Control of laboratory error through “Corrective and Preventive Actions”

Edward Randell

IFCC Committee on Clinical Laboratory Management - http://www.ifcc.org/ifcc-education-division/ems-committees/c-clm/

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Diagnostic Errors

Delayed
• In spite of available resources

Wrong
• Different from correct one

Missed
• No diagnosis

Diagnostic errors result in death or disability almost 2x more often than other medical errors (including medication errors, surgical errors, and others associated with treatment.)
Diagnostic Errors

Outside the Laboratory

Pre-Pre-Analytical
- Failure to order test
- Order wrong test

Post-Post-Analytical
- Misinterpreted results
- Failure to inform patients
- Failure to take timely action
- Inappropriate follow-up

Inside the Laboratory

Pre-Analytical
- Patient misidentification
- Specimen collection
- Order entry
- Handling/Transport/Storage

Analytical
- Equipment Malfunction
- Sample issues
- Undetected QC failure

Post-Analytical
- Data entry/validation
- Excessive TAT
- Delayed Critical Results

Diagnostic errors and errors in lab medicine are interconnected

Nonconformities

Nonconformities are accidents, errors, events, incidents, occurrences, and accidents

CLSI and ISO 15189:2012 define nonconformities as “Nonfulfillment of a requirement”

ISO 15189:2012 (section 4.9) holds clinical labs accountable to 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.”
Why is addressing nonconformities important?

55 year old male with type II DM with chest discomfort of 1 hr duration.

Several previous visits, all with normal ECG and mild troponin elevations.

Nonconformities are weaknesses in procedures that may lead to significant patient harm in certain circumstances.
Presentation Outline

• Defining corrective and preventive actions.
• CAPA Tools
• CAPA Process.
• Summarize Role in Quality Improvement and Patient Safety.

Passive and Active Nonconformities

Complaints
Incidents
Adverse Events

Passive
Active

Safety audits
Review of internal QC
Review of external QA
Review of QC failures
Quality Indicator Monitoring
Staff comments
Incident reporting
Near misses
Investigating instrument problems
Corrective Action

ISO 15189:2012 (section 4.9):

“When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur… the laboratory shall take action to identify, document and eliminate the cause(s).”

Corrective Action: Two types

**Damage Control**

Quick Action

Involves:
- Stop
- How much/how bad
- Contain effects
- Notify affected
- Document

**Remedial**

Immediate resolution

**Corrective**

Prevent repeat occurrence.

**Organized Process**

Requires:
- Identifying true cause
- Action plan to eliminate it
Corrective Actions

Reactive processes that address problems that have occurred.

**Focus:** Correcting an existing problem.

Preventive Actions

Proactive processes to prevent a problem from occurring or reduce potential severity.

**Focus:** Risks associated with trends or patterns.
How do we arrive at corrective and preventive actions?

Root Causes Analysis

**Reactive:**
- Determines why.
- Eliminates the problem.
- Minimizes probability for recurrence.

**Proactive:**
- Forecasts probable events.
- Identifies gaps between desired & actual.
- Determines what to change and how.
Root Cause Analysis

**RCA**

- Understand the Problem
  - Identify causes
  - Collect data on cause(s)
  - Analyze data on cause(s)
  - Determine Root Cause
  - Determine CAPA(s)
  - Implement and verify

**Root Cause Analysis**

**Flow Charts**

- Brainstorming
Root Cause Analysis

Understand the Problem

Identify causes

Collect data on cause(s)

Analyze data on cause(s)

Determine Root Cause

Determine CAPA(s)

Implement and verify

Sampling/Surveys/Check sheets

<table>
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<th>Day</th>
<th>Date</th>
<th>Cause 1</th>
<th>Cause 2</th>
<th>Cause 3</th>
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TOTAL: 2164, 1295, 869, 40.2%

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Pareto Charts

Affinity Diagrams

Histograms/Scattergrams

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Root Cause Analysis

- Understand the Problem
- Identify causes
- Collect data on cause(s)
- Analyze data on cause(s)
- Determine Root Cause
- Determine CAPA(s)
- Implement and verify

5 Whys

Fishbone analysis

Fault tree analysis

6 Thinking Hats

- Process
- Emotions
- Cautions
- Facts
- Benefits
- Creativity
Root Cause Analysis

RCA

Understand the Problem
Identify causes
Collect data on cause(s)
Analyze data on cause(s)
Determine Root Cause
Determine CAPA(s)
Implement and verify

Tree Diagram

FMEA

Describe Process
Identify potential Failure modes
Describe Effects of Failure
Determine Response

How can failure occur?
What are root causes?
What is impact of failure?
What needs to be done?

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A risk analysis process involving:
1. Assembling at Team
2. Identify Threats
3. Estimate the Impact
4. Identifying Actions to address risk.
5. Assign accountability for corrective actions

FMEA

Preventive Actions focus on higher RPN scores
(Greater effect on patient outcome/lab process/safety)

<table>
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<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Failure Causes</th>
<th>Failure Effects</th>
<th>OCC</th>
<th>DET</th>
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Risk Priority Number = OCC x DET x SEV

Likelihood of occurrence (Scale: 1 to #)
Severity of Failure (Scale: 1 to #)

Continuous Improvement Models

Other systematic strategies for CAPA:
• TQM
• RCA
• PDCA
• LEAN
• Six Sigma (DMIAC)
The big and small

- Opportunities for Improvement
- Nonconformities
  - Sample discarded
  - Erroneous test results reported
  - Sample mix-up
- Poor workload distribution
- Excessive reagent wastage

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CAPA as a process

- Potential or True nonconformity
- Major or minor?
  - Major
    - Corrective or Preventive Action Report (CAR or PAR)
    - CAPA process to resolve CAR or PAR
  - Minor
    - Proceed with nonconformity/OFI report and review.
    - CAPA to resolve nonconformity/OFI

Investigating Corrective Action Reports and Preventive Action Reports take time.

Minor nonconformities and Opportunities For Improvement can be addressed quickly.

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Addressing the Minor

Opportunity for Improvement (OFI) Report

Part A - Complete this section if information requested is not available - this section N/A.

1. Is there a suggestion for improvement?
2. Yes / No. If Yes, specify name, department, and group.
3. Is the action related to the situation? (If applicable)
4. Describe the action related to the situation. (If applicable)

Part B - to be completed by OFI Representative

All required actions complete. Sign off.

Corrective Action Report (CAR) required if: 
1. If Yes, assign OFI #
2. If No, sign off.

Preventive Action Report (PAR) required if: 
1. If Yes, assign CAR/PAR #
2. If No, sign off.

List items needing correction.

Record the issue.

Document the action.

Describe outcome of CAR/PAR.

Designated person signs off.

Record completion on log.

Sign off.

Begin report.

Record event.

Assign OFI #

Generally require lower level review and sign off.

Addressing the Major

Corrective Action Report (CAR)

Part A - to be completed by Management from senior or head of department/branch.

Part B - to be completed by Team Leader.

Report: Action taken: Date: 
Decision for the action: Usually written on the report, indicate who the decision was made by.
Date of the decision: Date of the action (if not already stated).

Root Cause Analysis

FMEA or other risk management tools

Generally require high level review and sign off.
The CAPA Process

Summary

Monitor QI/Occurrences /Audits

Document & Implement

Nonconformity or OFI

CAPA

RCA/FMEA or Other

The Patient

Post-Post Analytical

Pre-Pre-Analytical

Post-Analytical

Pre-Analytical

Analytical

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