INTERNATIONAL INSTITUTE FOR PATHOLOGY AND FORENSIC SCIENCE RESEARCH

COLLEGE of AMERICAN PATHOLOGISTS FOUNDATION

DAVID UMAHI FEDERAL UNIVERSITY OF HEALTH SCIENCES UBURU, EBONYI STATE.

Occurrence Management & Non-conformance Handling in Clinical Laboratories

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21 April//4:00 pm//2025

Week 7

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Advancing Laboratory Quality Management Systems for Better Patient Outcomes

Learning Objective

- This session aims to:
  - To understand the best practices for incident reporting, documentation and root cause identification.
  - To explain data analytics for trend monitoring and error prevention
  - To understand how to implement corrective actions to mitigate laboratories nonconformities.

Question 1:

In occurrence management cycle, one of the following is NOT correct

a. Retribution encourages efficient occurrence management cycle.

b. Reporting of an error should be seen as opportunity for improvement

c. Documentation is an essential part of occurrence management cycle

d. Incidence report form is an essential document used in detection of non-conformance event.

Question 2:

Which of the following is opportunity for improvement

a. Complaints

b. Corrective action

c. Preventive action

d. Remedial action

Question 3:

Non-conformances can be detected by

a. Enhancing staff welfare

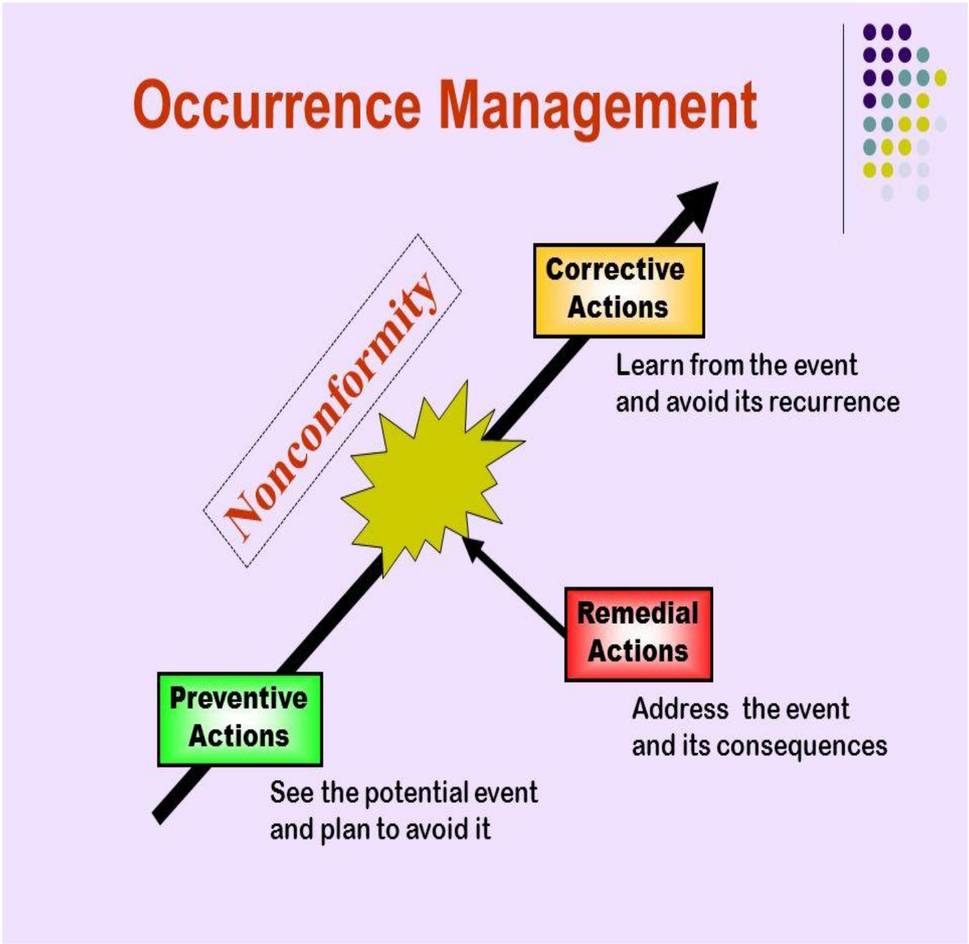
b. Training and re-training of staff

c. Calibration of equipment

d. Customer satisfaction evaluation

Introduction

- The laboratory is an extremely busy environment. Even with an attentive management team and well implemented QMS, “things happen” that fall outside of the expectations and sometimes may not be detected until later.
- Occurrence management, or dealing with laboratory errors, is important in ensuring good customer satisfaction and quality result from the laboratory.
- It is one of the 12 quality essentials and must be addressed in laboratory quality management.
- Occurrence management is a central part of continual improvement.



Introduction – contd:

- **ISO 15189:2012; 4.9 Identification and Management of Nonconformities**
  - The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes.

When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented.

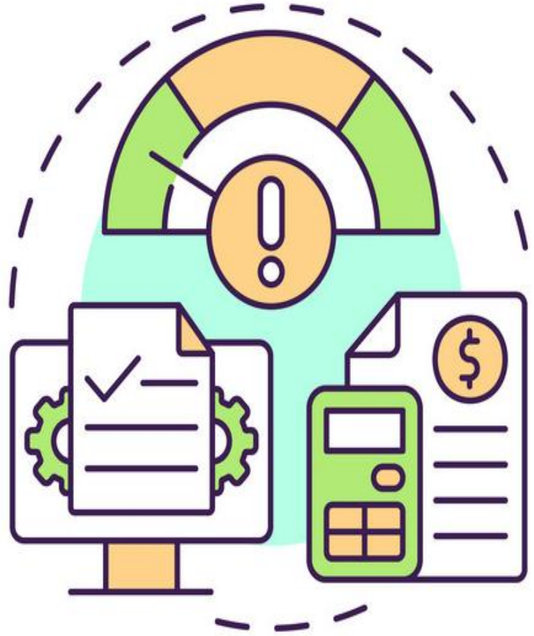
Definition of Terms

- **Occurrence** – any event that has a negative impact on an organization, which includes personnel, product, equipment, or the environment.
- **Non-conforming event** – something that happened that shouldn't have happened
- **Non-conformity/Non-conformance** – non-fulfilment of a requirement; Also referred to as *accident, adverse event, error, event, incident, and occurrence*.
- **Occurrence management** – the process by which errors or near errors (also called near misses) are identified and handled.

The goal of Occurrence Management…

The goal of an occurrence management programme

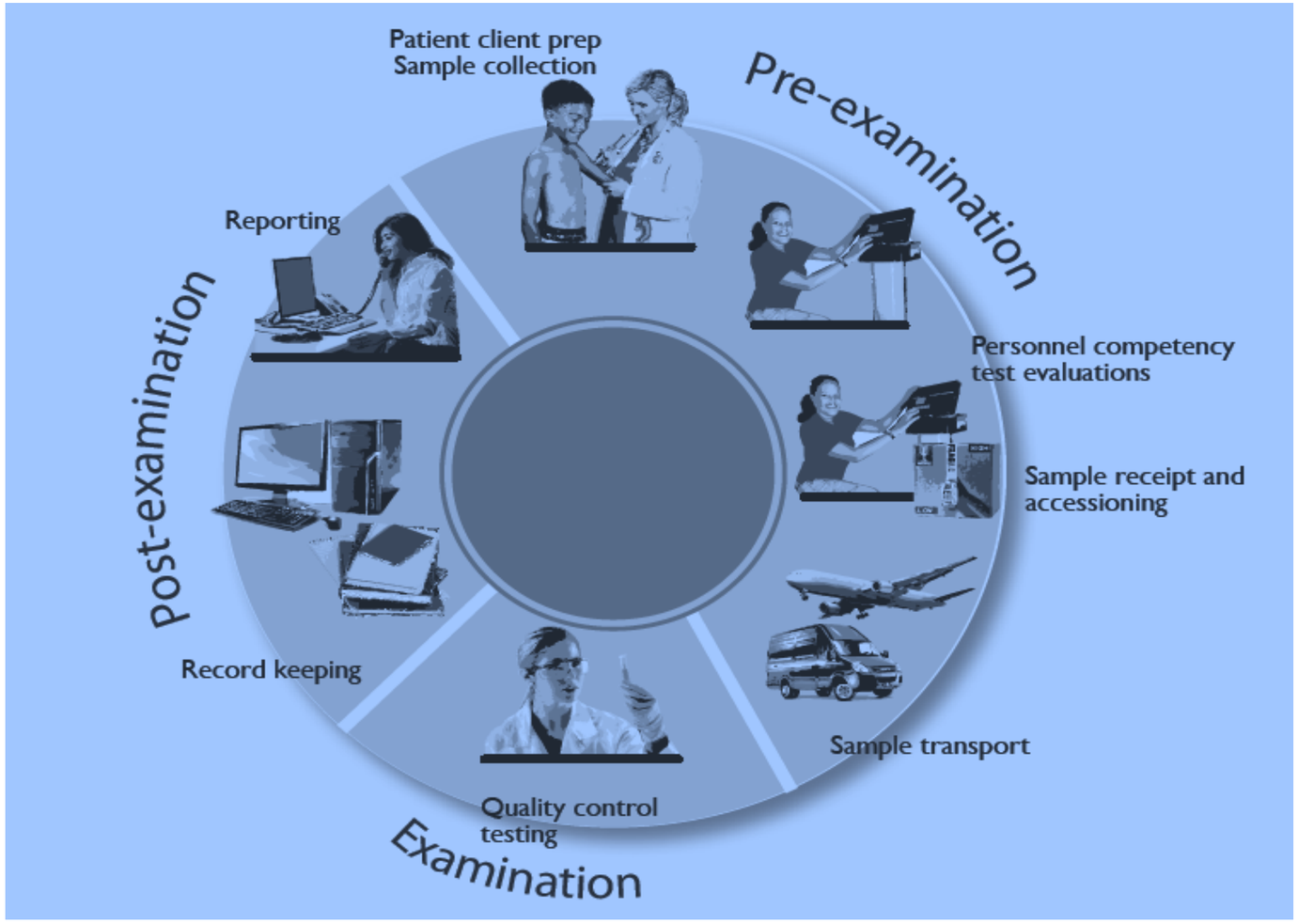
- To correct the errors in either testing or communication that result from an event, and
- To change the process so that the error is unlikely to happen again.



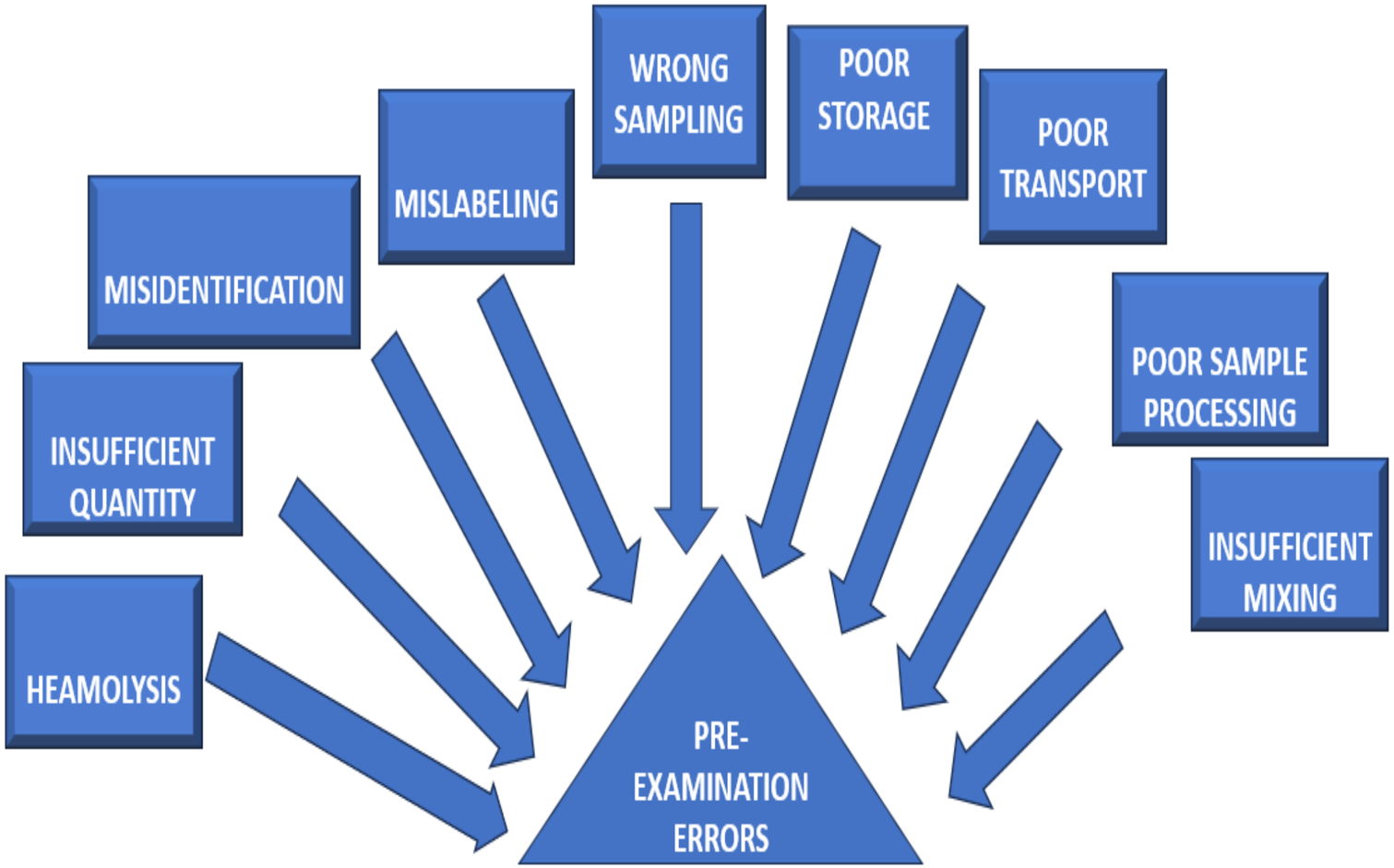
Minimize Errors

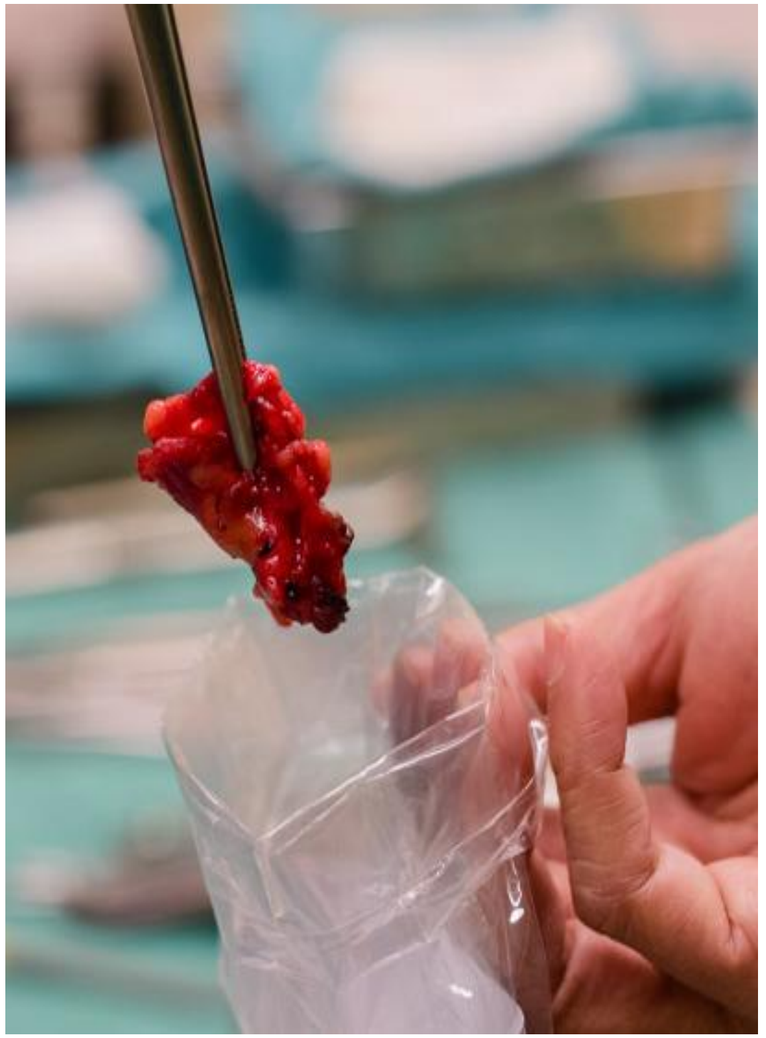
What are the causes of laboratory error?

The Path of Workflow

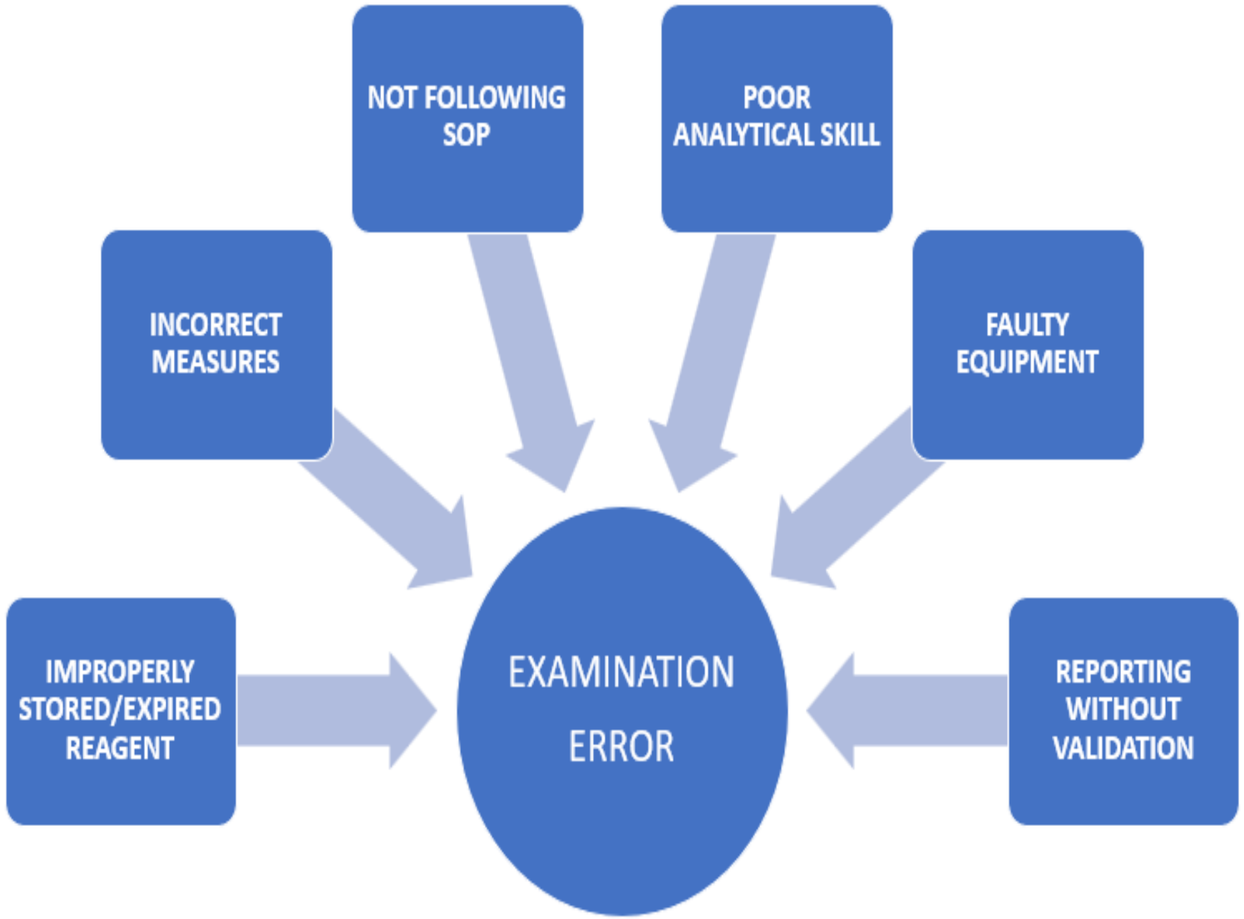


Pre-analytical…





Analytical…

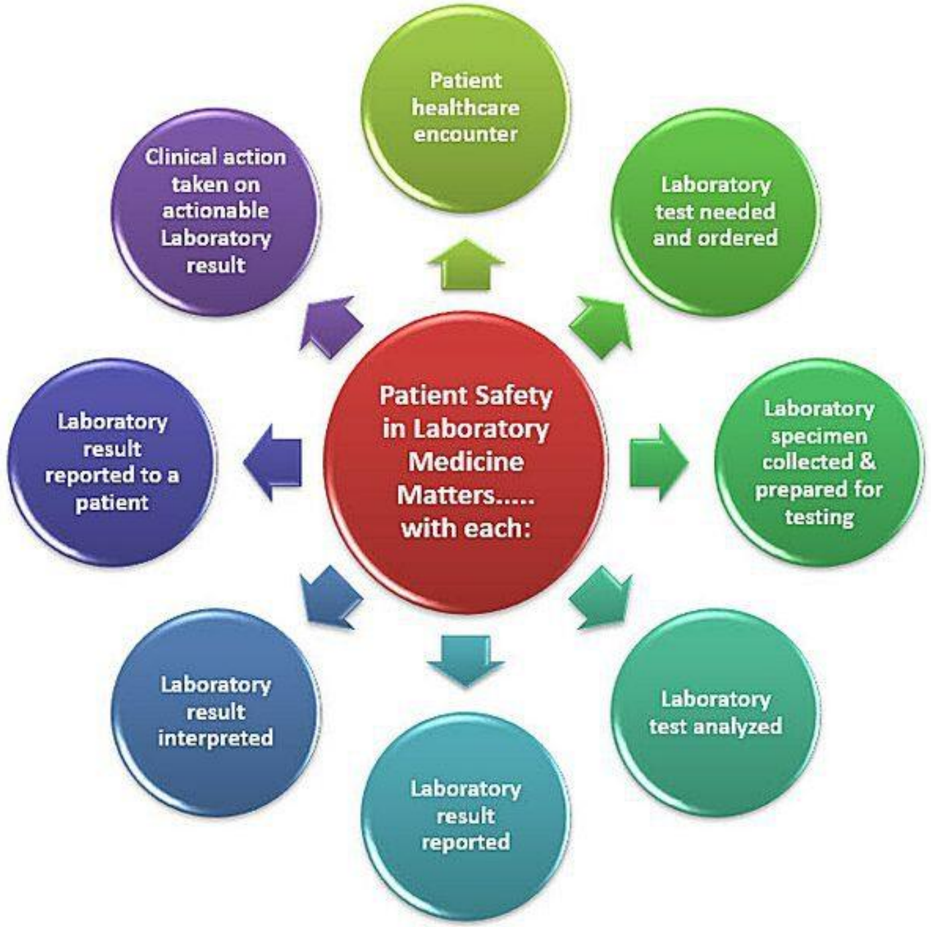

NOT FOLLOWING SOP
POOR ANALYTICAL SKILL
INCORRECT MEASURES
FAULTY EQUIPMENT
IMPROPERLY STORED/EXPIRED REAGENT
EXAMINATION ERROR
REPORTING WITHOUT VALIDATION

Post-analytical…

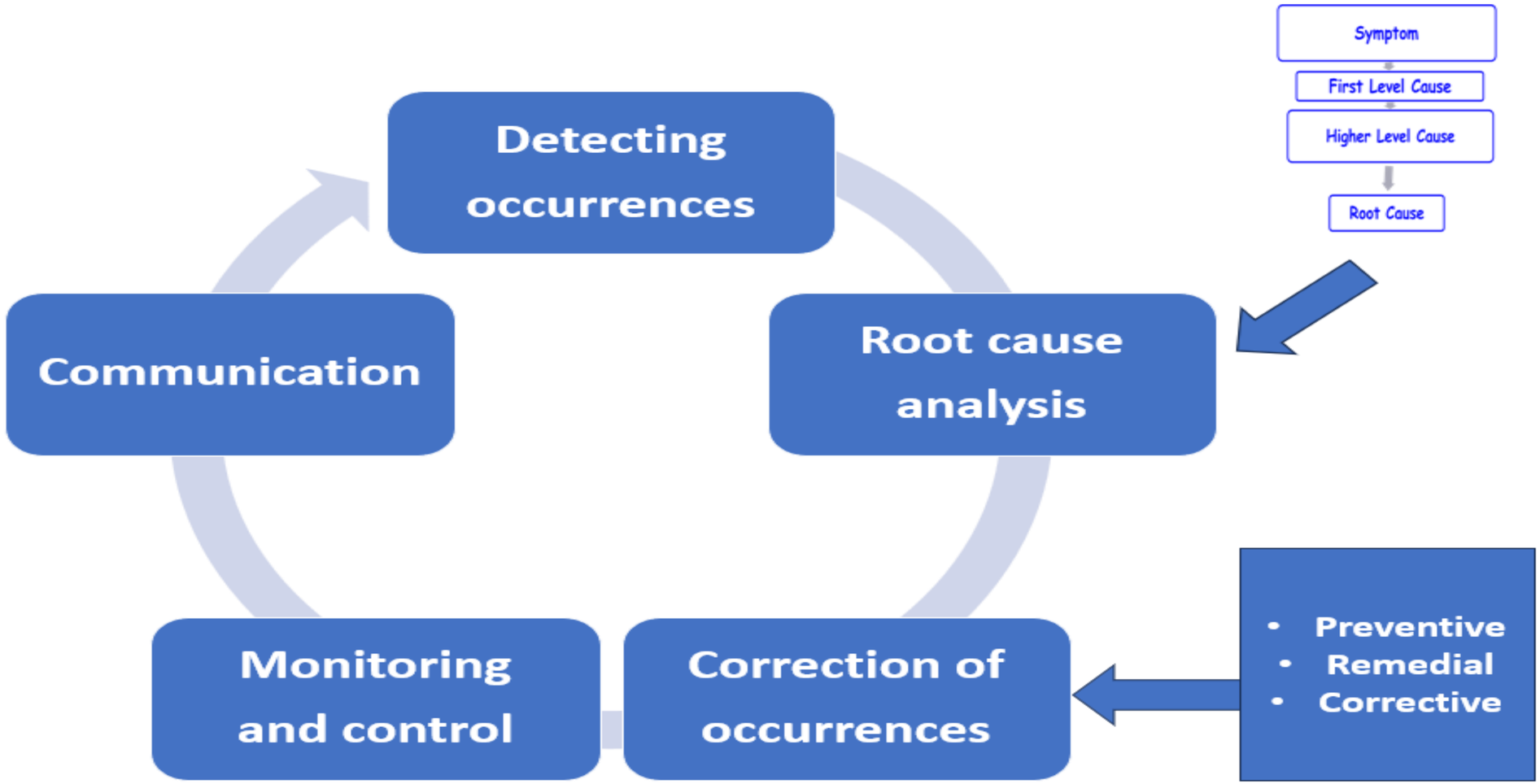
- TRANSCRIPTION ERROR
- ILLEGIBLE WRITTING
- UNTIMELY REPORT
- FAILURTE TO SEND REPORT
- REPORT SENT TO WRONG LOCATION

Consequences of laboratory error…

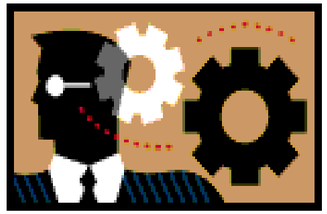
- Delay in treatment
- Waste Of Resources
- Insufficient Public Health Action
- Communicable Diseases Outbreak
- Loss of credibility Of the laboratory
- Study discontinuation
- Death



Occurrence Management Cycle



How are occurrences detected?

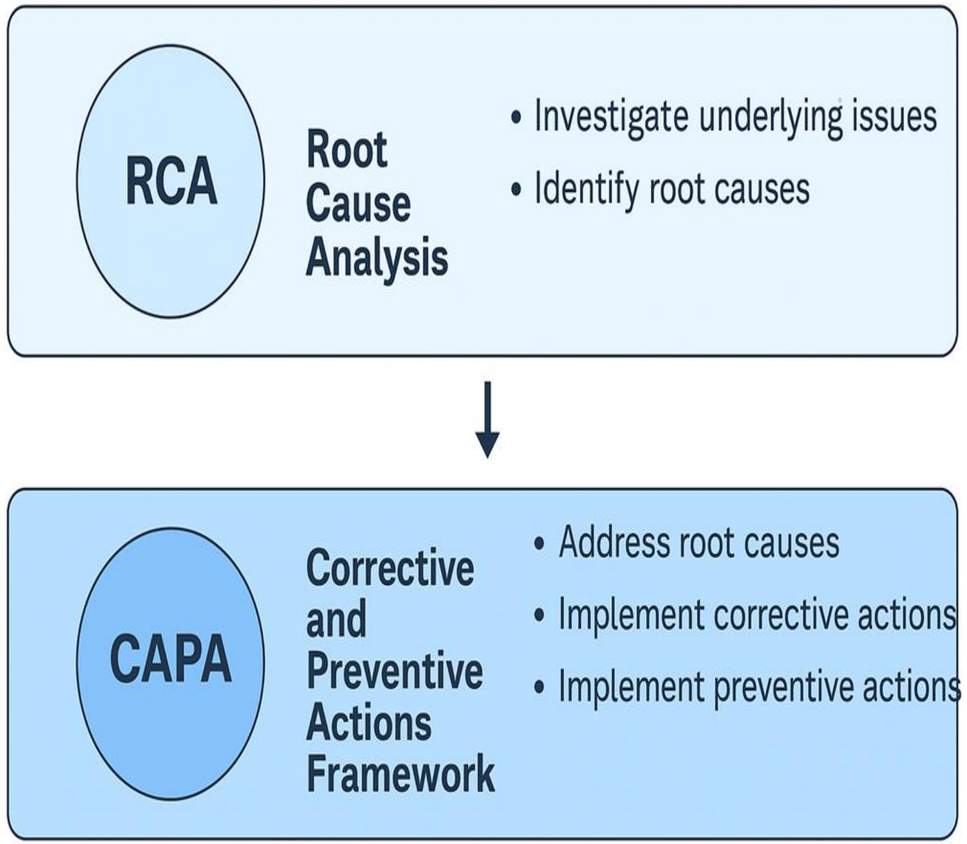


Severity of the occurrence

I	Severe	Adverse outcome without successful intervention.
II	High	Adverse outcome with successful intervention.
III	Medium	Minor self-limiting adverse outcome.
IV	Low	No known adverse outcome.

Root Cause Analysis

- Tools for Ascertaining Root Cause Include the following:
  - The five whys, a simplistic approach exhausting the question “Why?”.
  - Fishbone diagram, aka Ishikawa diagram.
  - Pareto analysis, the 80/20 rule premised on a predefined database of known problems.
  - Fault tree analysis, a quantitative diagram used to identify possible system failures.



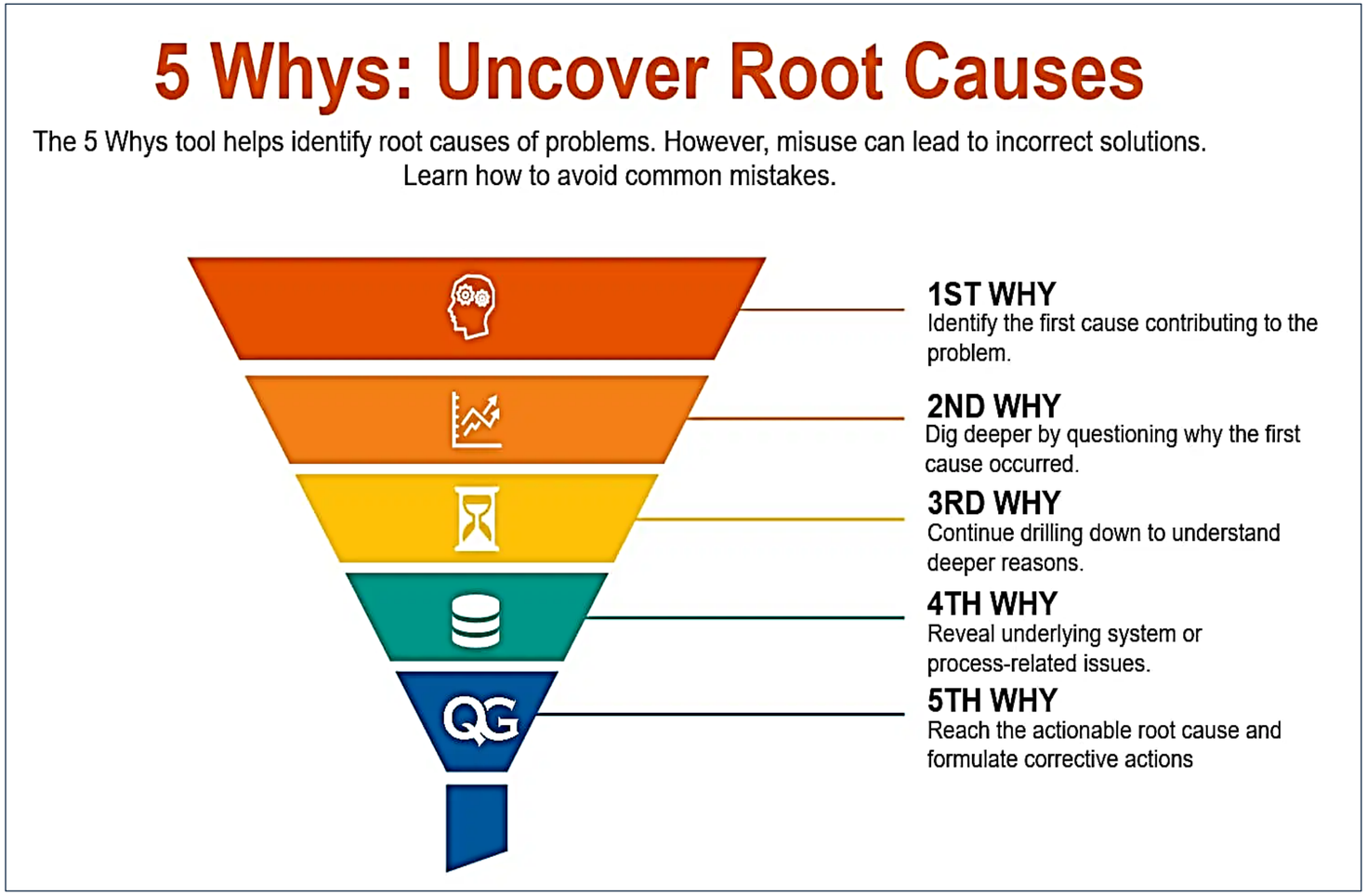
RCA – 5 Whys Analysis:

The 5 why technique:

- Ideal investigations of specific accidents as opposed to chronic problems.
- Brainstorming technique that identifies root causes of accidents by asking why events occurred or conditions existed.
- Involves selecting one event associated with an accident and asking why this event occurred.
- Produces the most direct cause of the event.

- **Disadvantages of the 5 Whys Technique**
  - **Tedious.**
  - **Results are not reproducible or consistent.**
  - **Root causes may not be identified.**

RCA – 5 Whys Analysis – contd:



Common mistakes in 5 Whys Analysis:

- Stopping at symptoms instead of root causes
- Jumping to conclusions
- Failing to involve the right team
- Using vague or generic answers
- Not verifying causes with data
- Neglecting systemic factors
- Lack of follow-up on corrective actions

RCA – Fishbone Diagram (Ishikawa):

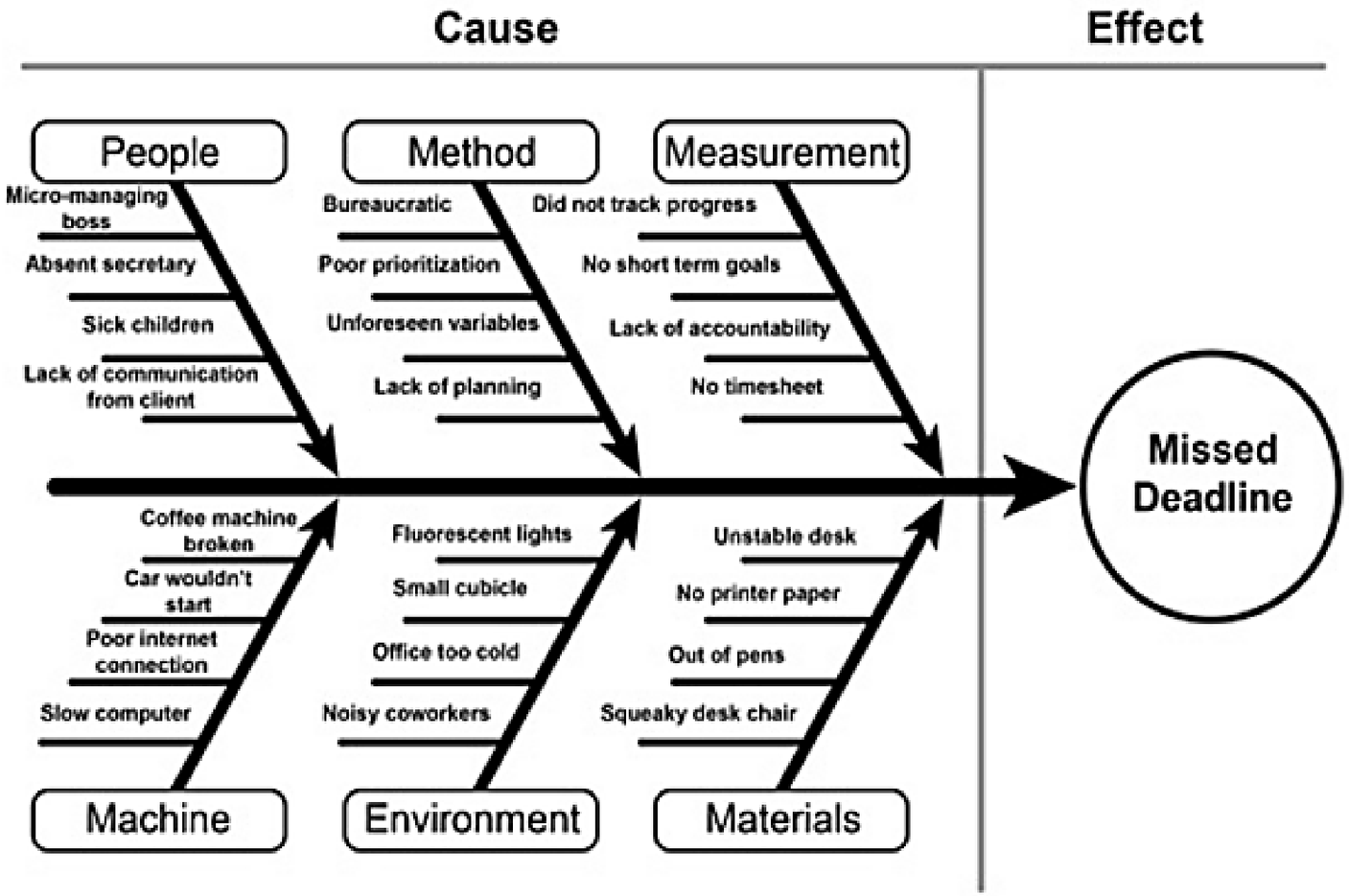
The Fishbone Diagram – tool used to identify and visualize the various factors that contribute to a problem or effect.

It helps teams systematically explore potential causes across different categories.

Key Elements of the Fishbone Diagram:

- **People:** Factors related to human resources, including staff training, performance, and communication.
- **Process:** Issues in the workflow, procedures, or methods used that could contribute to the problem.
- **Equipment:** Failures or inadequacies in the tools, machines, or technology used in the process.
- **Materials:** Problems related to raw materials, chemicals, or consumables, such as quality or availability issues.
- **Environment:** External conditions like temperature, humidity, or workspace setup that may impact the process or results.

RCA – Fishbone Diagram (Ishikawa) – contd:

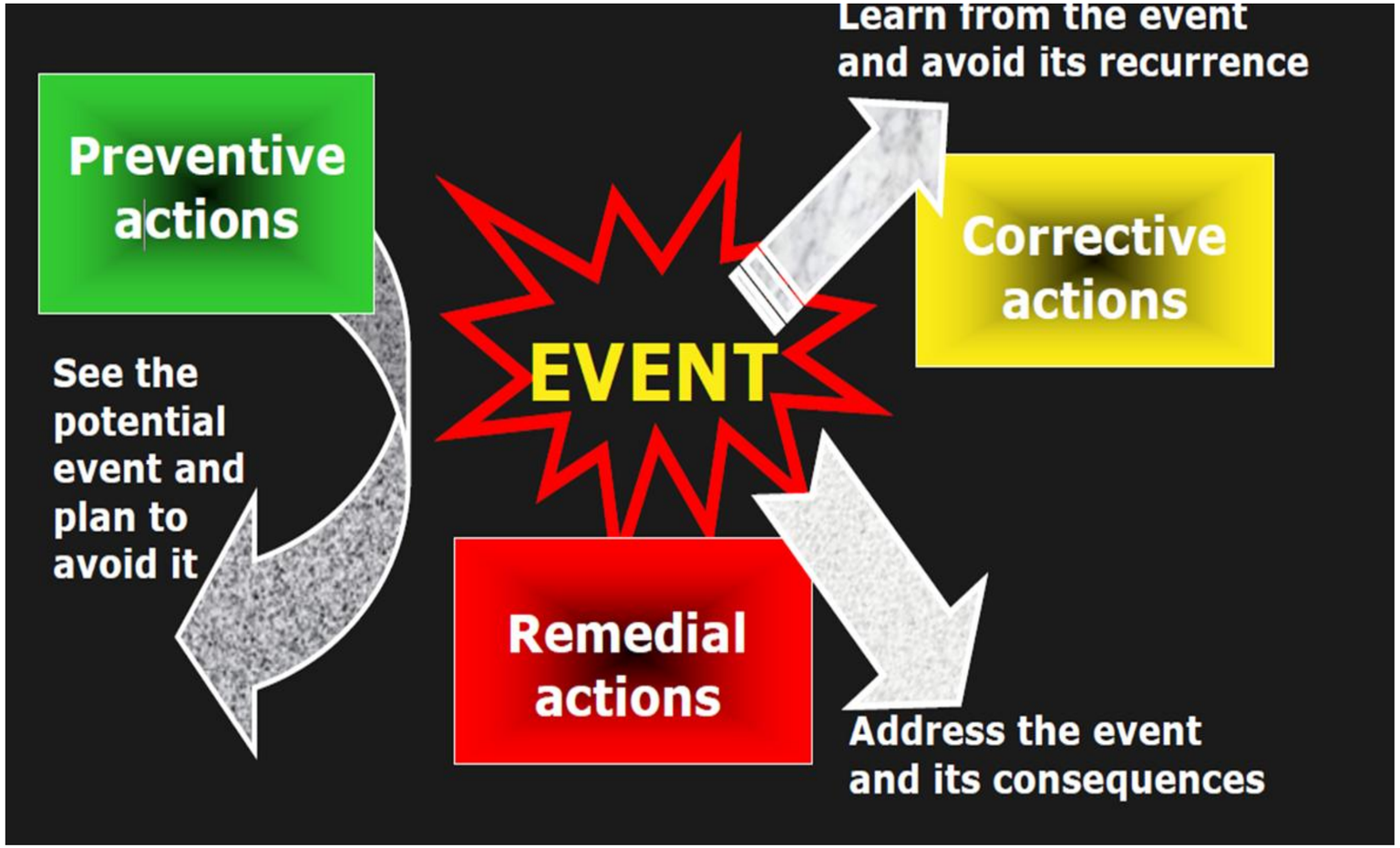


The Fishbone Diagram helps in organizing thoughts, uncovering hidden causes, and fostering teamwork in problem-solving efforts.

RCA – Fishbone Diagram (Ishikawa): Advantages

- **Fishbone diagrams *do* provide value in that they:**
  - Organize potential causes
  - Help a team to think through causes they might otherwise miss, and
  - **Provide a living document that shows the status of all potential causes and whether they have been proved/disproved/acted upon.**

Correction of Occurrences



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

Steps in Occurrence Management and Non-conformance Handling: ISO 15189:2022

Detection and Reporting	• Identify any non-conformance (e.g. deviation from SOPs, equipment failure, quality control issues, or patient result errors). • Encourage all staff to promptly report occurrences without fear of blame.
Documentation	• Record the occurrence in a **non-conformance/incident log**, including: Date and time, Description of the event, Personnel involved, and Initial impact assessment
Immediate Containment	• Take immediate action to minimize impact (e.g., stop using faulty equipment, notify affected stakeholders). • Isolate affected samples or results if applicable.
Root Cause Analysis (RCA)	• Use tools like **5 Whys** or **Fishbone (Ishikawa) diagrams** to investigate and identify the underlying cause(s).

Steps in Occurrence Management and Non-conformance Handling: ISO 15189:2022 – contd:

Corrective Actions	• Define and implement actions to correct the problem (e.g., retraining, SOP revision, equipment repair).
Preventive Actions	• Establish measures to prevent recurrence (e.g., audits, new controls, design changes).
Evaluation of Effectiveness	• Monitor and evaluate whether corrective/preventive actions resolved the issue.
Communication	• Inform relevant staff and stakeholders of findings, changes, and lessons learned.
Review and Closure	• Review the case, ensure all actions are documented and verified, then formally close the record.
Trend Analysis	• Periodically analyze non-conformances to identify recurring issues and improve the quality system.

Case Scenario

Background:

- At a Diagnostic Laboratory, five recurring errors were identified over a 3-month internal audit:

1. Mislabeled patient samples
2. Delayed sample transport
3. Incomplete test request forms
4. Equipment downtime due to poor maintenance
5. Failure to record QC results before releasing patient reports

Incident:

A routine chemistry sample was received in the lab with a label for *Patient A*, but the accompanying request form was for *Patient B*. The error was detected during the sample reception verification.

Why Did It Occur?

- New phlebotomy staff were inadequately trained on patient identification and labelling SOPs.
- No double-checking system in place at sample collection points.

Case Scenario - Actions

Immediate Remedial Actions:

- Sample testing was halted.
- The clinician was notified.
- A fresh sample was requested from the correct patient.

Corrective and Preventive Measures:

- Refresher training on patient ID and labelling.
- Implementation of a two-person verification system.
- Color-coded patient ID wristbands introduced.
- Phlebotomy checklist updated to include a final ID confirmation step.

Documentation:

- Incident logged in the Non-Conformance Register.
- Root Cause Analysis completed.
- CAPA (Corrective and Preventive Action) form filed.
- Actions reviewed during the monthly Quality Improvement meeting.

Ongoing Improvement Strategy:

- Review of sample collection SOPs across all departments.
- Integration of barcode labelling systems being considered.
- Monthly audits to monitor compliance and error trends.

Case Scenario – Discussion Questions:

- What other immediate risks did this error pose?
- Could the incident have gone undetected? What would have been the consequences?
- Are there parallels in your lab? What systems do you have to catch such errors?
- How can technology support better error 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 Message

- **Laboratories not implementing aquality management system guarantees UNDETECTED ERRORS.**

- **Therefore laboratories should:**
  - **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**

💡 Final Thought! 💡

- 🚀 **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.** 🚀

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Thank You

NEXT WEEK (28th April 2025):

Leveraging Digital Transformation & Information Management in QMS – Dr. Mba I.N (MBBS, FMCPath., IFCAP)

- The evolving role of Laboratory Information Systems (LIS) in modern labs
- Ensuring data integrity, cybersecurity, and compliance with digital regulations
- AI applications in diagnostics, automation, and laboratory quality control

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