THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Laboratory Quality Management System

Module 6: Occurrence Management

Venue:

Presenter:

Date:

1. Introduction

- Occurrence management, or dealing with laboratory errors, is important in assuring good service from the laboratory.
- It is the process by which errors, or near errors (also called near misses) are identified and handled.
- The goal is to correct the errors that result from an event, and to change the process so that the error is unlikely to happen again

Learning Objectives

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

define the term “occurrence”;

describe the essential quality monitoring tools;

differentiate among preventive action, remedial action, and corrective action;

describe the relationships between preventive action and risk management practices;

Module Outline

- Definition of occurrence
- Role of occurrence in QMS
- Causes of laboratory occurrences/errors
- Consequences of laboratory occurrences/errors
- Detection of occurrences
- Root cause analysis
- Occurrence management process

The Quality Management System

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2. What is an occurrence?

Any event that has a negative impact on an organization, which includes personnel, product, equipment, or the environment.

3.Some common laboratory occurrences

- patient ID error
- lost sample
- sample delayed in transit
- contaminated samples
- wrong test performed
- test performed inconsistent with the written procedure

- proficiency testing error
- no action on out of range controls
- false negative result
- late reports
- missing reports
- complaints
- laboratory accident
- “near miss”

Errors can occur throughout the testing process

THE PATIENT → Test selection → Sample Collection

Preexamination Phase

Sample Transport

Laboratory Analysis
Examination Phase

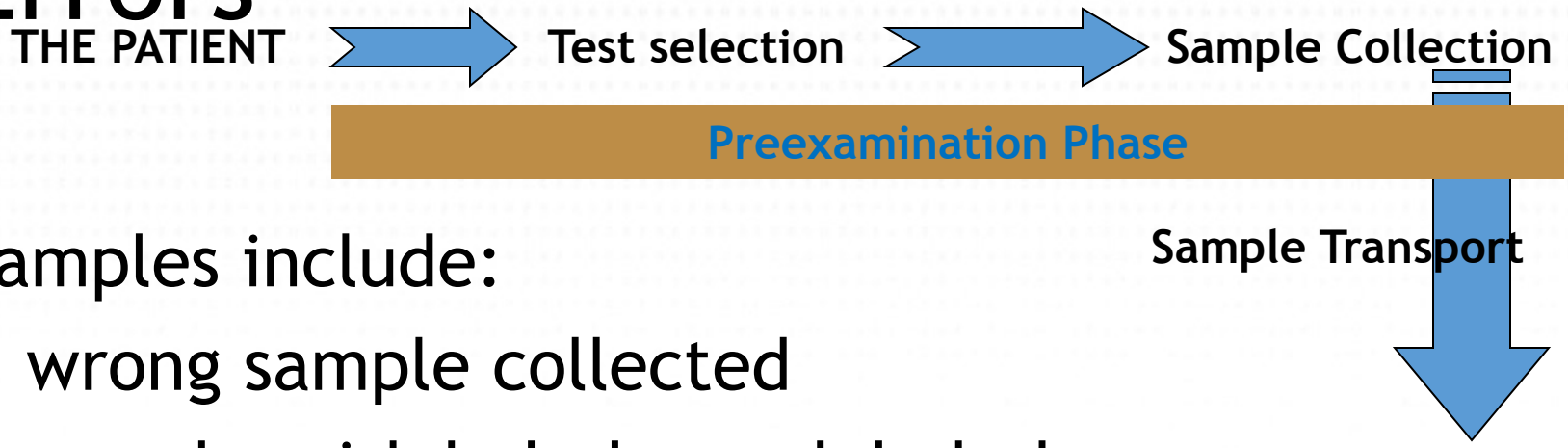
Report Creation

Report Transport

Result Interpretation

Postexamination Phase

Pre-examination Errors

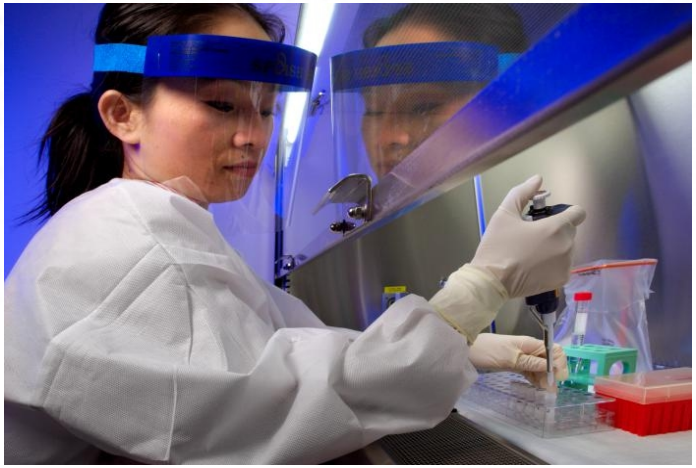


Examples include:

- wrong sample collected
- sample mislabeled or unlabeled
- sample stored inappropriately before testing
- sample transported inappropriately
- reagents or test kits damaged by improper storage

Examination Errors

Laboratory Analysis
Examination Phase



Examples include:

- established algorithm not followed
- incorrect timing of test
- results reported when contro results out of range
- improper dilution and pipetting of sample or reagents
- reagents stored inappropriately or used after expiration date

Post examination Errors

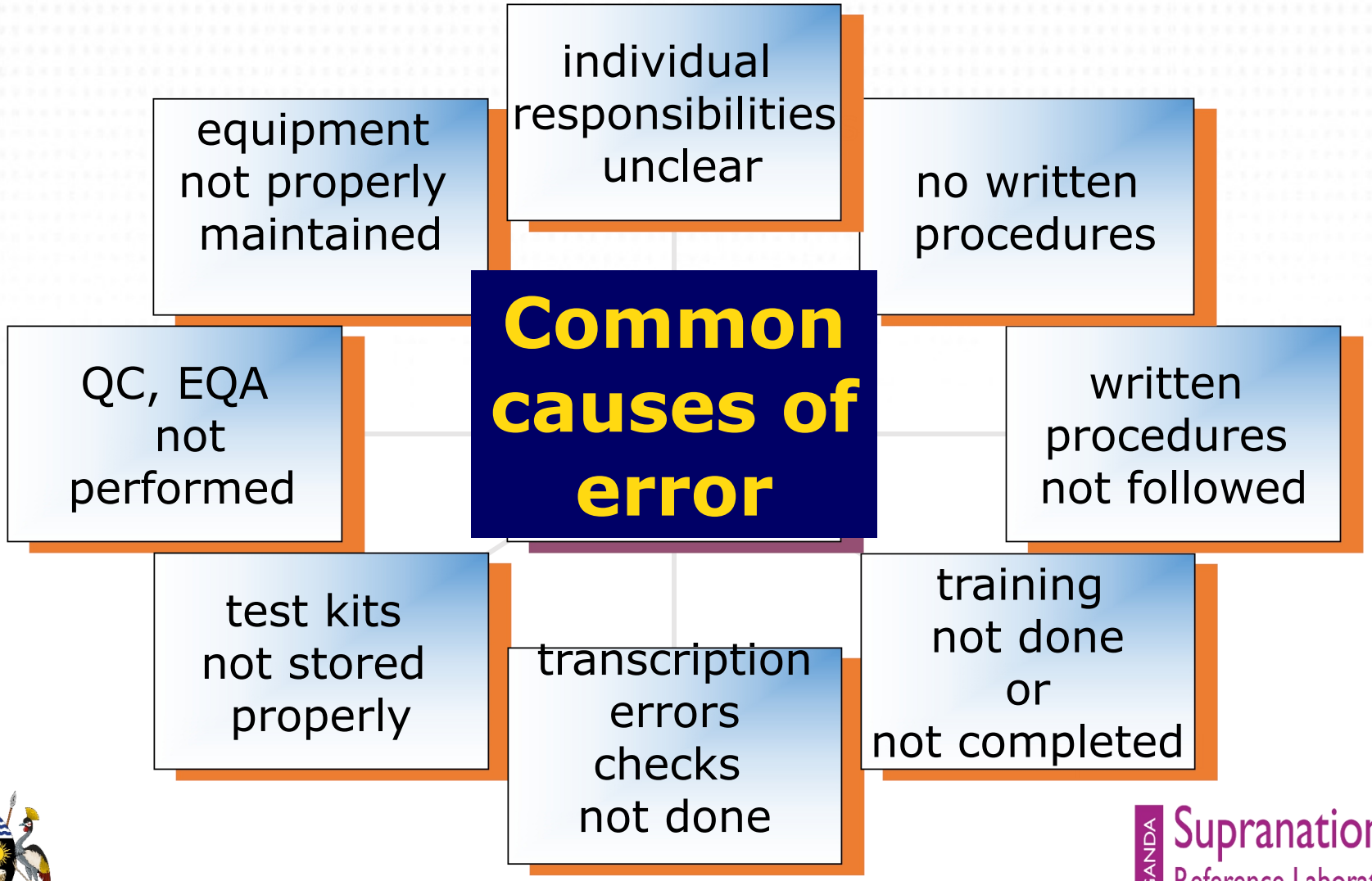
Examples include:

- transcription error in reporting
- report illegible
- report sent to the wrong location
- report not sent

Report Creation → **Report Transport** → **Result Interpretation**

Postexamination Phase

4.Causes of error



Activity 6-1: Consequences of Laboratory Error

Purpose:

To provide an opportunity for participants to investigate the cause of a laboratory error and consider the related consequences.

Suggested time: 10 minutes

Scenario

An 83 year-old male was admitted to hospital with fever, weight loss, and cough, and was being investigated for possible tumor. His sputum culture was reported positive for tuberculosis, but on later review, it was found to be a false positive. Further investigation found 14 additional patients with false positive TB culture reports.

- ***How would you have found the source of the error?***
- ***What are the likely consequences of this***

5. A laboratory occurrence and its consequences

Consequences included:

- delay in correct diagnosis
- unnecessary treatment
- treatment complications
- pattern of other contaminations discovered
- problem resolution required 6 months of investigation, contacting of more than 200 patients, many requiring culture and X-Ray re-examination
- revision of laboratory procedures eradicated the problem

Laboratory errors cost in time, energy, money, personnel, and patient outcomes

Consequences of Laboratory Error

Inadequate or inappropriate patient care

Inappropriate public health action

Wasteful of resources

Death

Undetected communicable disease outbreaks

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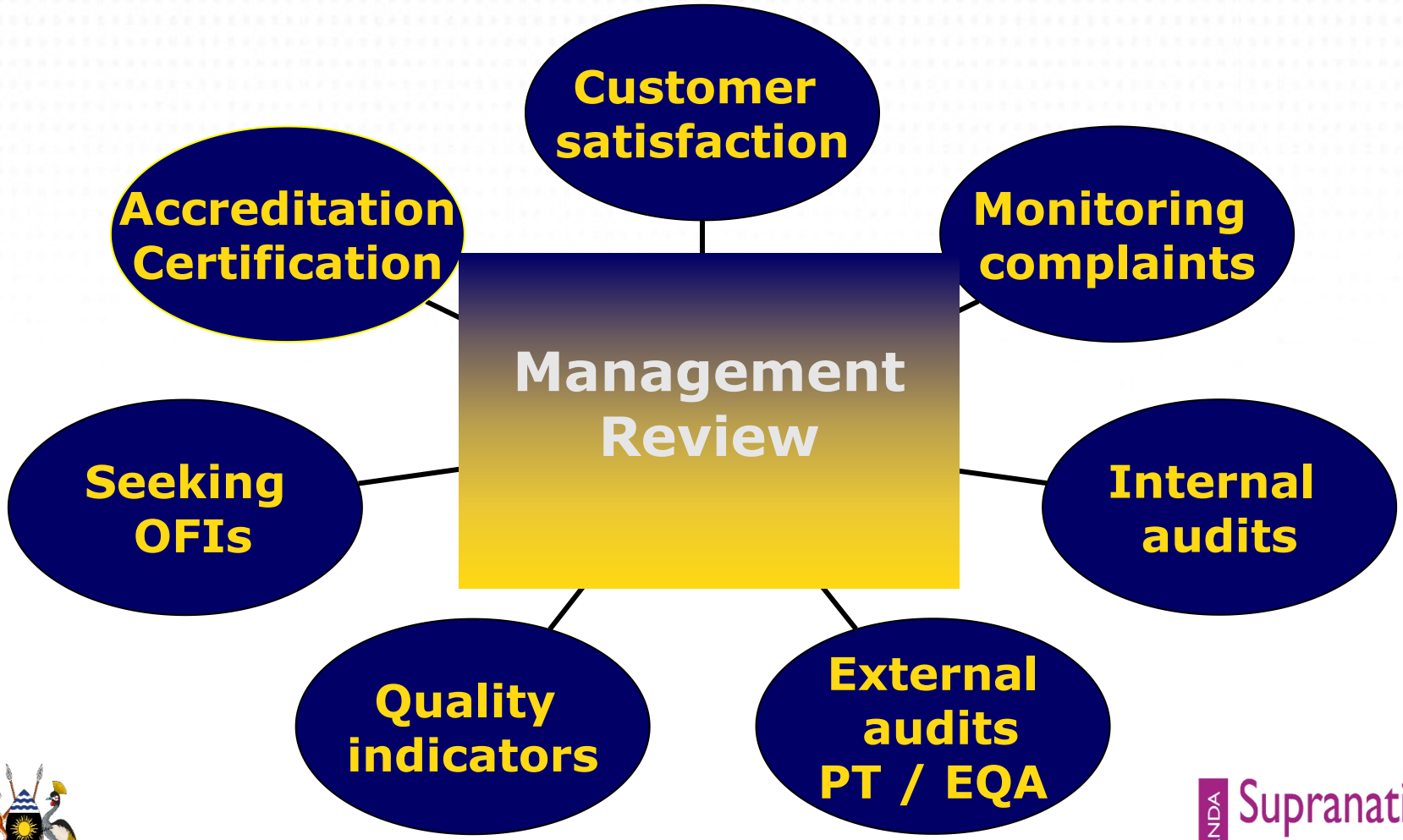
6. How are occurrences detected?



7. The Occurrence Cycle

Awareness

Investigate

Communicate

ACTION

Investigation steps

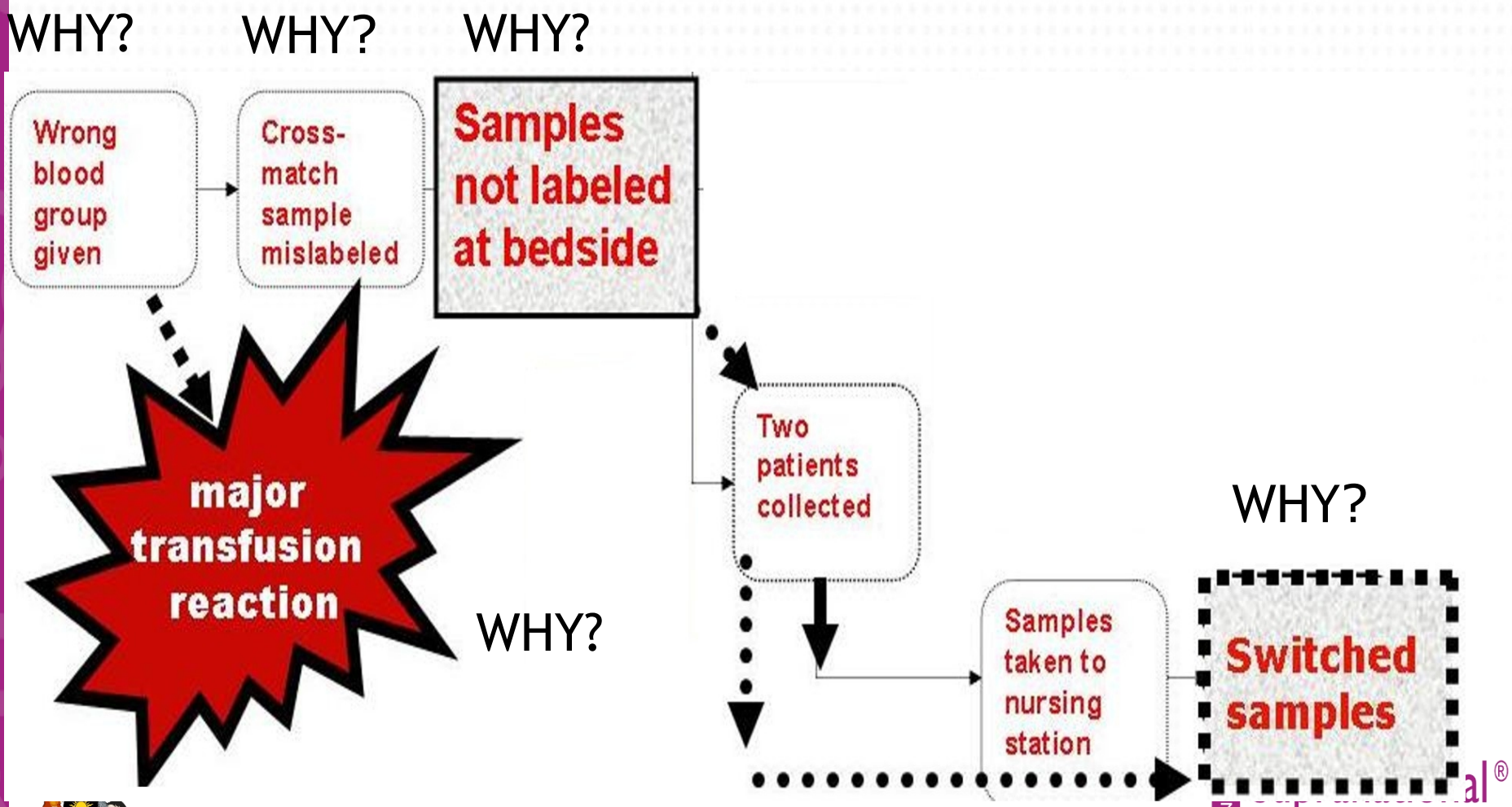
- information gathering
  - thorough investigation
    - root cause analysis

8. Root Cause Analysis

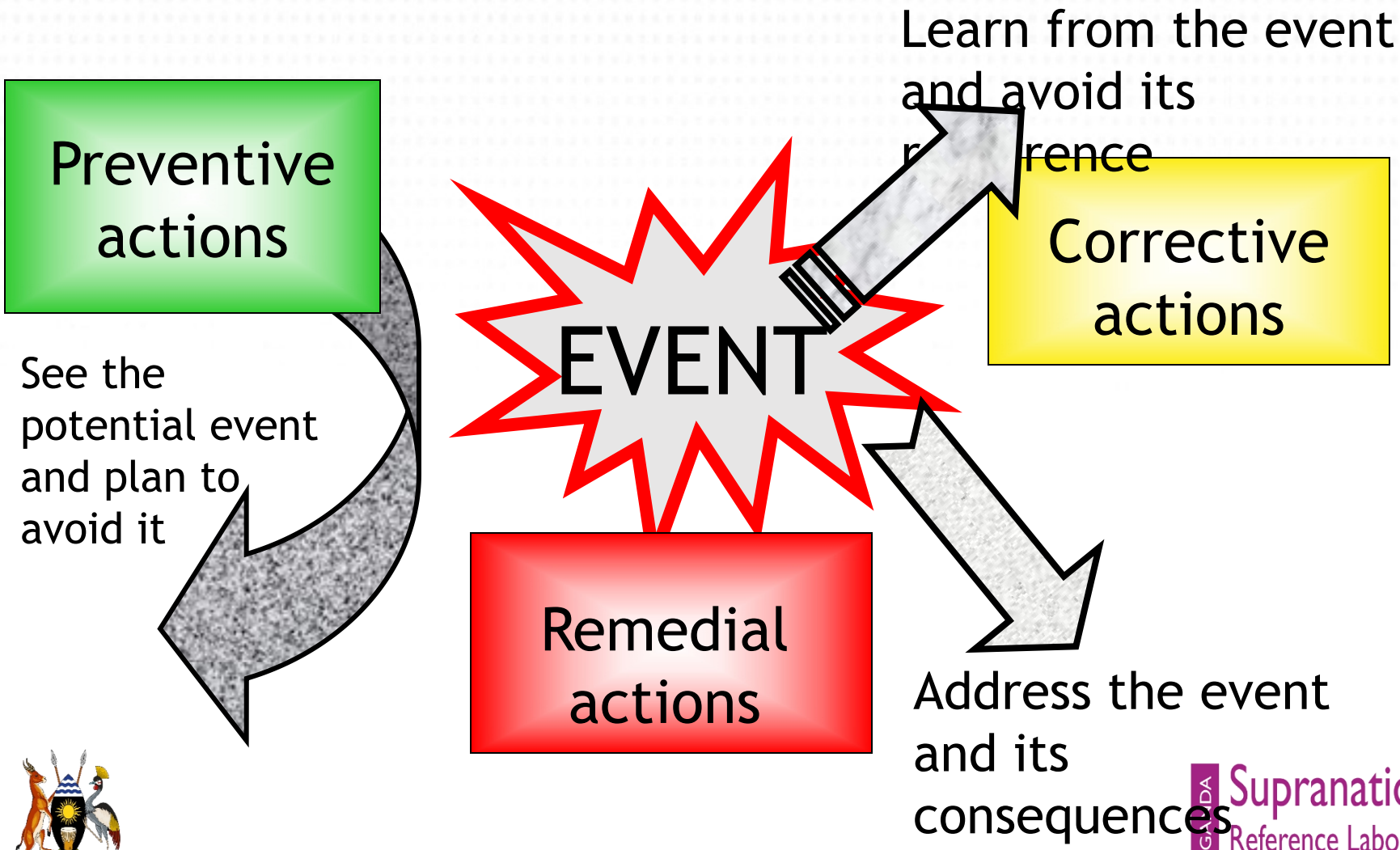
Structured investigations that focus on identifying the underlying true causes of occurrences

- every cause has a deeper reason
- for each occurrence seek 5 levels of explanation, asking WHY, before being satisfied as to the true (root) cause

Root cause analysis example



Occurrence Management



9. Occurrence Management Process

1. Establish a process to detect problems

2. Log findings and actions

3. Investigate causes, analyze information

4. Take appropriate action

5. Monitor for recurring problems

6. Provide information to all needing it

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Activity 6-2

Laboratory errors — what about your laboratory?

Purpose:

To provide an opportunity for participants to share frequent occurrences in their laboratories.

Suggested time: 10 minutes

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Instructions

- What are the 5 most common errors occurring in your laboratory?
- Why do they occur?
- What remedial actions did you take to address the immediate consequences?
- What measures could you put in place to correct the problem and prevent recurrence?
- How did you document the problem and action?
- Can you look at some of your common procedures to seek improvement and problem prevention?

Assessment

List the 5 most common errors occurring in your laboratory.

- Why do they occur?
- What remedial actions did you take to address the immediate consequences?
- What measures could you put in place to correct the problem and prevent recurrence?
- How did you document the problem and action?
- Can you look at some of your common procedures to seek improvement and problem prevention?

Summary

The laboratory should:

- employ an active process for occurrence management and take a positive approach
- try to detect problems early, and take immediate remedial and corrective action
- seek opportunities to identify potential error, thus preventing its occurrence
- keep good records of all problems, investigations, and actions taken

Key Messages

The difference between a quality-managed laboratory and those with no system in place is that the quality laboratory detects the problem, investigates, and takes actions.

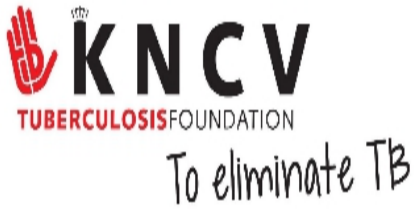
References

- ISO 15189:2012 Medical Laboratories – Requirements for Quality and Competence

  « Clause 4.9, 4.10, 4.11, 4.12 and 4.14.4.»

- CLSI
- ASLM

Acknowledgement



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