory
- High burden of TB
- Several hundreds of geographically dispersed peripheral laboratories
- Intermediate laboratories' infrastructure is not well developed; many intermediate labs experience lack of staff
- NRL is well equipped and staffed

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Situational Analysis: How to Identify the Most Feasible EQA method(s) For a Country? (II)

COUNTRY B:

- Less populated (compared to Country A); compact territory
- High burden of TB
- Smear microscopy laboratory network: one microscopy center for 100 000 population
- High to medium positivity rates
- Well developed structure of intermediate laboratories, supervised by NRL
- Lack / rotation of staff is a typical problem for many laboratories

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Situational Analysis: How to Identify the Most Feasible EQA method(s) For a Country? (III)

COUNTRY C:

- Populous country
- Low burden of TB
- Only few laboratories dealing with sputum smear microscopy
- Low volume sputum smear examinations; very low positivity rates
- AFB smear-positive specimens are rechecked at NRL

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Management of EQA

- All laboratories need procedures and tools for managing the EQA processes.
- The procedures and schedules should always be adhered to .

Assessment

- What is EQA?
- To which QSE does external quality assessment belong?
- List the different methods of EQA

SUMMARY

- EQA is a system for objectively checking the laboratory's performance using an external agency or facility
- All laboratories should participate in an EQA process for all tests performed, whenever possible.
- EQA should not be punitive.
- EQA is a critical element of laboratory quality management system. Therefore it is a requirement for accreditation

REFERENCES

- WHO Laboratory Quality Management System Handbook
- John, R. (1999). External Quality Assessment for AFB Smear Microscopy. *Public Health Practice Program Office Centers for Disease Control and Prevention, Rosemary Humes. Association of Public Health Laboratories, 17.*
- GLI Training package on EQA overview & Planning

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Acknowledgments