KCRI Kilimanjaro Clinical Research Institute

Kilimanjaro Clinical Research Institute (KCRI)

PANDORA: Laboratory quality control in low and middle income countries

Quality management - Auditing

22 October 2020

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Quality Management - Auditing

Learning objectives

- Understand the concept of Auditing in Laboratory Quality management
- Understand the kinds of auditing in laboratories
- Understand the areas to be audited in the laboratories

What is an Audit

The ISO 9000:2005definition

"a systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which required criteria are fulfilled"

What is an Audit

A GCP (ICH-GCP 1.6) definition

"a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data recorded, analysed and accurately reported according to the protocol, sponsor's SOPs, GCP and the applicable regulatory requirements"

Why perform an audit?

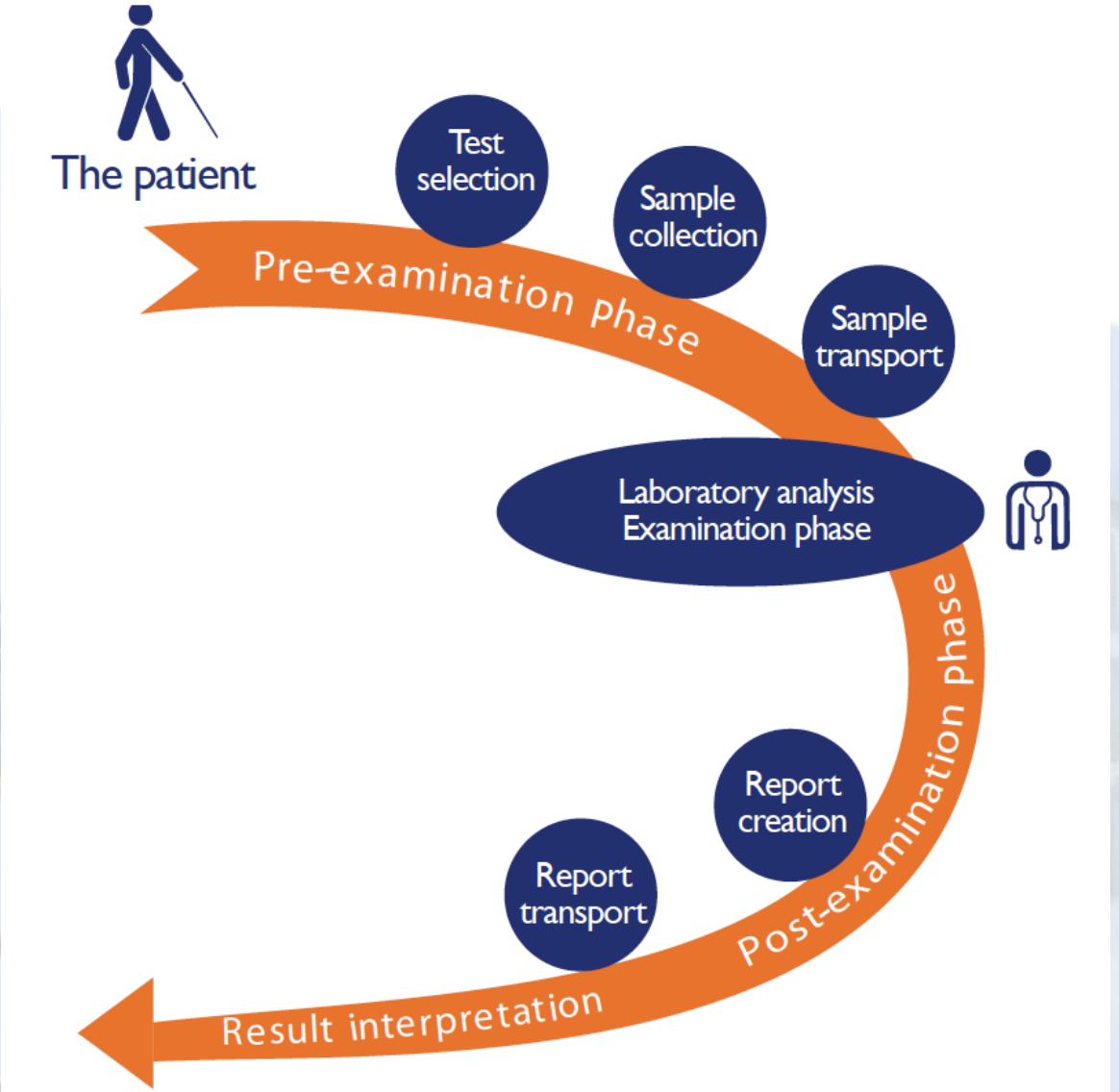
For the purpose of accreditation, certification or licensure – **External audit**	• *conducted by groups or agencies from outside the laboratories*
Performance of the laboratory and whether it is in compliance with policy requirements - **Internal audit**	• *staff working in one area of the lab conduct audits on another area of the same laboratory*

An audit, allows the laboratory to understand how well it is performing when compared to a benchmark or standard.

This information about its performance is important for:

- planning and implementing the quality system
- monitoring effectiveness of the quality system
- correcting any deficiencies that are identified
- working toward continuous improvement

Audits should include the **evaluation of steps** in the whole **laboratory path of workflow**. They should be able to **detect problems** throughout the entire process.



Adopted from Laboratory quality management system: handbook

Auditing

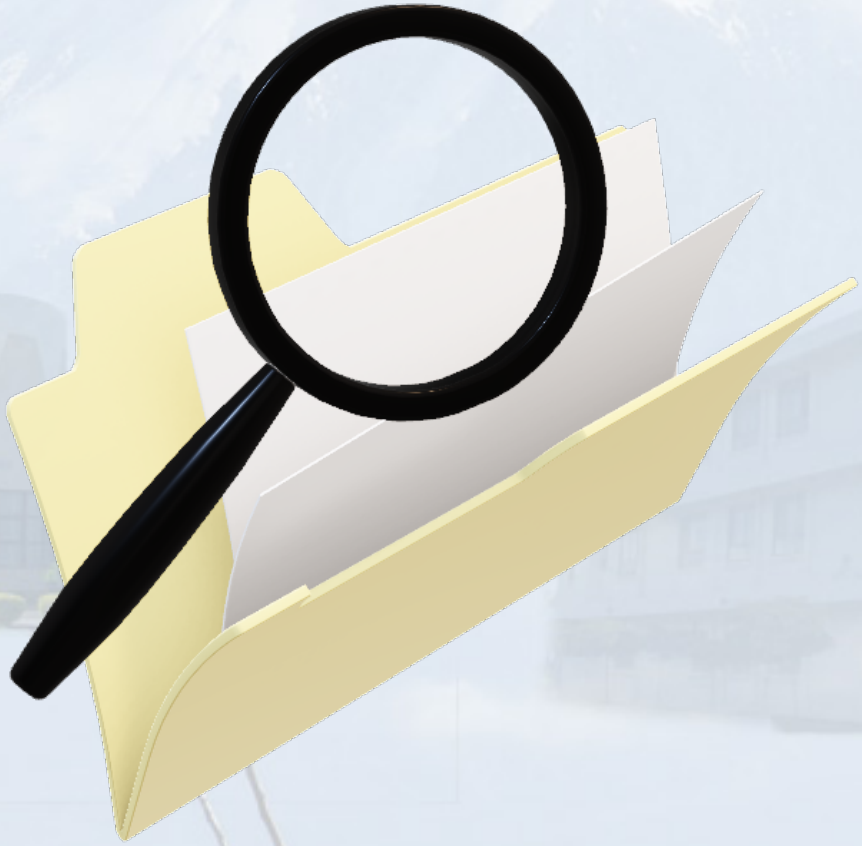
- The value of a well-designed audit is that it will **reveal weaknesses** in the pre-exam, exam and post-exam phases

During audits, information is gathered about:

- processes and operating procedures
- staff competence and training
- equipment
- environment
- handling of samples
- quality control and verification of results
- recording and reporting practices

- Audit **findings** are compared with the laboratory's **internal policies** and to a **standard** or external benchmark.
- Any **breakdown** in the system or departure from procedures will be **identified** and form a basis for continuous improvement process

Sample forms and documents



- Laboratory readiness checklist
- Continuous QC improvement form
- Contamination rates
- Reagent QC forms
- Recording and processing samples
- Equipment maintenance and calibration schedule

Resources

- TBA MycoLab QC Manual version 2, 2Mar2019
- Laboratory Quality Management: Handbook
- Global Health Training Centre

Acknowledgement

PANDORA
Pan-African Network For Rapid Research, Response and Preparedness for Infectious Diseases Epidemics

ALERRT
African coaLition for Epidemic Research response and Training

CANTAM
Central Africa Clinical Research Network

KCRI Kilimanjaro Clinical Research Institute
An Institution of the Good Samaritan Foundation

UCL

Eastern Africa Consortium for Clinical Research (EACCR2)

THE GLOBAL HEALTH NETWORK