Tackling the Error Reporting Conundrum: Using Lean Thinking to Determine What Non-conformances Need to be Investigated, Reported, and Who Needs to be Involved

Anne T. Daley
MS, CMQOE, CSSBB, CLC, MT, DLM
President, Daley Consulting LLC

Learning Objectives

By the end of the Master Session, you will be able to:

- learn how to apply Lean thinking to determine the course of action needed in response to a nonconforming event.
- learn what critical questions need to be asked when responding to a nonconforming event.
- learn how to utilize a common Lean tool to guide a laboratory's decision response process.

Understanding the Terms

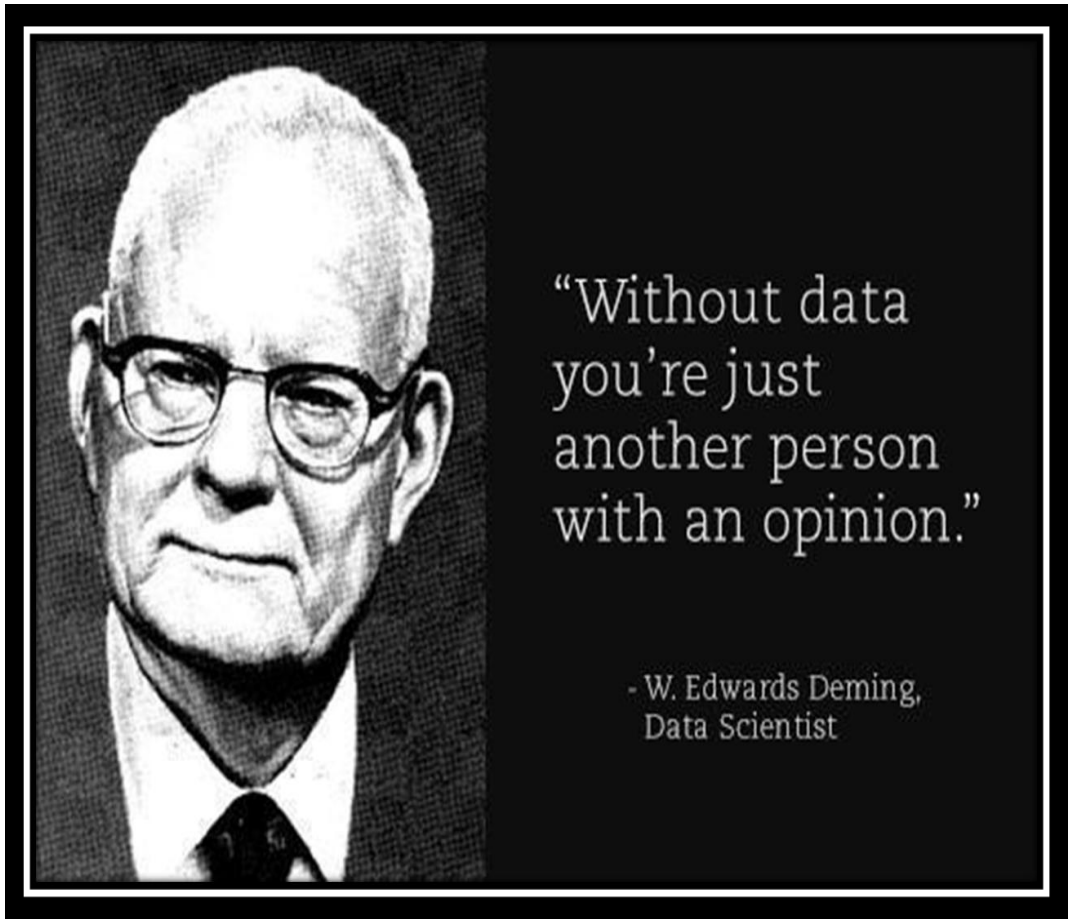
Nonconformity – nonfulfillment of a requirement (ISO 9000)

Nonconforming event (NCE) – an occurrence that does not conform:

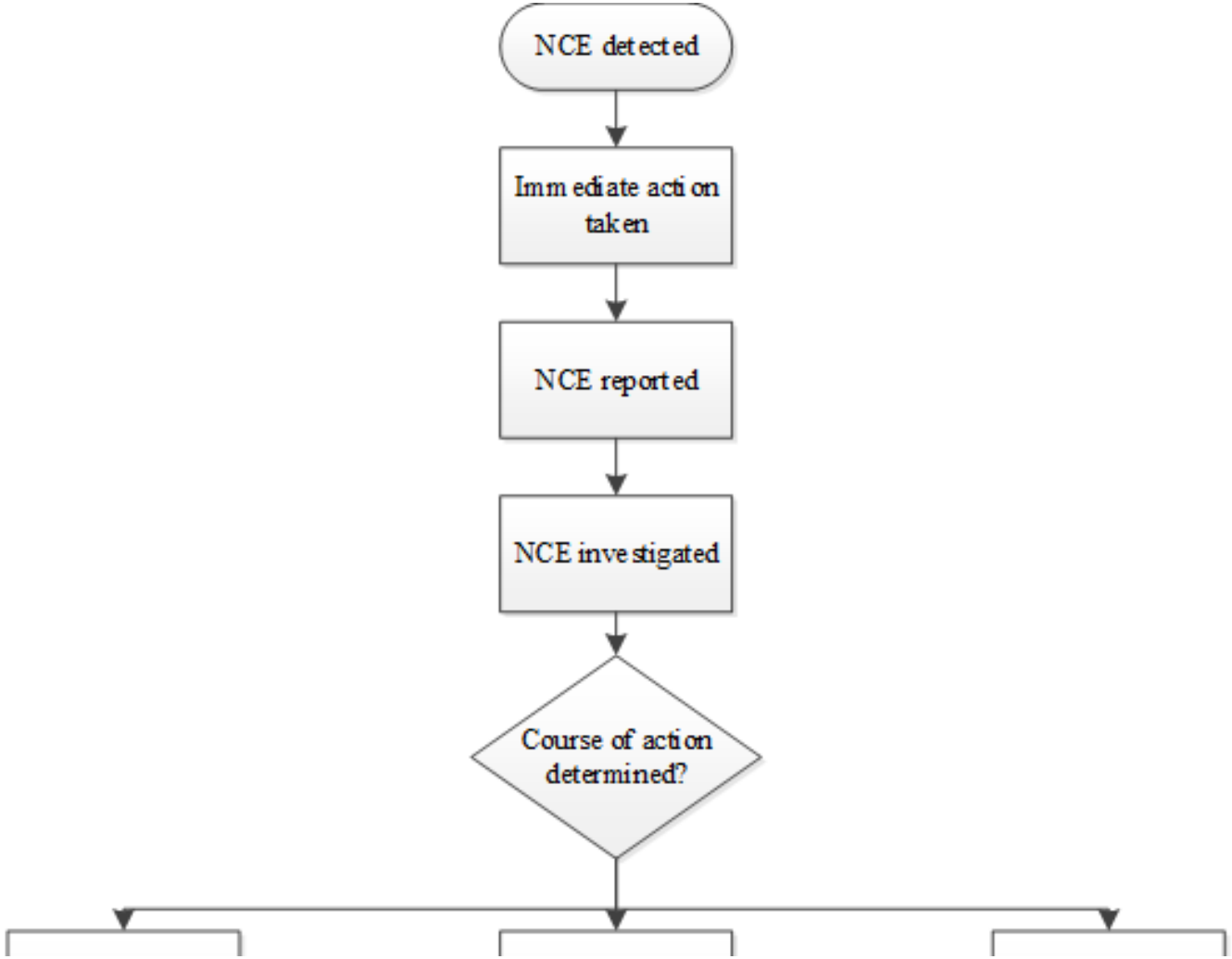
- to the laboratory's policies, processes, and/or procedures;
- with applicable regulatory or accreditation requirements;
- or has the potential to affect (or has affected) patient, donor, or employee safety.

Objective #1:

How to apply Lean thinking to determine the course of action needed in response to a nonconforming event.

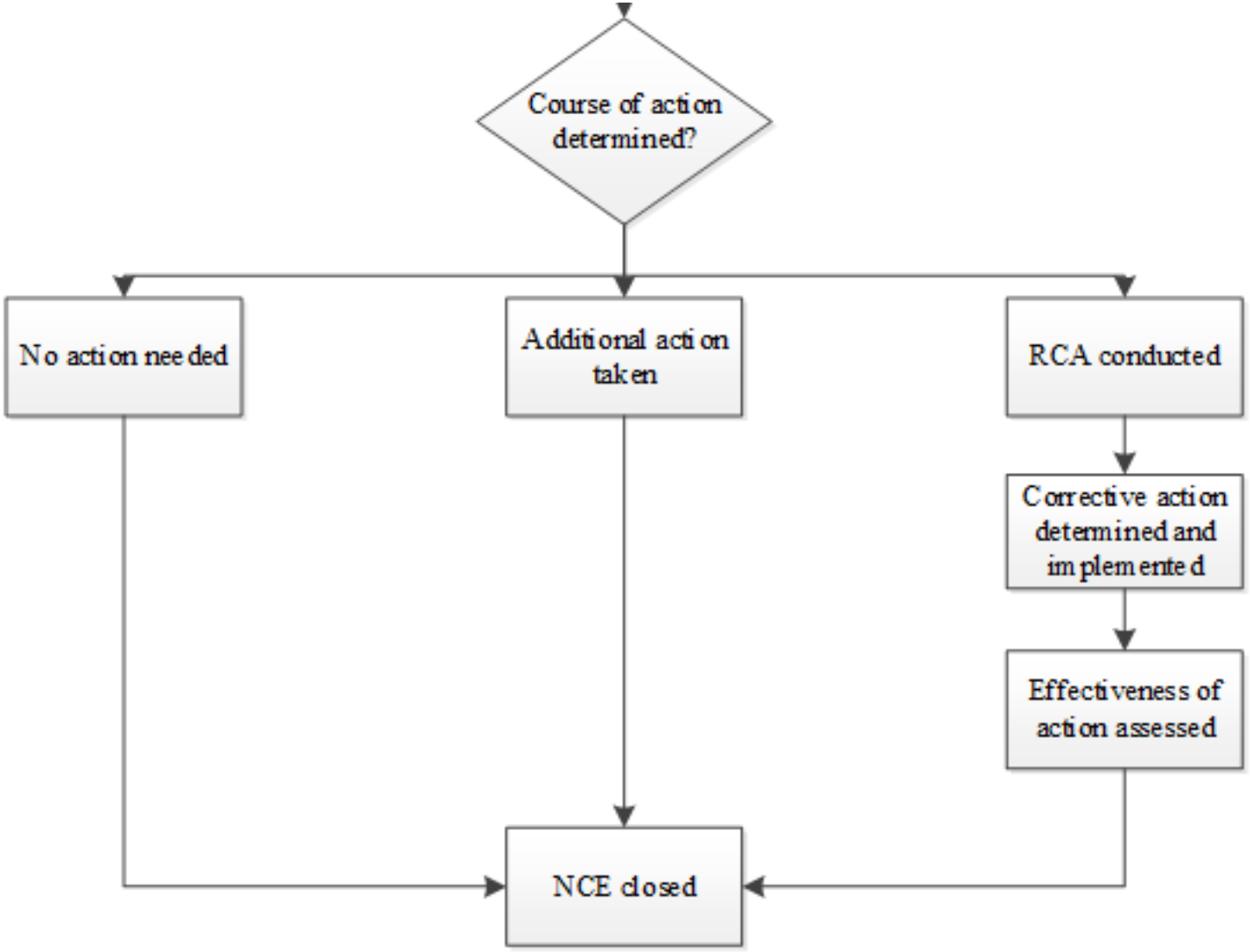


NCE Response Process – Part 1



Source: QMS11-A2, Section 2.2, Figure 3

NCE Response Process – Part 2

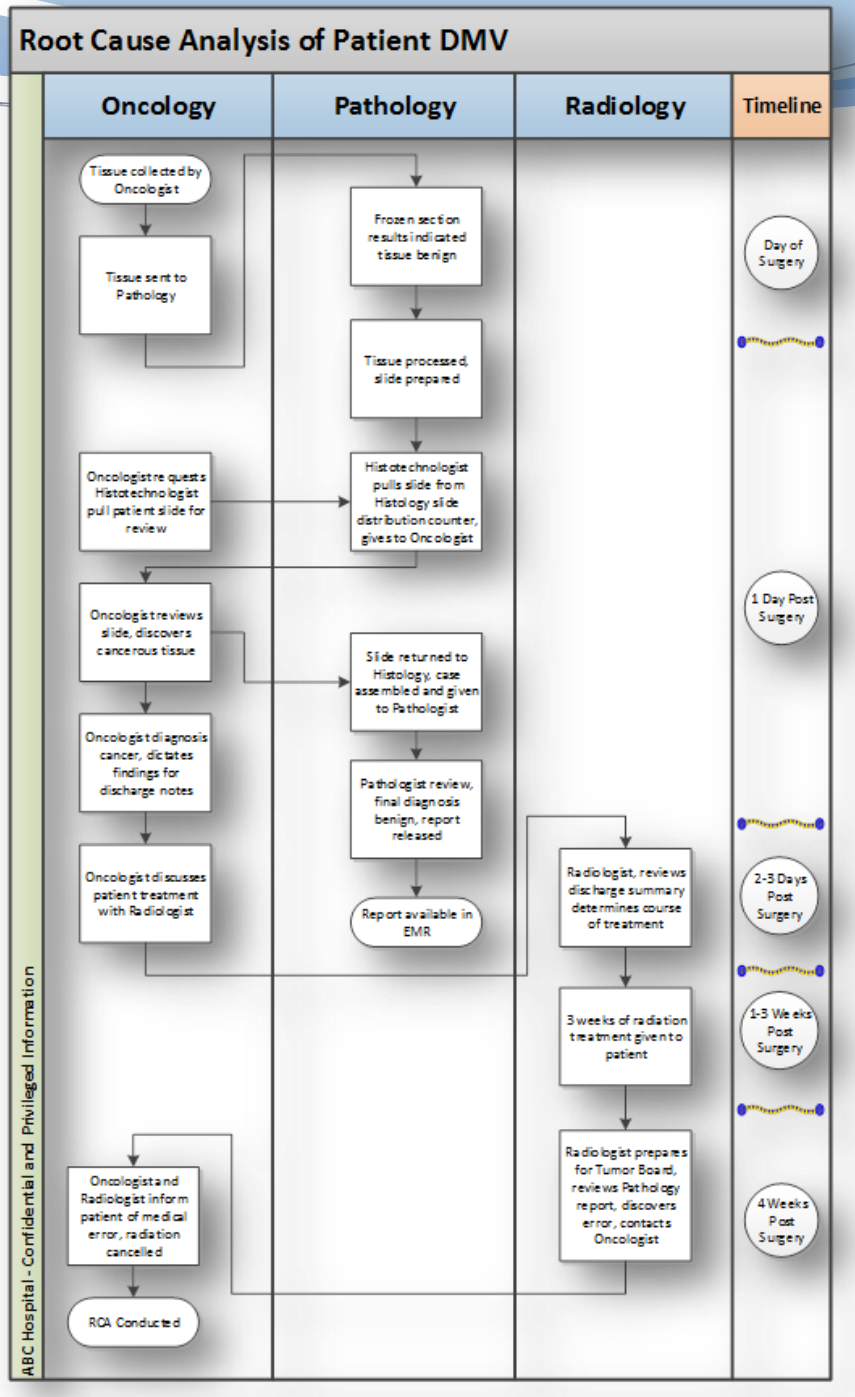


Source: QMS11-A2, Section 2.2, Figure 3

What Happened?

Conduct an investigation to understand the sequence of events.

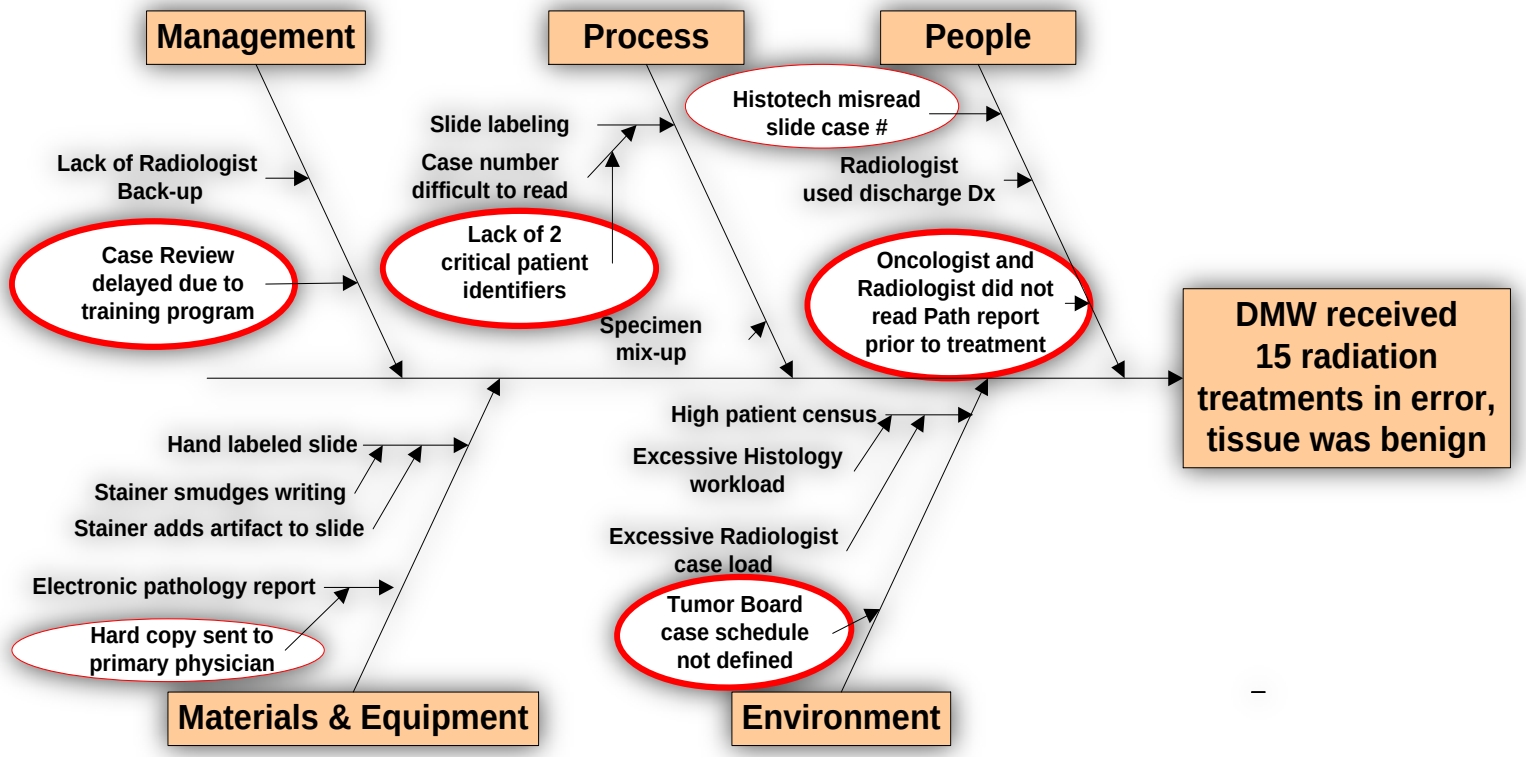
Tool: Process Map



What Could Have Caused This?

Brainstorm possible causes then identify the primary "pain points."

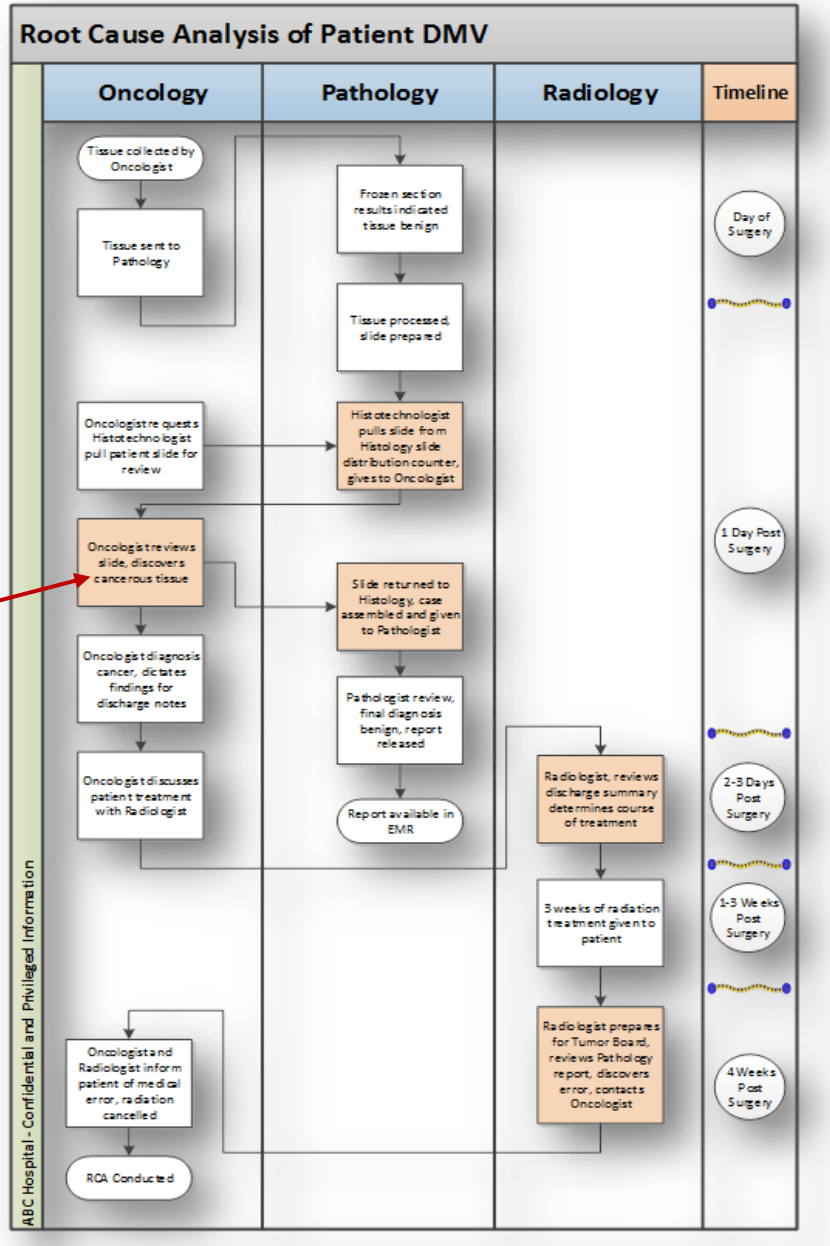
Tool: Cause-and-Effect (C-E) Diagram



Sources of Error

Review process to identify process steps that could be the source of error.

Tool: Process Map



Why Did This Happen?

Determine root cause(s).
Tool: 5 Whys

1. Why was radiation given to DMW?
   - Because patient discharge notes stated cancer.
2. Why did discharge notes state cancer?
   - Because oncologist discovered cancer on patient slides in lab.
3. Was the slide DMW's?
   - No, the slide was another patient's.
4. How do you know the slide was another patient's?
   - Because DMW's pathology report stated tissue was benign, consistent with frozen section preliminary results (slide was reviewed, confirmed diagnosis).
5. Why was the oncologist given the wrong slide?
   - Because the number "8" looked like the number "3" to the histotech. Only one critical patient identifier was on the slide.

Determine what needs to change.

Tools: Brainstorming, Affinity Diagram, Decision X-Y Matrix

XY Decision Matrix - Prioritizing Solutions													
Desired Criteria / Expectations:		**Corrects Root Cause**		**Minimizes Risk / Potential to Reoccur**		**Can Be Done Within 30 Days**		**Uses Minimal Amount of Resources**		**Involves Training of Staff**		**Solution Can Be Applied to Other Processes**		**TOTAL**
Criteria Weight (Low=1, Med=3, High=9)		**9**		**9**		**3**		**3**		**1**		**1**		
		Score	**Wtd. Score**	Score	**Wtd. Score**	Score	**Wtd. Score**	Score	**Wtd. Score**	Score	**Wtd. Score**	Score	**Wtd. Score**	
Potential Solution	**Comments**													
Obtain slide label printer	Eliminates manual writing on slides, easier to read.	9	**81**	9	**81**	5	**15**	5	**15**	9	**9**	9	**9**	**210**
Train staff to write more legibly on slides	Utilize NCE as a training case study to emphasize importance of writing clearly on slides	1	**9**	1	**9**	9	**27**	5	**15**	9	**9**	9	**9**	**78**
Add patient name to slide	Add additional patient identifier to slide	3	**27**	3	**27**	9	**27**	9	**27**	9	**9**	9	**9**	**126**

Understanding the Difference in Actions

- **Corrective action:** Action to eliminate the cause of a detected nonconformity or other undesirable situation. Corrective action is taken to prevent recurrence.
  - **Immediate action:** Act or deed performed without hesitation upon recognition or awareness of an NCE
    Note: The action should be documented.
- **Preventive action:** Action to eliminate the cause of a potential nonconformity or any other undesirable potential situation.

Corrective Action to Eliminate Root Cause

Root Cause Analysis (RCA) is the process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a nonconforming event

RCA is usually done for the following reasons:

- The hazard or harm associated with the NCE is of a moderate to high risk or severity.
- The NCE has a moderate to high probability of occurrence.
- Aggregate data have reached or exceeded acceptable threshold criteria for the NCE type (trend analysis).

Determining Single Event Course of Action

	Severity			
Probability	Critical	Important	Minor	Negligible
Continually	Corrective action to eliminate root cause	Corrective action to eliminate root cause	Corrective action to eliminate root cause	Correction of immediate problem
Frequently	Corrective action to eliminate root cause	Corrective action to eliminate root cause	Correction of immediate problem	Correction of immediate problem
Occasionally	Corrective action to eliminate root cause	Correction of immediate problem	No action necessary	No action necessary
Rarely	Correction of immediate problem	Correction of immediate problem	No action necessary	No action necessary

Source: QMS11-A2, Section 2.2.5, Table 7

RCA focuses primarily on systems and processes, not individual performance.

Implement prioritized changes.

Tools:

Implementation/Action Plan

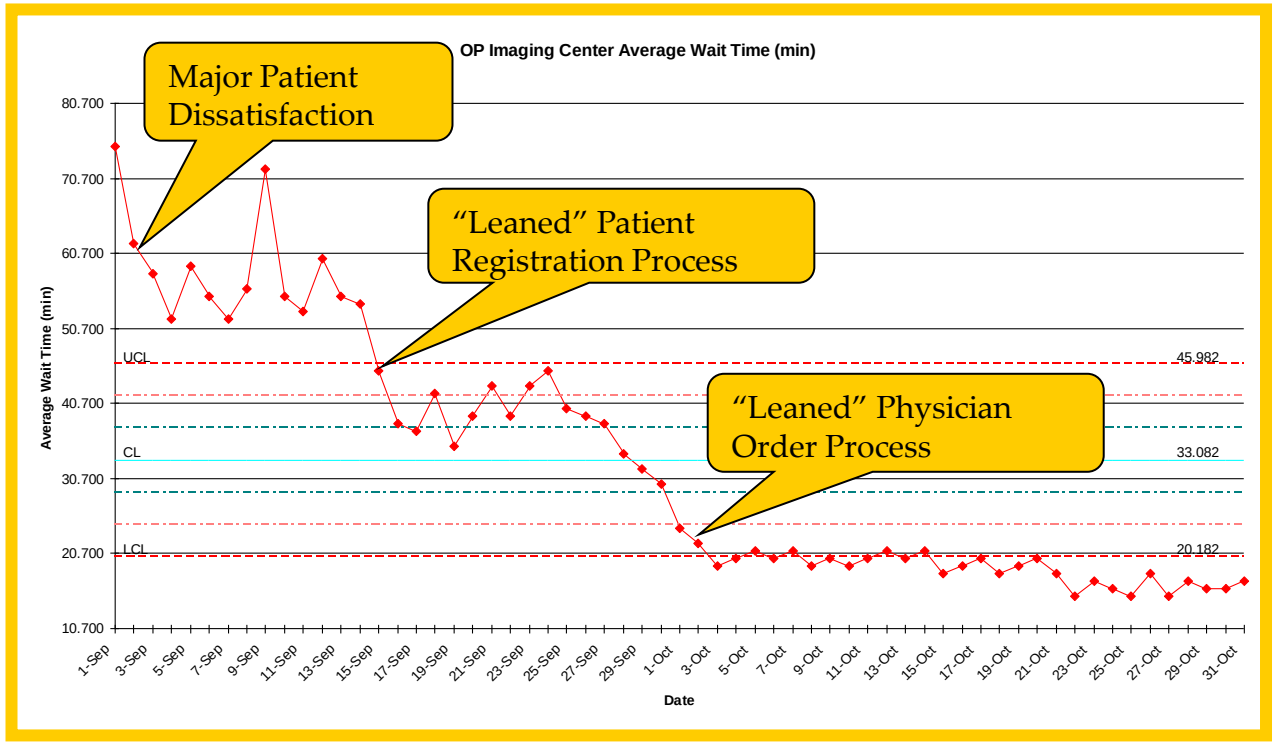
Ref. No	Action Steps	Task Leader(s)	Comments	Mar	Wk of 4/7	4/14	4/21	4/28	5/5	5/12	5/19	5/26	6/2	Later
	List Category #1													
	List Action Step	List Leader Name	Add notes or provide update on progress		Done									
	List Action Step	List Leader Name	Add notes or provide update on progress											
	List Action Step	List Leader Name	Add notes or provide update on progress					Delay						
	List Category #2													
	List Action Step													
	List Action Step													
	List Action Step													
	List Action Step													

	Planned Activity
	On Schedule / Activity Completed
	Off Schedule - Should Not Impact Timeline
	Off Schedule, Will Impact Overall Project Timeline

Assessing Effectiveness

Assess effectiveness of changes- performance metrics.

Tools: Audits, Run Charts, Pareto Charts

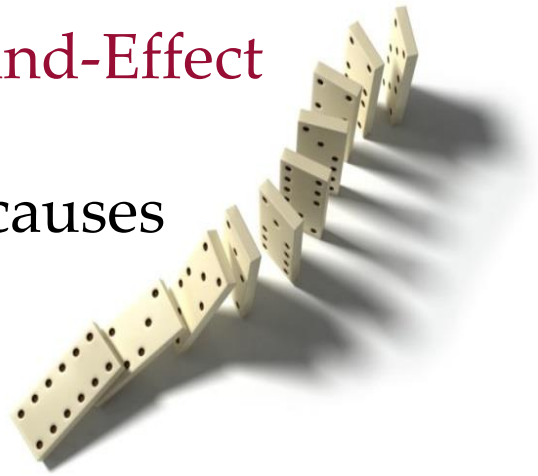


Outcome: Reduced Outreach Imaging Center Patient Wait Time

Most improvement actions involve multiple solutions.

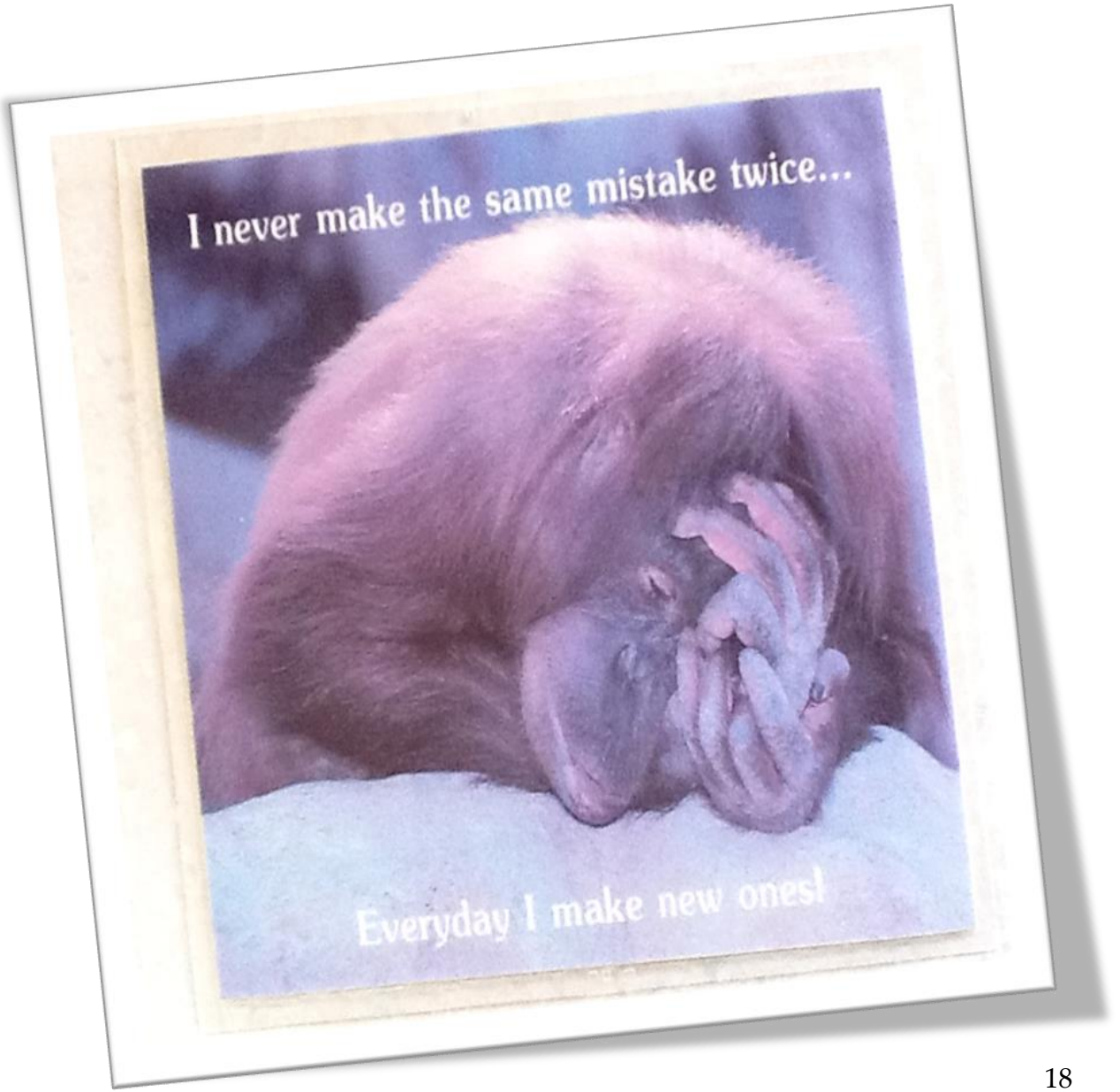
Essential Steps Summarized

1. Identify series of steps (Process Map).
2. Brainstorm possible causes that could create the error (Cause-and-Effect Diagram).
3. Investigate the possible causes, identifying the most probably causes (5 Whys).
4. Analyze the most probable causes (Process Map).
5. Repeat steps 3 and 4 until root cause is identified.
6. Determine corrective action (Brainstorming, Affinity Diagram, X-Y Decision Matrix).
7. Implement (Implementation/Action Plan).
8. Assess effectiveness (Audits, Run Charts, Pareto Charts); repeat steps 3 to 8 if needed.
9. Trend and track performance to ensure correction is sustained.



Objective #2:

What critical questions need to be asked when responding to a nonconforming event.



Error Correction Report Case Study

- Test ABC has been reported for over 5 years with a normal reference interval of 300 – 500 units.
- The linearity range in the LIS was 100 – 1500. The linearity range is not included in the patient report.
- After 5 years an error was noted, the actual validated range was 100 – 1000, range was corrected in LIS.
- About 20,000 test results were released during the 5-year period.
- No potential impact to patient was determined (all very "high" results were still very "High")
- If a corrected report was to be generated, a typical change would be from "1,200 units" to >1,000 units (both results remained significantly above the normal reference interval).

ECR Case Study Questions

1. Should the patient be notified of the nonconformance?
2. Should the clinician be notified of the nonconformance?
3. Should the report be corrected?

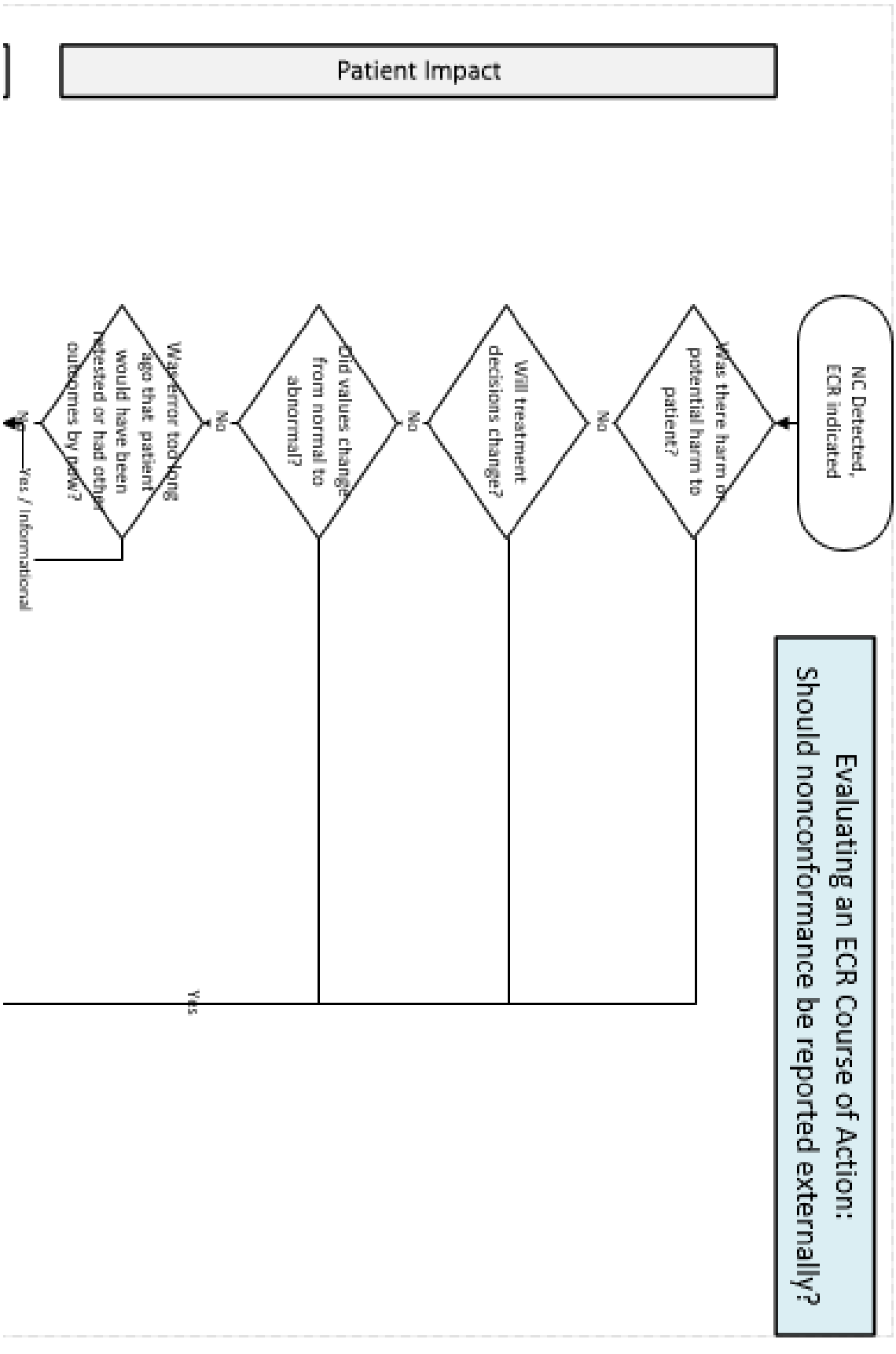
Critical Questions to be asked

- Who needs to be involved?
- Does it need to be investigated?
- Does it need to be reported?
  - Was there harm or potential harm?
  - Will the clinician do anything different?
  - Is there any benefit to the patient or clinician to be notified?
  - Is there any benefit to the laboratory to send out a notification?
  - Is there any risk to the laboratory?

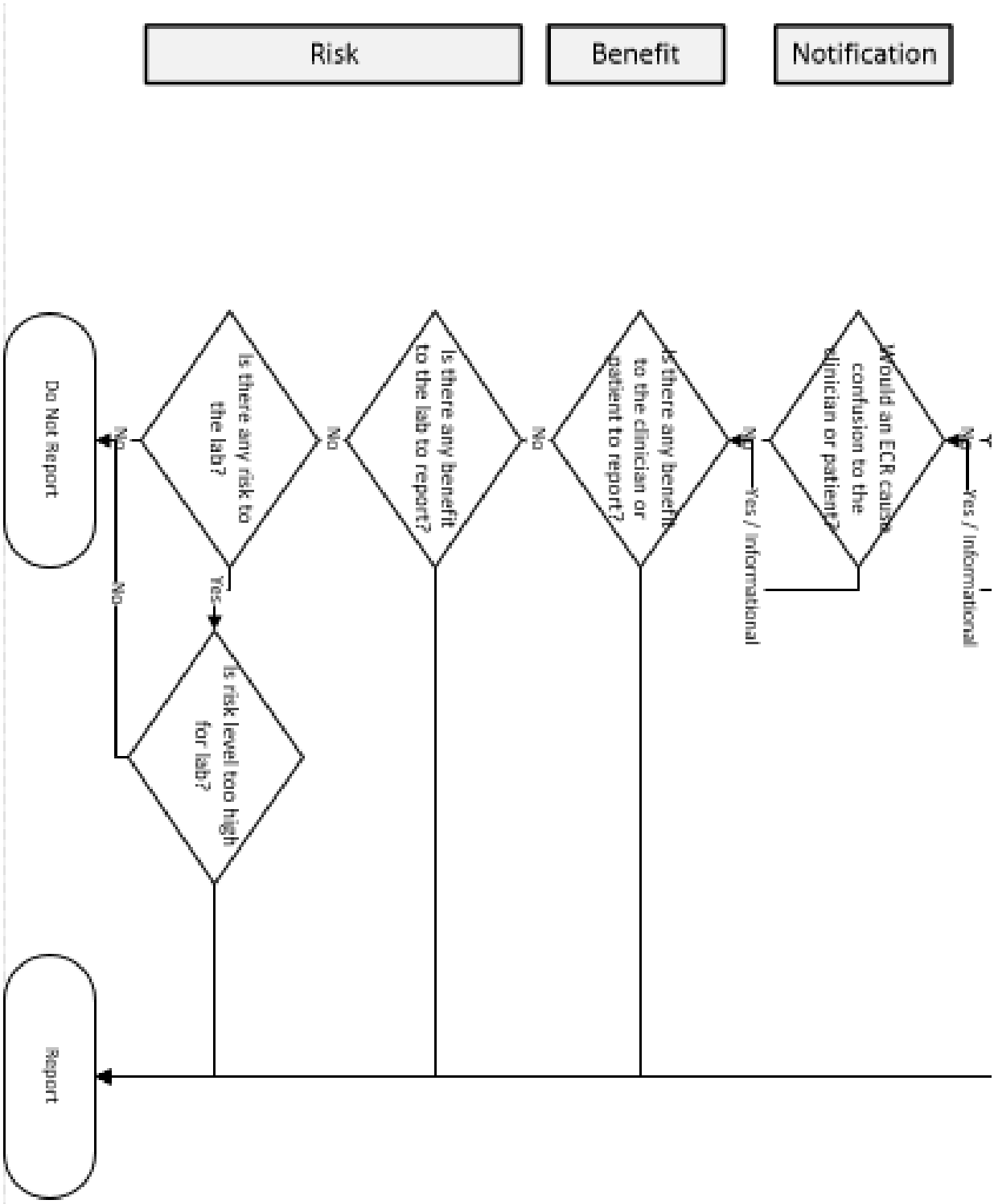
Objective #3:

How to utilize common Lean tools to guide a laboratory's decision response process.

ECR Decision Process Map – Part 1



ECR Decision Process Map – Part 2



Valuable Resources:

CLSI QMS11 *Nonconforming Event Management*

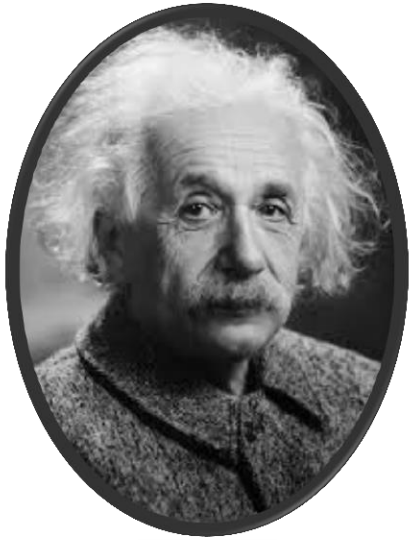
CLSI QMS06 *Continual Improvement*

Discussion

- Questions
- Clarification
- Comments

Anne T. Daley
MS, CMQOE, CSSBB, CLC, MT, DLM
President, Daley Consulting LLC
anne@daleyconsulting.net
www.daleyconsulting.net

"The significant problems we face today cannot be solved at the same level of thinking we were at when we created them."



Albert Einstein

1879-1955