Laboratory Management of a Quality System

Module 7: Occurrence Management Internal & External Assessments

ACKNOWLEDGEMENT

- Ministry of Health and Social Welfare – Tanzania
- Muhimbili University of Health and Allied Sciences
- World Bank
- ECSA- HC

Learning Objectives

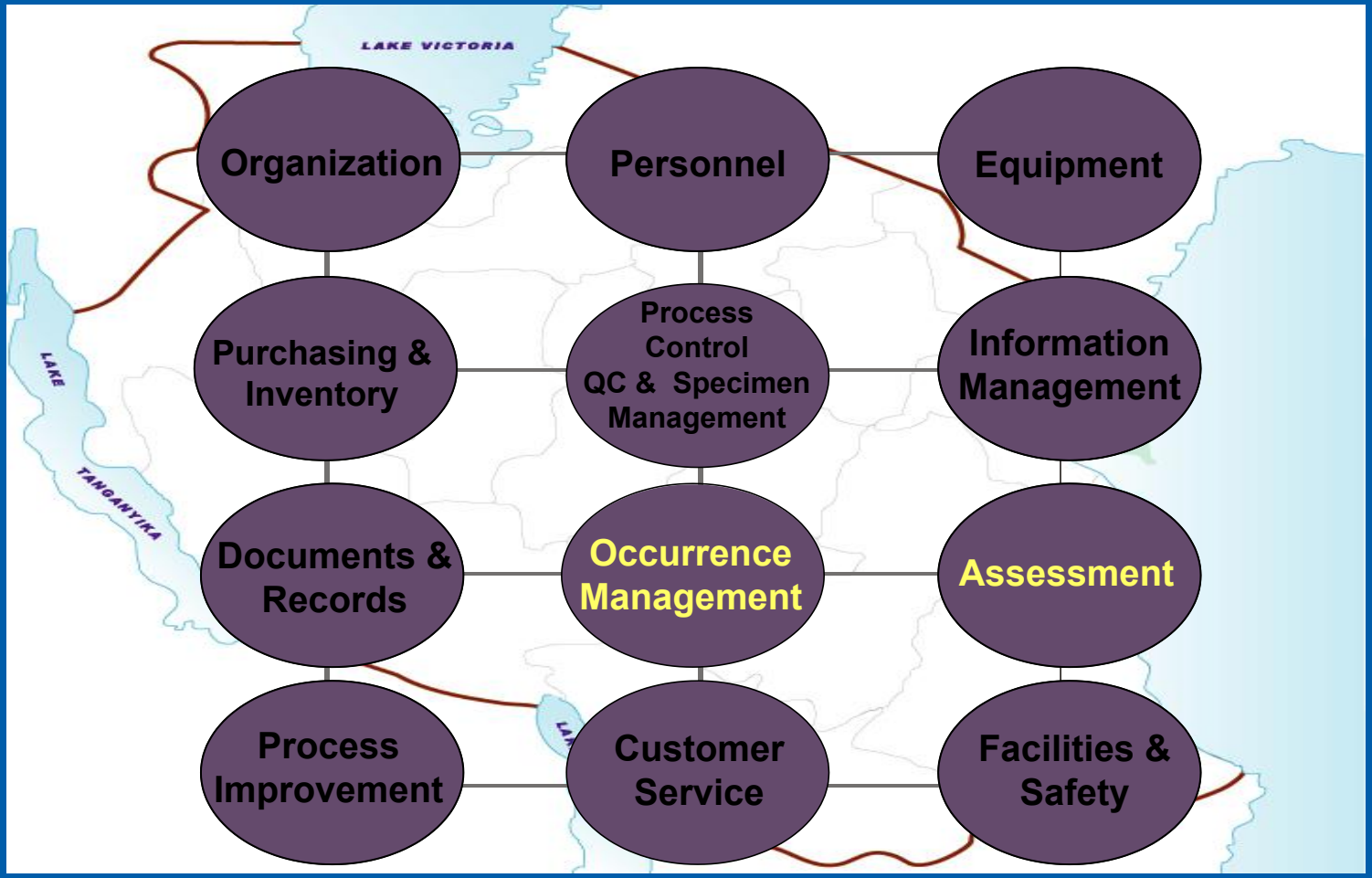
- Describe how to set up an effective occurrence management system
- Provide operational and quality benchmarks
  for monitoring lab operations
- Develop audit tools for conducting internal audits
- Describe the components and implementation of an effective external quality assurance program, including proficiency testing

Today's Agenda

The Quality System

- Occurrence Management
- Assessment
  - Internal Audits
  - External Assessment
- Module Summary

The Quality System



Monitoring Laboratory Quality

Monitoring laboratory operations on a routine basis is essential in order to maintain control, and develop a high quality of service

- The effectiveness of a Quality Laboratory System is measured against benchmarks

The Quality Manager's (QM) Role

- Plans and organizes the quality processes and audit schedules
- Assures the institution of corrective and preventive actions when deficiencies or opportunities for improvement are noted
- Verifies corrective and preventive action is documented and carried out

What questions do you so far?

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What is an Occurrence?

- An occurrence is any incident involving laboratory processes for any laboratory specimen
  - Complaints
  - Process deviations
  - Errors and accidents
  - Instrument problems
- Occurrences are detected by:
  - External customer complaints
  - Employee reporting
  - Management review

Occurrence Management System

- A process for documenting and addressing problems that occur in the laboratory
  - Log occurrence
  - Investigate occurrence
  - Take corrective action
  - Report results / trends
  - Prioritize problems and assign to a process improvement (PI) team
  - Conduct focused audit to ensure resolution

Occurrence Logs

- Occurrence logs are used to capture:
  - Who was involved?
  - What occurred?
  - When did it occur?
  - Where in the laboratory proces did the problem occur?

Occurrence Investigation

- Management will:
  - Review and evaluate the data on the occurrence
  - Determine how the event occurred including any contributing factors
  - Determine the root cause by evaluating system or people issues (knowledge and behavior)

Occurrence Corrective Action

- Manager will document:
  - Remedial actions taken to solve immediate problem
  - Corrective actions to be taken to solve system or people issues identified
  - Audit the system later in time to assure stability of the fix

Occurrence Reporting (Data)

- Occurrence documentation is part of quality reporting system
- Occurrence data and trends are used to identify problems for process improvement activities
  - Management prioritizes the problems
  - Management assigns the process improvement (PI) team to develop solutions

Occurrence Audits

- Occurrence data must be monitored with a focused audit after intervention to assure the fix is stable

Tips: Occurrence Management

- Develop and promote a no-blame culture
- Focus on the system and not the people
- View every documented situation as an opportunity for improvement

Case Study

- Doctor Cohen called and said

  the WBC report on his patient was incorrect yesterday. It did not match the clinical picture.

  How would you handle th e?

What questions do you have on occurrence management?

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The Role of Assessments

- Assessments are a major component of the Quality Laboratory Systems framework
- Assessments are a systematic and ongoing examination of processes within the quality system

Assessments / Audits

- Internal Audits
  - Periodically conducted to assess if management has implemented adequate and effective controls of laboratory operations and quality systems
  - Define and report on quality indicators/monitors with benchmarks
- External Assessments
  - Used to identify systematic error or methodological problems
  - Usually performed by an outside organization

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Internal audits

What to Audit

- High volume procedures
- High risk procedures
- Problem-prone processes
- Issues highlighted in occurrence documentation

Internal Audit Methods

- Tracer Methodology
  - Follow the path of the workflow for an activity from the beginning to the end
- Confirmation/Corroboration
  - Asking employees or others to verify that collected information is accurate
- Sampling
  - Selecting a statistically valid smaller number of records to review

Example: Internal Audit

- Process to be audited
  - Blood collection for transfusion testing
- Methodology
  - Tracer Methodology

Example: Internal Audit (Continued)

- Audit Steps
  - Examine the request slip and tube labels for complete information
  - Review the SOP for accuracy and completeness
  - Compare the SOP with performance by observing blood drawn and labeled in multiple areas
  - Check final labeled tubes for criteria defined in SOP
  - Review data on specimen rejections in Blood Bank
  - Examine training and competency assessment records on phlebotomists

Exercise

- Create an internal audit (assessment) list for your laboratory
- For every item on your audit list, identify what audit method you will use

Quality System Monitors

- What is a monitor?
  - The item that will be benchmarked and measured as an indicator of quality
  - Good monitors involve information easy to collect and relevant to your lab operations
- Why have monitors?
  - If you don't measure it, it will never improve

What questions do you have about internal audits thus far?

Example Quality System Monitors

- Phlebotomy wait time
- Specimen rejection rate
- Phlebotomy competency
- Turnaround time (TAT)
- Technologist competenc
- Quality control failures
- Corrected reports

Example Quality System Monitors (Continued)

- Internal and external assessment findings
- Critical result notification
- Critical supply inventory levels

Exercise

- Identify at least one monitor you could use for each item on the audit list your created earlier.

What questions do you have on internal audits and monitors?

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External Quality Assessment (EQA)

- A system for objectively checking the laboratory's performance using an external agency or facility
- Used to supplement internal audits to identify opportunities for process and quality improvement

EQA / Inter-Lab Comparison Benefits

- Allows inter-lab comparison of performance
- Provides objective evidence of laboratory quality
- Serves as an early warning system and an indicator for focusing improvement efforts
- Identifies systematic reagent/kit problems
- Identifies training needs
- Source of continuing education

EQA Comparison Methods Overview

Proficiency Testing

Re-checking / Re-testing samples exchange

3rd Party On-site Evaluation

EQA On-Site Evaluation Method

Proficiency Testing

Re-checking / Re-testing samples exchange

3rd Party On-site Evaluation

On-Site Evaluations /Supervision

- Define the standards to be used in evaluating the laboratory
  - For example: facilities, quality control, procedure manual, specimen management, and personnel)
- Develop checklist of items to check on the evaluation and define tracer method to use
- Third-party quality officer evaluates the laboratory and produces an evaluation report
- Evaluated laboratory must respond with documentation to all deficiencies

On-Site Evaluations /Supervision

Uses:

- Direct observation
- Review QC & Documentation
- Administer individual proficiency testing
- Collect & compare data from multiple sites
- Opportunity for mentoring and evaluation of other programs

On-Site Evaluations / Supervision

Limitations:

- Evaluators must be trained in consistent observation
- Checklists must be developed

Regulatory Inspection

- Health Laboratory Board
- All Labs subject to Law
  - Standards
  - Checklist
  - Sanctions –Withdrawal of License

EQA Proficiency Testing Method

- Proficiency Testing

Re-checking / Re-testing samples exchange

3rd Party On-site Evaluation

EQA Proficiency Testing

- ISO Definition (guide 2:1996)
  - Determination of laboratory testing performance by means of inter-laboratory comparisons.
- CLSI Definition
  - A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others.

EQA Proficiency Testing (Continued)

- External proficiency testing program (e.g. EQAS, SANAS, CDC)
- Internally stabilized PT samples
- Alternative assessment mechanism – use previously analyzed specimen as blind sample or split sample analysis

EQA Proficiency Testing Process

- Central organization sends out challenge specimens for testing
- Laboratories analyze specimens, return results to central organization
- Results evaluated, laboratories sent scores, performance report
- Laboratories take appropriate corrective actions and document

EQA Proficiency Testing

Uses

- Most common form of EQA
- Development of specimen panels by the National/Zonal Reference Lab
- Easiest type of program to implement where serum-based tests are performed

Limitations

- Usually involves only a few specimens
- Test results may not represent routine test performance
- Preparing and distributing samples significant effort

EQA Blinded Rechecking

Proficiency Testing

Re-checking / Re-testing samples exchange

3rd Party On-site Evaluation

EQA Blinded Rechecking

- Uses
  - Forwarding a selected sample of tests for rechecking to assess the quality of testing
  - Best utilized in high-volume settings
- Limitations
  - Must develop a systematic sampling method to avoid bias in selecting samples for referral
  - Requires retesting to be done on a high percentage of samples
  - Practicality limited by lack of capacity at NRL/Zonal and excessive delays

Evaluation of EQA Reports

- Where are the problems?
  - Pre-Analytic
    - Specimen compromised during preparation, transport, or after receipt by improper storage or handling
  - Analytic
    - Reagents, instruments, methods, calibration
    - Calculation
    - Competency of Staff*

Evaluation of EQA Reports (Continued)

- Where are the problems?
  - Post-analytic
    - Report format
    - Interpretation
  - Data
    - Clerical/transcription error

EQA Documentation

- Establish written procedures for:
  - Handling of samples
  - Analysis of sample
  - Recording of results on report forms
  - Verification of clerical accuracy
  - Use of statistical tools
  - Handling corrective actions

What questions do you have on external assessments?

Activity

- Work in pairs
- Identify possible inter-laboratory evaluations for your laboratory. Then:
  - Define the EQA method you will use and the i standards to be used
  - Develop a checklist of items to be checked on evaluation and define tracer method to used
  - Identify what procedures need to be developed to support the evaluation

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Any questions on Occurrence Management or Internal and External Assessments?

Thank you