Welcome to the Assessments and External Quality Assurance Module
Module Objectives

At the end of this module, participants will be able to:

- Develop a process to prepare your laboratory staff for an external audit;
- Plan and manage an internal audit;
- Discuss how to use results from a laboratory audit;
- Advocate for the importance of taking corrective actions.
- Explain the purpose of External Quality Assurance (EQA);
- Describe what an EQA panel is;
- Discuss the advantages and disadvantages of EQA:
- Discuss Data analysis;
- Discuss how daily operating procedures provide quality service
- Identify any changes needed to maintain quality service
- Describe how to adjust quality system in response to external and internal influences
The Quality Management System
Activity

The purpose of this activity is to discuss the main elements of organizing an audit based on the experience of the participants.

**Duration:** 10 minutes

“You are the quality manager in your laboratory and you want to organize an internal audit.”

**What steps will you take?**
Assessment is determining the effectiveness of a laboratory’s quality management system through internal and external audits, and evaluation of performance in an external quality assessment (EQA) program.

“Laboratory Management shall review the quality Management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care” – ISO15189:2012

Process Improvement institutes a program for helping to guarantee continual improvement in the laboratory quality over time.
What is an Assessment?

- Systematic examination of some part (or all) of the quality management system;
- Conformance with requirements;
- Questions asked
- According to ISO standards, assessment = audit
Why Perform an Assessment / Audit

- A laboratory needs the information from an audit to understand how it is performing in terms of quality management.

- Audits help to do the following:
  - Planning and implementing the quality system;
  - Examining the effectiveness of the quality system;
  - Amending any faults that are identified;
  - Working toward continuous improvement.
There are two types of assessments:

1. **Internal Audit**
   - Performed in-house. Staff working on one area conduct assessments on another area in the same laboratory. Easily assists to understand how the laboratory is performing and how well staff comply with policy requirements.

2. **External Audit**
   - Agencies or groups from outside the laboratory come to the facility and conduct the assessments. These audits may also be used for the purpose of accreditation, certification, or licensure.
What Information to gather during Audits

Information that is collected and reviewed during audits is as follows:

- Processes and operating procedures
- Staff competence and training
- Equipment
- Environment
- Handling of samples
- Quality control and verification of results
- Recording and reporting practices.
Internal Audits & Benefits

- Lab looks at its own procedures & processes
- Perform audits anytime and on a regular basis
- Less Costs involved

An internal audit can help the laboratory to:

- Prepare for an external audit;
- Increase staff awareness of quality system requirements;
- Identify gaps or noncompliance that need to be corrected;
- Understand where preventive or corrective action is needed;
- Identify areas where education or training needs to occur;
- Determine if the laboratory is meeting its own quality standards.
Responsibilities of Laboratory Director

- Laboratory Director determines the internal auditing policy.
- Laboratory Director supports corrective action measures.
- Quality Manager assigns responsibility for the internal audit program.

Internal audit outcomes.
Responsibilities of Quality Manager

Quality Manager establishes and maintains an internal audit system

- develop schedule
- select & train auditors
- manage corrective actions
- report to management
- report audit outcomes
- coordinate the audit process
ISO Standard Requirements

Under ISO, internal audits are required and the standard states the following:

- The laboratory must have an audit program;
- The auditors should be independent of the activity;
- Audits must be documented and reports retained;
- Results must be reported to management for review;
- Problems identified in the audits must be promptly addressed and appropriate actions taken.

Can I audit my own work?

PREFERABLY NOT
Using the PDCA Model in the Audit Process

**ESTABLISH THE AUDIT PROGRAMME**
- Objectives and extent
- Responsibilities & Resources
- Procedures

**INITIATE THE AUDIT**
- Appoint the audit team leader
- Define the audit objectives, scope and criteria
- Establish initial contact with the auditee

**CONDUCT DOCUMENT REVIEW**
- Review relevant management system documents and include records
- Determine document adequacy with respect to audit criteria

**PREPARE FOR ON-SITE ACTIVITIES**
- Prepare the audit plan
- Assign work to the audit team
- Prepare work documents

Source: CLAS: Internal Auditing of Laboratory Quality Systems
Using the PDCA Model in the Audit Process (continued...)

PREPARE, APPROVE AND DISTRIBUTE AUDIT REPORT
- Prepare the audit report
- Approve and distribute the audit report

CONDUCT ON SITE ACTIVITIES
- Conduct opening meeting
- Ensure effective communication during the audit
- Define roles and responsibilities
- Collect and verify information
- Generate audit findings
- Prepare audit conclusions
- Conduct a closing meeting

COMPLETE THE AUDIT
- Identify needs for corrective and preventive actions and implement
- Identify opportunities for improvement and implement

AUDIT FOLLOW UP
- Monitor and review

CHECK

ACT
Critical Skills for Auditors

1. Attention to detail
2. Know standards & Organisational Policies
3. Trained
4. Tactful
5. Technical/Quality Management Proficiency
6. Good Communication skills
Audits lead to Actions

- Audits done to advance the process of continual improvement in the Laboratory by identifying opportunities for improvement (OFI).
- Audits must lead to actions.
- Preventive and corrective actions are steps taken to improve a process or to correct a problem and need to be carried out within an agreed time.
- Keep a record of OFIs as well as all actions that are taken.
- The Quality Manager is responsible for starting actions.
Problem-solving

- If at any time, the cause of the problem is not easily identified, a team to perform problem-solving should be formed and the following should be done:
  - Look for root causes;
  - Recommend the appropriate corrective action;
  - Execute the actions decided upon;
  - Check to see if the corrective actions are effectual;
  - Monitor the procedures over time.

- By recording all actions and findings during the monitoring phase, the laboratory will be able to learn from these activities.
Continuous Improvement

Monitoring & Evaluation
- Customer satisfaction
- Quality control
- Proficiency testing
- Audits
External Quality Assurance / Assessment Overview

Module Presented By: Mahlatse Maleka
Objectives

At the end of this module, participants will be able to:

- Definition and Purpose of EQA
- Why is there a need for EQA
- What is an EQA panel
- Advantages and disadvantages
- EQA in the lab
- Data analysis
What is EQA?

- EQA is the objective assessment of a laboratory's operations and performance by an external, independent agency or personnel.
- It is designed to test the processes in a laboratory from receipt of samples to resulting.
- Essential tool for monitoring quality in the laboratory.
- **EQA is not there to:**
  - make the laboratory look bad
  - be used as a discipline tool for staff
  - catch out staff/labs in their testing
  - give special treatment and be done by the “best” staff member or lab manager
  - be tested over and over until the “right” results are obtained.
Why is there a need for EQA?

If your quality procedures are in place, why is there a need for EQA?

- Required by ISO standards
- Opportunity to “test” your laboratory’s total operations – from receiving samples to sending out results
- Comparison of performance & results among different labs
- Early warning for systematic problems associated with kits or operations
- Objective evidence of testing quality
- Highlights areas that need improvement
- Identifies training needs
Types of EQA

EQA Methods

- Proficiency Testing
- Rechecking Retesting
- On-site Evaluation
What should you look at when choosing an EQA?

What is an EQA panel?

- An EQA panel consists of samples with unknown status – in some EQA schemes a clinical history is provided as part of the panel.
- Most panels contain one or more samples designed to challenge the limits of detection of assays – in this manner they are designed to almost serve as a “problem” sample.
What is an EQA panel?

- Different EQA programs have different types of panels, but there are a few factors that should be common to any panel:
  - Samples should have the same matrix as patient specimens, (including viscosity, turbidity, composition, and colour)
  - Be simple to use
  - Be clinically significant
EQA samples are identical to clinical samples in one major aspect – the lab does not know what the result is!
### Advantages and Disadvantages

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<th>Advantages</th>
<th>Disadvantages</th>
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<td>- Large number of participants – locally and internationally</td>
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<td>- Identifies technical needs for new equipment and methods</td>
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<td>- Assesses staff competency and assists in improving staff confidence</td>
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<td>- Evaluation over time provides information on improvements made or long-term trends</td>
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<td>- Samples mimic patient samples in clinical significance and matrix</td>
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<td>- Often little participant input on EQA design</td>
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<td>- Practical problems with specimen transport</td>
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<td>- Slow turnaround time</td>
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<td>- Increased costs for testing and evaluation</td>
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<tr>
<td>- Depending on EQA, samples are not always able to mimic patient samples in terms of matrix</td>
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Choosing an EQA program to participate in is determined by two major factors:

- **BENEFITS**
- **COST**
EQA Management Process in the laboratory

- Handle and analyse EQA samples
- Treat EQA samples same as patient
- Monitor and maintain records
- Investigate deficiencies
- Manage corrective action efforts
- Communicate outcomes
Managing EQA: Handling Samples

- All EQA/PT samples should be treated as patient samples and booked in for testing alongside routine samples.
- This ensures that they:
  - Follow the same testing process as routine/clinical samples.
  - They are captured on DISA and form part of budgeting.
- Do not keep testing EQA samples until a “right” result is obtained.
Managing EQA: Assign Testing Responsibilities

- Expected panels for the year are allocated to staff in such a manner that each person involved in the testing has a chance to complete an EQA panel during the year.
- This roster is based on the testing responsibilities of staff.
- No preference is given to “more experienced” staff.
- EQA results are used as competency/proficiency testing for staff.
- Each staff member is responsible for testing, results submission and report analysis.
Managing EQA: Multiple Datasets

- Depending on the assay covered by the EQA panel, multiple datasets are submitted for each panel (if the scheme will accommodate it)
- Similarly, where multiple assays are used for a specific test method, at least one dataset is submitted for each technology
- Can also be a helpful tool in determining level of agreement within lab
Managing EQA: Acting on Results

- Staff must be able to interpret reports and identify possible problems
- Where required, do:
  - Root cause analysis to identify cause of problem
  - Corrective action
  - Preventative action
- Discuss EQA in laboratory meetings – encourage sharing of experiences and ideas
EQA Performance Problems

If the laboratory performs poorly on EQA, the problems may lie anywhere along the path of workflow. All aspects of the process will need to be checked.

- Pre-examination
- Examination
- Post-examination
Data Analysis: EQA Reports

- EQA reports vary in complexity – often related to the type of test they were used for
- Ensure that all staff responsible for an EQA know how to interpret the reports – this includes identifying errors and basic root cause analysis
- Don’t skip to the bottom line and only look at the final score
- Most importantly…**DON’T PANIC**
Data Analysis: Root Cause Analysis

- Incorrect results don’t always mean that the lab has made a mistake
- Different errors have different degrees of severity and will elicit different corrective actions
- Evaluate kind of error – first time or a problem that has been encountered before
- Look at IQC data if available
- Identify cause before taking action
- Keep assay parameters in mind when reviewing EQS
Data Analysis: Common Problems

Problem
- False positive
- False negative
- Incorrect quantitative value

Probable causes
- Samples swapped during testing
- Contamination during testing
- Transcription error
- Reagent and/or kit problems
- Equipment failure or problems
Don’t always assume that your assay was inadequate and that the EQA is 100% correct
Don’t immediately start changing assay parameters – your assay must still be “clinically correct” for testing
Don’t single out staff and blame them for poor performance
Activity

Read the scenario and then jot down some answers to the question.

**Duration:** 10 minutes (3 minutes for answers & 7 minutes discussion)

The lab participated in a Bacteriology EQA. Out of 4 samples received, one was reported as no growth. In the final report, it’s noted that the no growth was supposed to be reported as Bacteroides fragilis. According to the commentary, 86% of participants recorded an acceptable result for this sample, and 14% recorded an unacceptable response.

**What should the lab do about the incorrect result?**
Read the scenario and then jot down some answers to the question.

**Duration**: 10 minutes (3 minutes for answers & 7 minutes discussion)

The lab tested a panel of 10 serum samples for HIV Serology. Out of 10 samples, they had 9 positive and 1 negative results. Upon inspection, it’s found that one of the positive results is incorrect and is in fact negative. The lab therefore had a false positive result.

**What should the lab do about the false positive result?**
Assessment is important in monitoring the effectiveness of the laboratory quality management system.

Both external and internal audits yield useful information.

An outcome of assessment is finding root causes of problems and taking corrective actions.

All laboratories should establish an internal audit program. Conducted on a regular basis, it will provide information for continual improvement.

Problems become opportunities for improvement.
EQA should be a point of pride for laboratories;
It is an opportunity to empower staff;
Provides a platform on which performance can be measured internationally;
EQA is not there to “catch out” laboratories;
EQA participation instills confidence in the operation of a lab and the results it produces;
Also empowers staff and gives them a measurable way of testing their individual proficiency.
References

- WHO: Quality Management Toolkit
- Guidance for Laboratory Quality Manuals (Ontario Laboratory Accreditation Division)
- Exploring the Medical Laboratory Quality Toolbox-A by Michael Noble
Wrap Up

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- Plan and manage an internal audit;
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Questions