Control of laboratory error through "Corrective and Preventive Actions"

Edward Randell

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

Satellite Educational Workshop on Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement

Hilton Durban - October 22, 2017

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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.)

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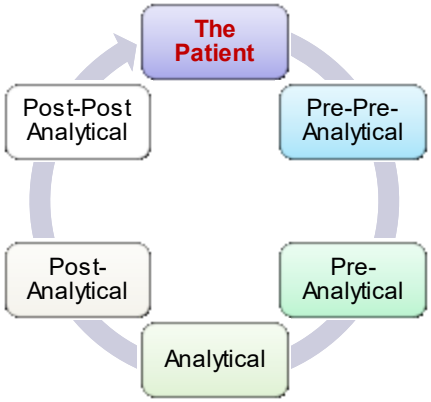
Diagnostic Errors

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

Diagnostic errors and errors in lab medicine are interconnected



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

Nonconformities

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

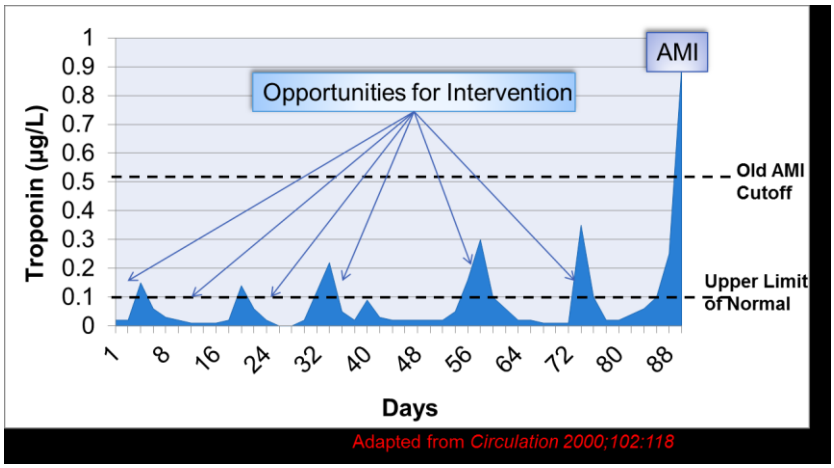
CLSI and ISO 15189:2012 define nonconformities as "***Nonfulfillment of a requirement***"

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?

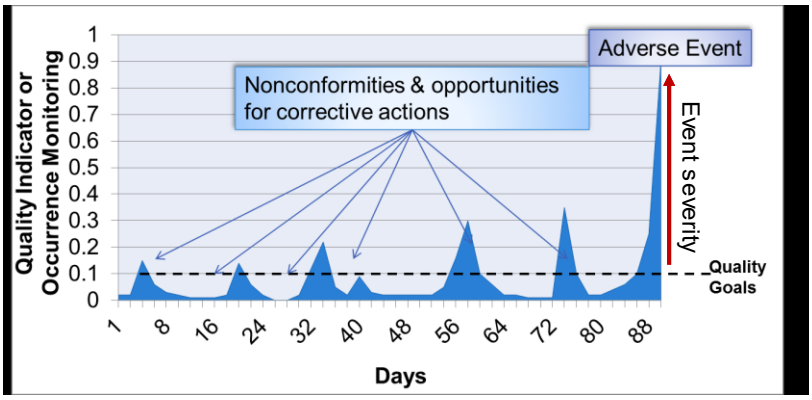
55 year old male with type II DM with chest discomfort of 1 hr duration.

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



Why is addressing nonconformities important?

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

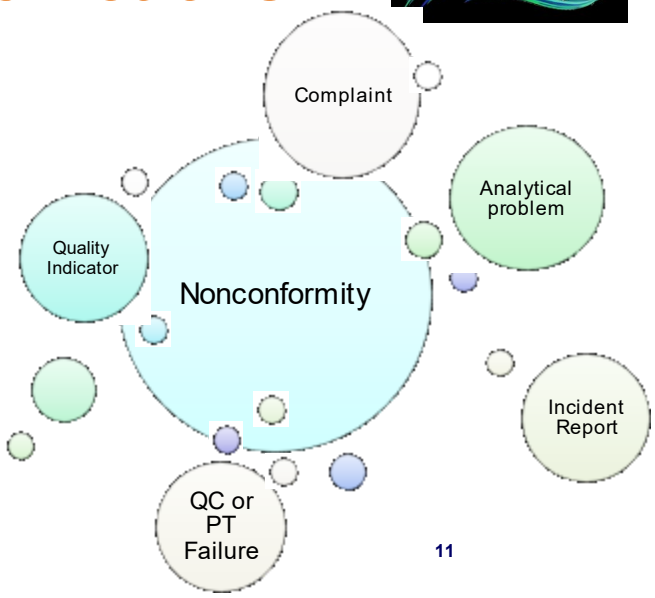
Corrective- prevent repeat occurrence.

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.

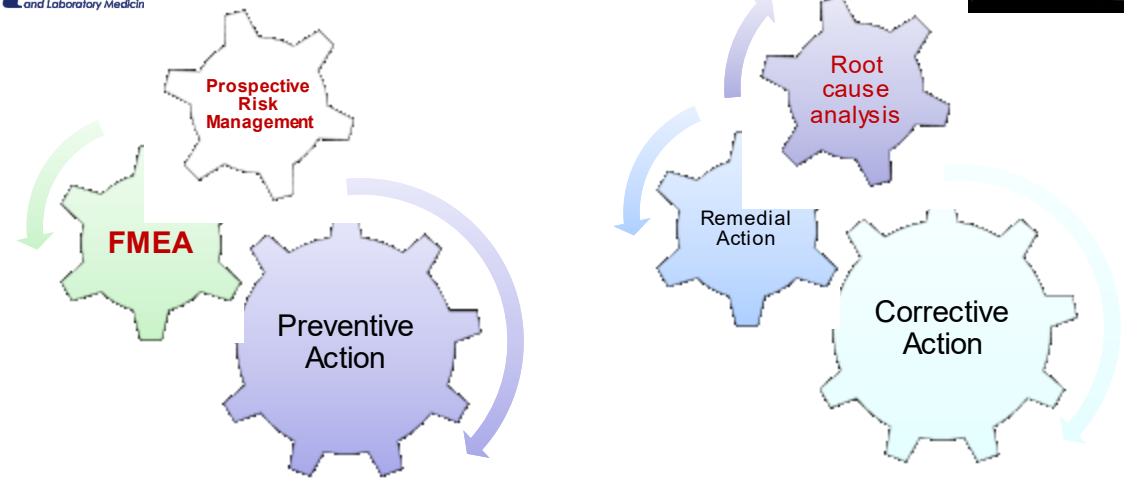


Preventive Actions

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

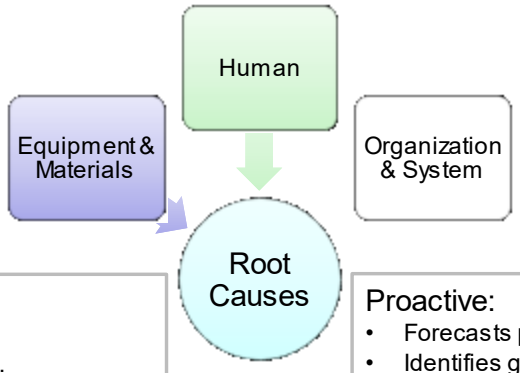
Focus: Risks associated with trends or patterns.

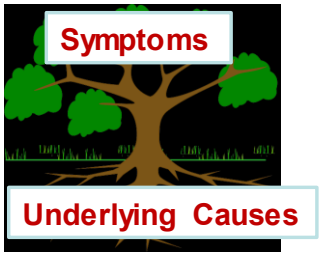
CAPA



How do we arrive at corrective and preventive actions?

Root Causes Analysis





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

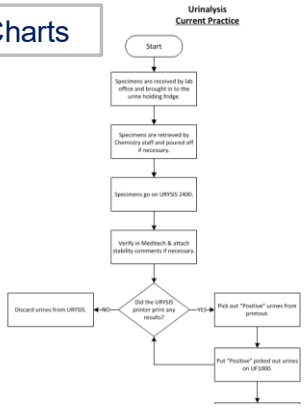
Proactive:
- Forecasts probable events.
- Identifies gaps between desired & actual.
- Determines what to change and how.

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

Flow Charts



Incident Reports

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Root Cause Analysis

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Brainstorming

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Root Cause Analysis

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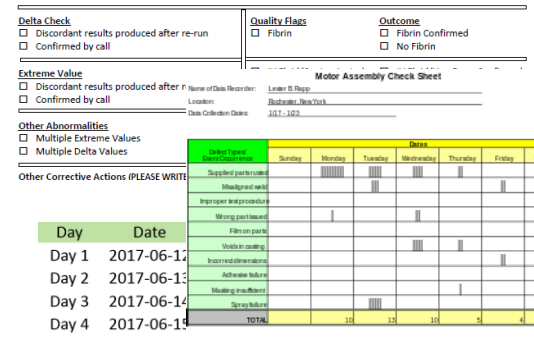
Sampling/Surveys/Check sheets



Day	Date				
Day 1	2017-06-12				
Day 2	2017-06-13				
Day 3	2017-06-14				
Day 4	2017-06-15				
Day 5	2017-06-16	363	240	123	33.9%
Day 6	2017-06-17	123	87	36	29.3%
Day 7	2017-06-18	102	70	32	31.4%
TOTAL		2164	1295	869	40.2%

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Root Cause Analysis

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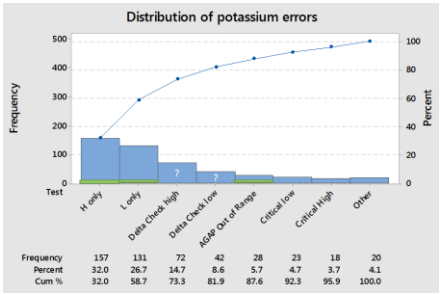
Pareto Charts



Affinity Diagrams

Histograms/Scattergrams

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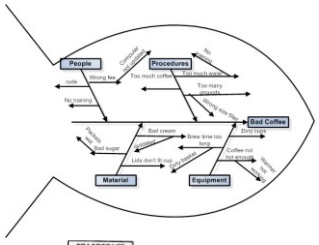
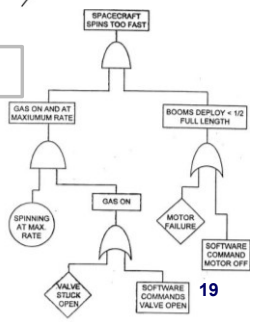
5 Whys

Fishbone analysis



Fault tree analysis



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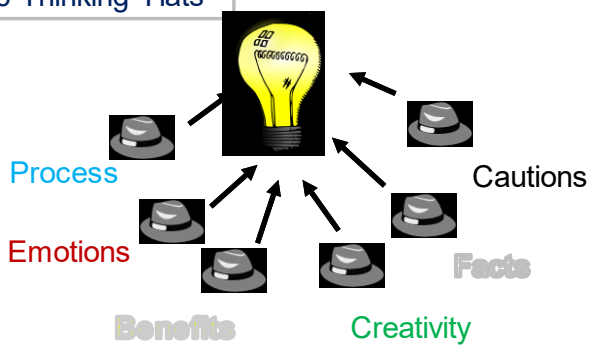
6 Thinking Hats



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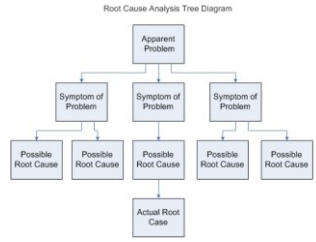
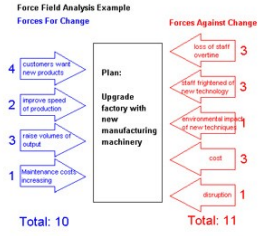
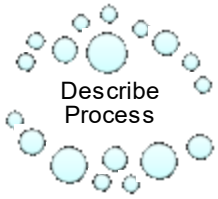
Tree Diagram



Force-Field Analysis



FMEA



Identify potential Failure modes

Describe Effects of Failure

How can failure occur?

What are root causes?

What is impact of failure?

What needs to be done?

FMEA

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

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

Likelihood of occurrence (Scale: 1 to #)

Severity of Failure (Scale: 1 to #)

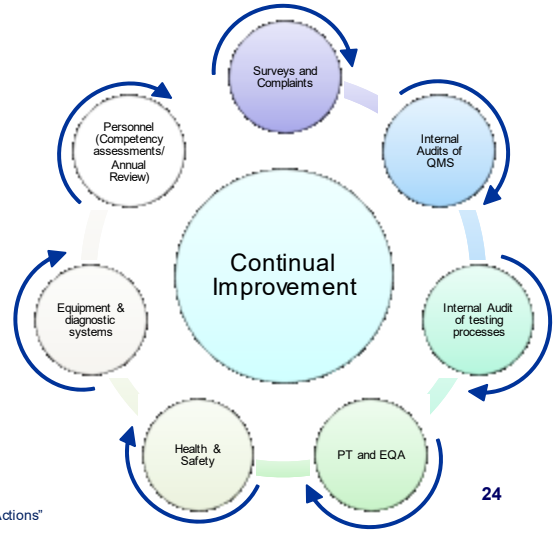
Step	Failure Mode	Failure Causes	Failure Effects	OCC	DEC	SEV	RPN	Actions to reduce Occurrence
Specimen analyzed	Hemolysis	Traumatic Draw	Erroneous Result	4	2	4	32	Educate collectors
	Uncentrifuged	Improper processing	Erroneous Results	1	2	3	6	None
	Clot	Improper mixing	Erroneous result	1	4	1	4	None

Likelihood of detecting (Scale: 1 to #)

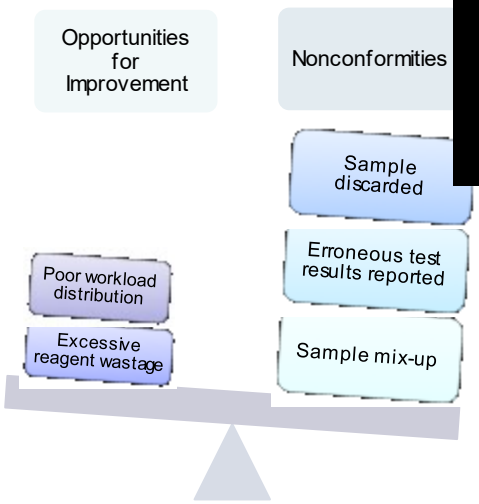
Risk Priority Number = OCC x DET x SEV

Continuous Improvement Models

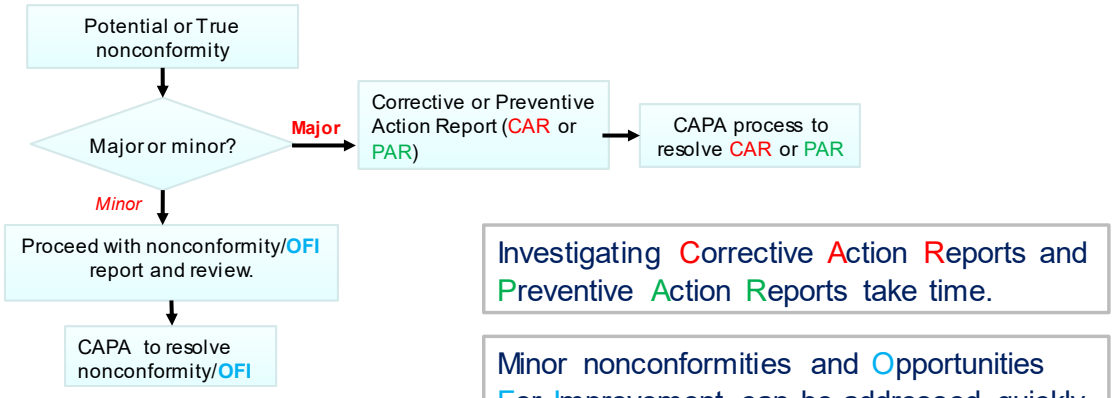
Other systematic strategies for CAPA:
- TQM
- RCA
- PDCA
- LEAN
- Six Sigma (DMIAC)



The big and small



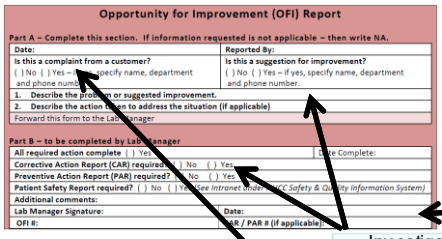
CAPA as a process



Investigating Corrective Action Reports and Preventive Action Reports take time.

Minor nonconformities and Opportunities For Improvement can be addressed quickly.

Addressing the Minor



Generally require lower level review and sign off.

Sign off

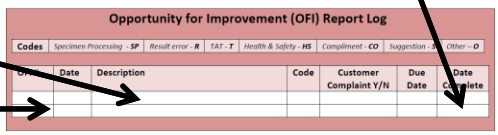
Record completion on log.

Investigate & decide actions

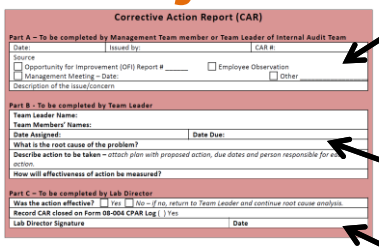
Begin report

Record event

Assign OFI#



Addressing the Major



Assign CAR/PAR #

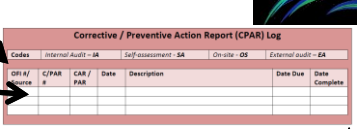
List items needing correction

Document the issue

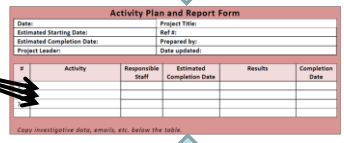
Document Actions

Describe outcome of CAPA

Designated person reviews and signs off.



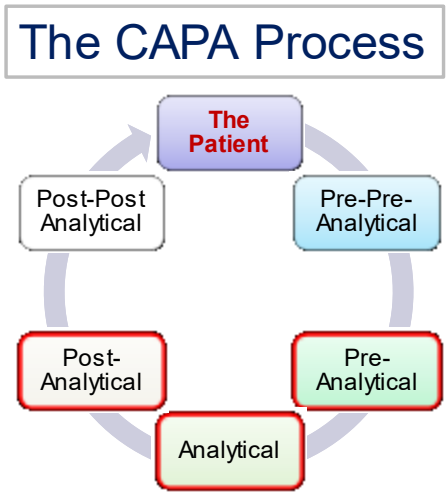
Root Cause Analysis

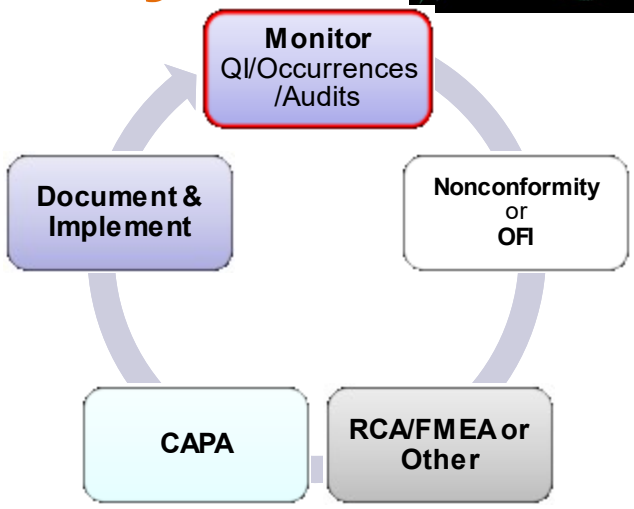


FMEA or other risk management tools

Generally require high level review and sign off.

Summary





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