Nonconformance Management – Responding to a Major Nonconformance, Determining the True Root Cause, and Ensuring Corrective Actions are Sustained

Anne T. Daley

Quality Officer, ARUP Laboratories

Lab Quality Confab 2019

Learning Objectives

- To learn how to determine the “true” root cause of a nonconforming event.
- To learn how to identify corrective actions needed and ensure improvements are sustained.
- To develop immediate strategies to address common pitfalls within the participant’s organization.

What is Root Cause Analysis?

Root cause analysis (RCA) is a collective term used to describe a wide range of methods and tools used to uncover the underlying or “root” causes of problems. Root causes are eliminated by identifying factors that contribute to the problem and finding solutions.

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

Question:

Are these common root causes?

“Swiss Cheese” Model of Error

Resource: CLSI, QMS11 *Nonconforming Event Management,* 2nd Ed., 2015

When to Perform an RCA

- RCA must be performed on any nonconformance that caused harm or had the potential to cause harm to a patient – many organizations also include employee and reputation.
- RCA should be done on any high-risk or high-cost nonconformance.
- RCA may be done on a high frequency nonconformance.

Is an RCA needed?

Determining Course of Action

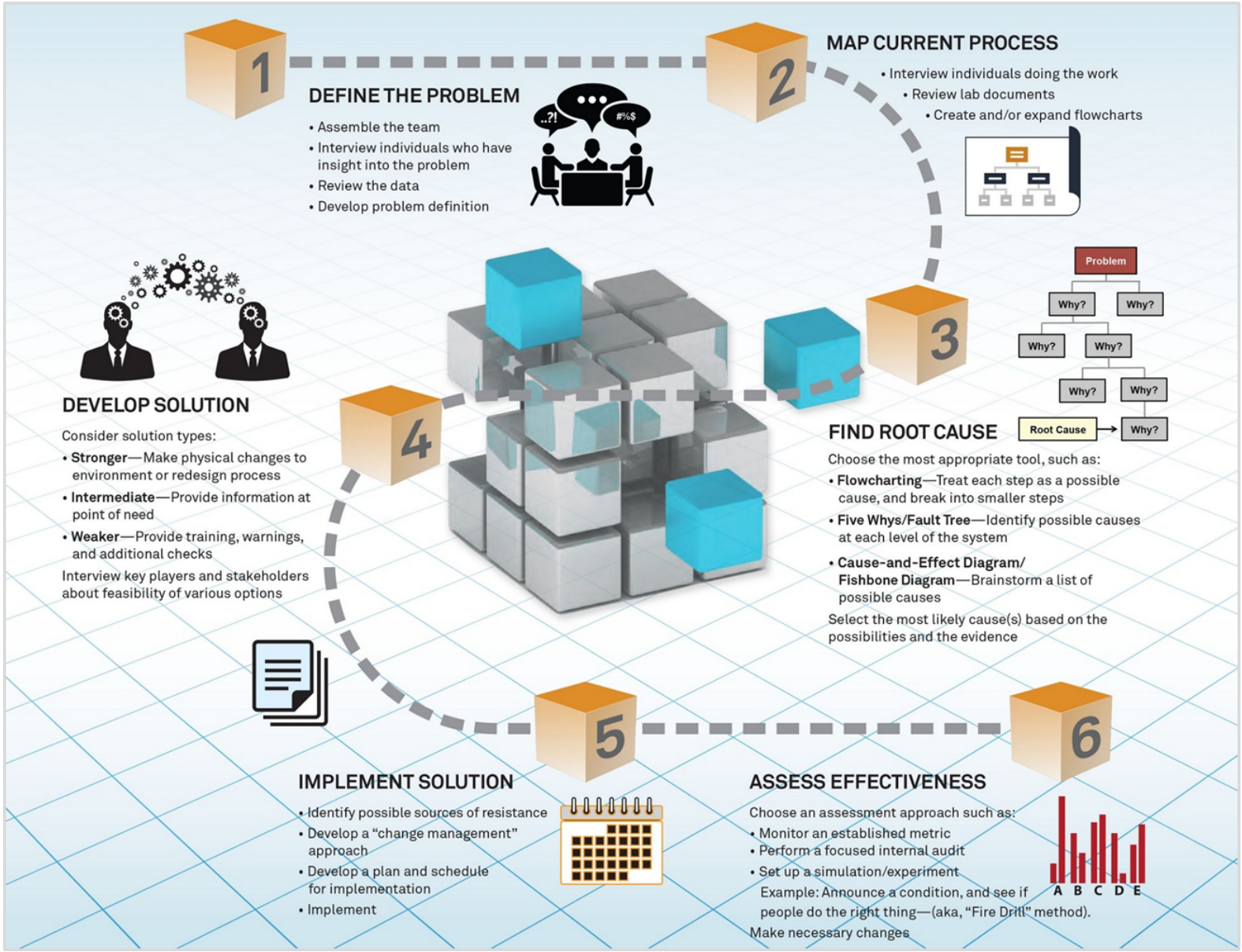
Assessing Risk

			Impact (Severity)			
			Negligible	Minor	Important	Critical
			1	3	5	10
Frequency (Probability)	Continually	5	5	15	25	50
	Frequently	3	3	9	15	30
	Occasionally	2	2	6	10	20
	Rarely	1	1	3	5	10

Score Classification	Risk Assessment Score	Is a Root Cause Analysis Needed?
Acceptable (Green)	1-3	Not necessary
Undesirable (Yellow)	5-10	May be necessary
Unacceptable (Red)	15-50	Required

Resource: CLSI, QMS11 *Nonconforming Event Management,* 2nd Ed., 2015

Root Cause Analysis



Resource: CAP ISO 15189, *RCA Performance and Feedback Toolkit - Overview*

Step 1: Define the Problem

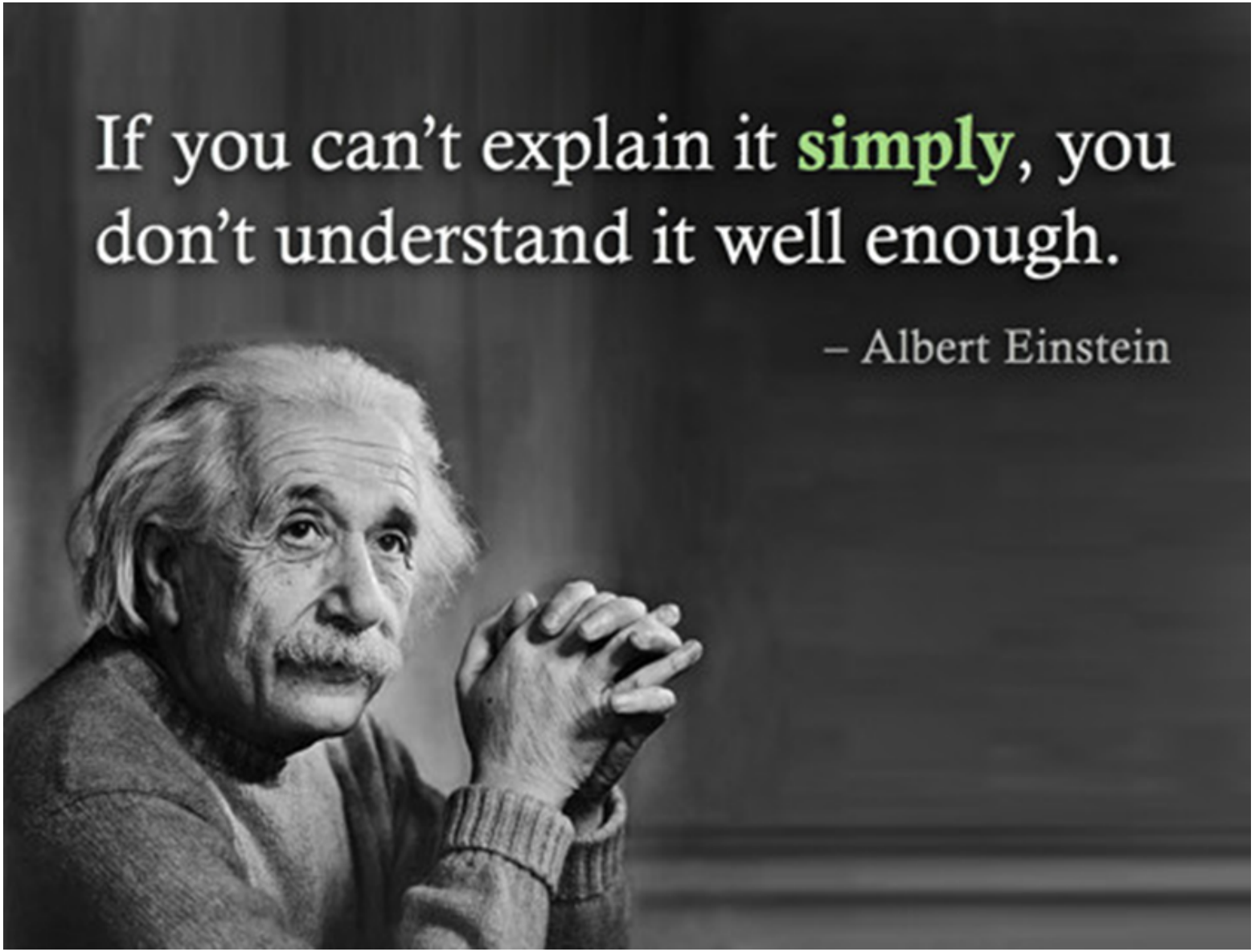
The problem statement is crucial to starting the investigation. If you can't understand the problem, how are you going to know what to do?

- **What:** What happened and what was impacted?
- **When:** When did the nonconformance occur?
- **Where:** Where did it happen?
- **Who:** Who was involved?
- **How:** How does what happened differ from what *should* have happened?

Focus on facts!
Tool: Interview

Step 1: Define the Problem

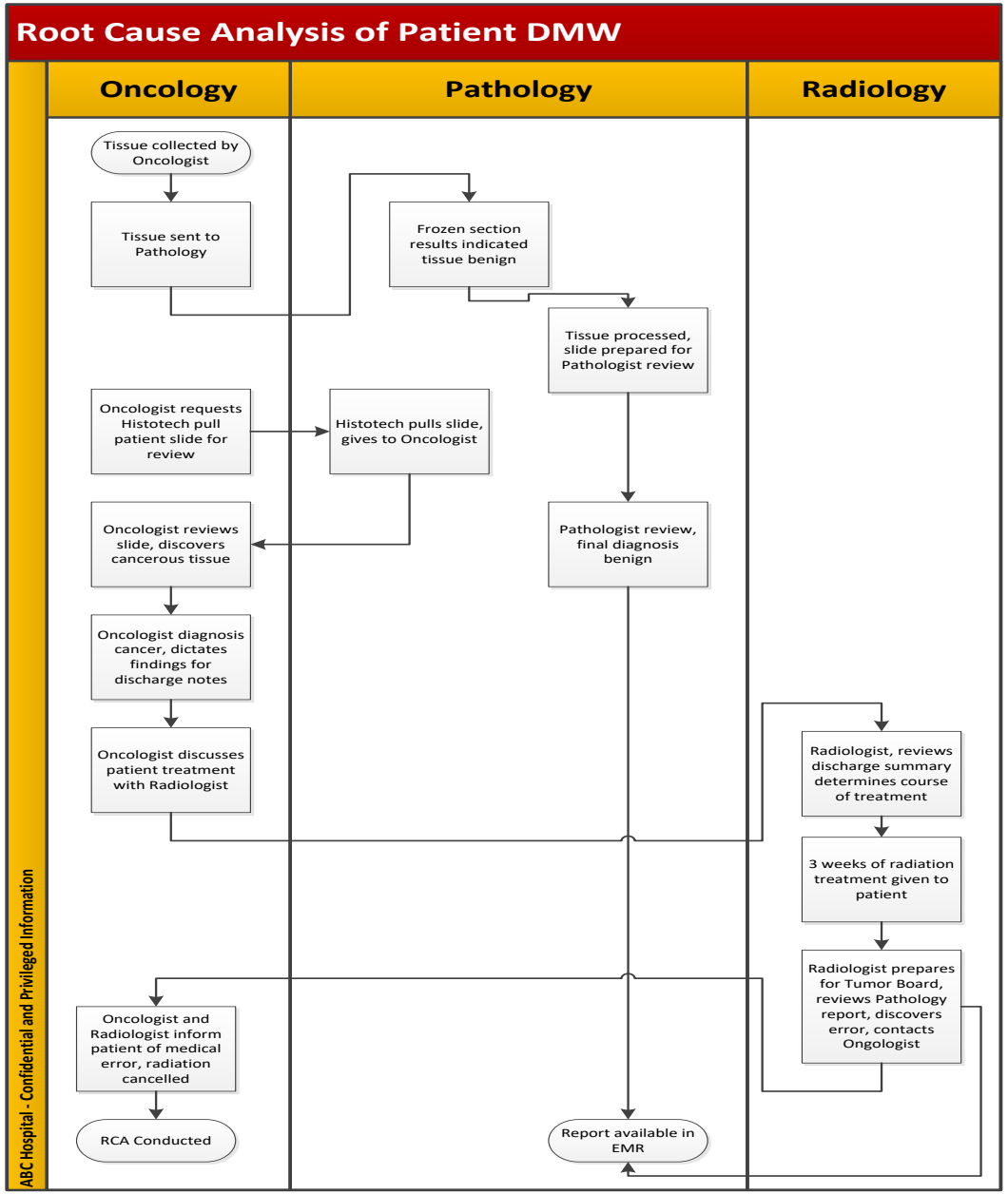
- 71-year-old female (DMW) had lump on neck surgically removed by an oncologist.
- Oncologist informed patient the lump was cancerous and recommended radiation treatment.
- Patient received 15 radiation treatments, 5 per week for 3 weeks, then was informed there was an error, she did not have cancer.
- Patient's treatment side effects:
  - Right arm paralysis – took 1 year to regain feeling.
  - Loss of salivary glands – dry mouth for rest of life.
  - Loss of hair under arms – patient happy with this one!


If you can't explain it simply, you don't understand it well enough.
– Albert Einstein

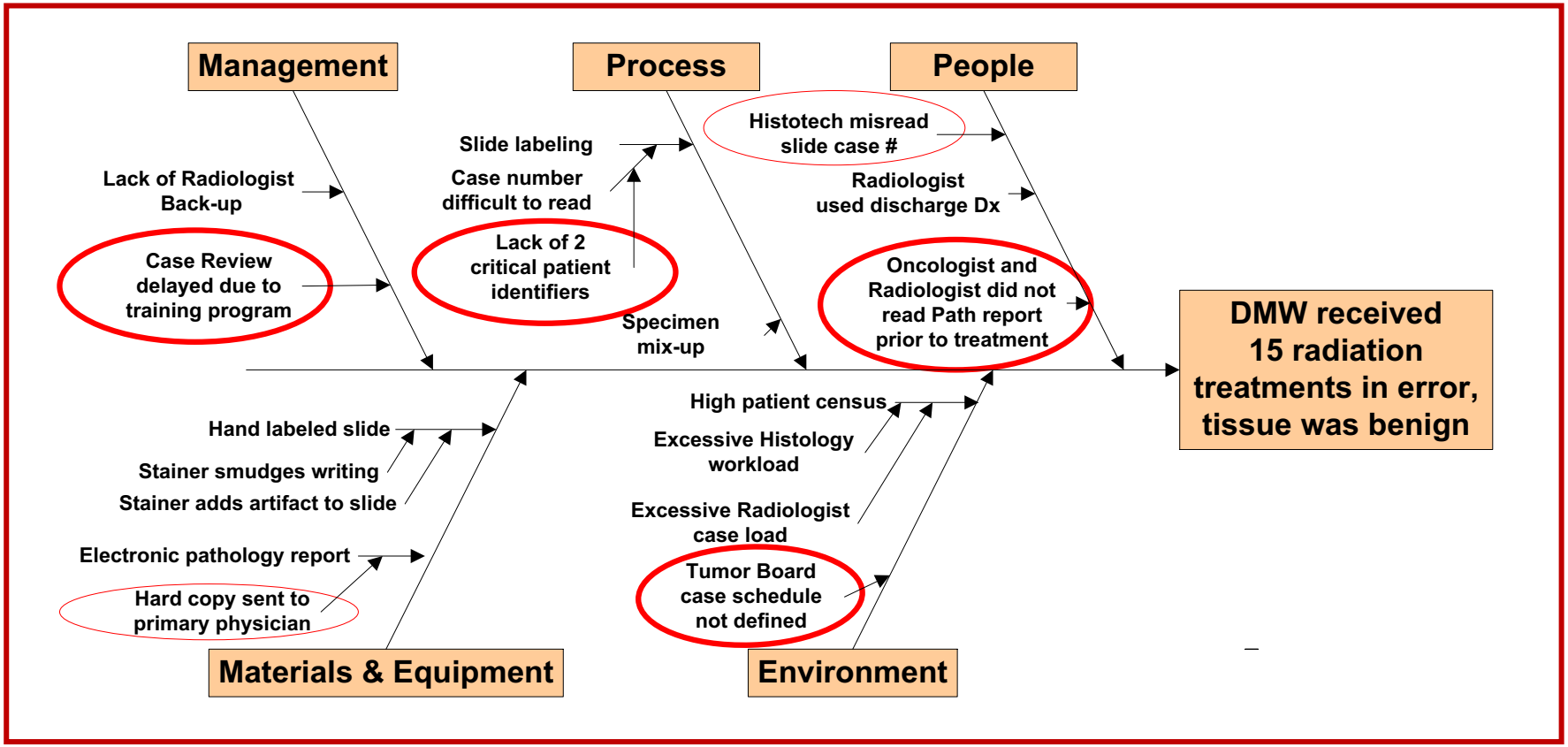
Step 2: Map Current Process

Identify sequence of events.

Tool: Process Map



Step 3: Find Root Cause

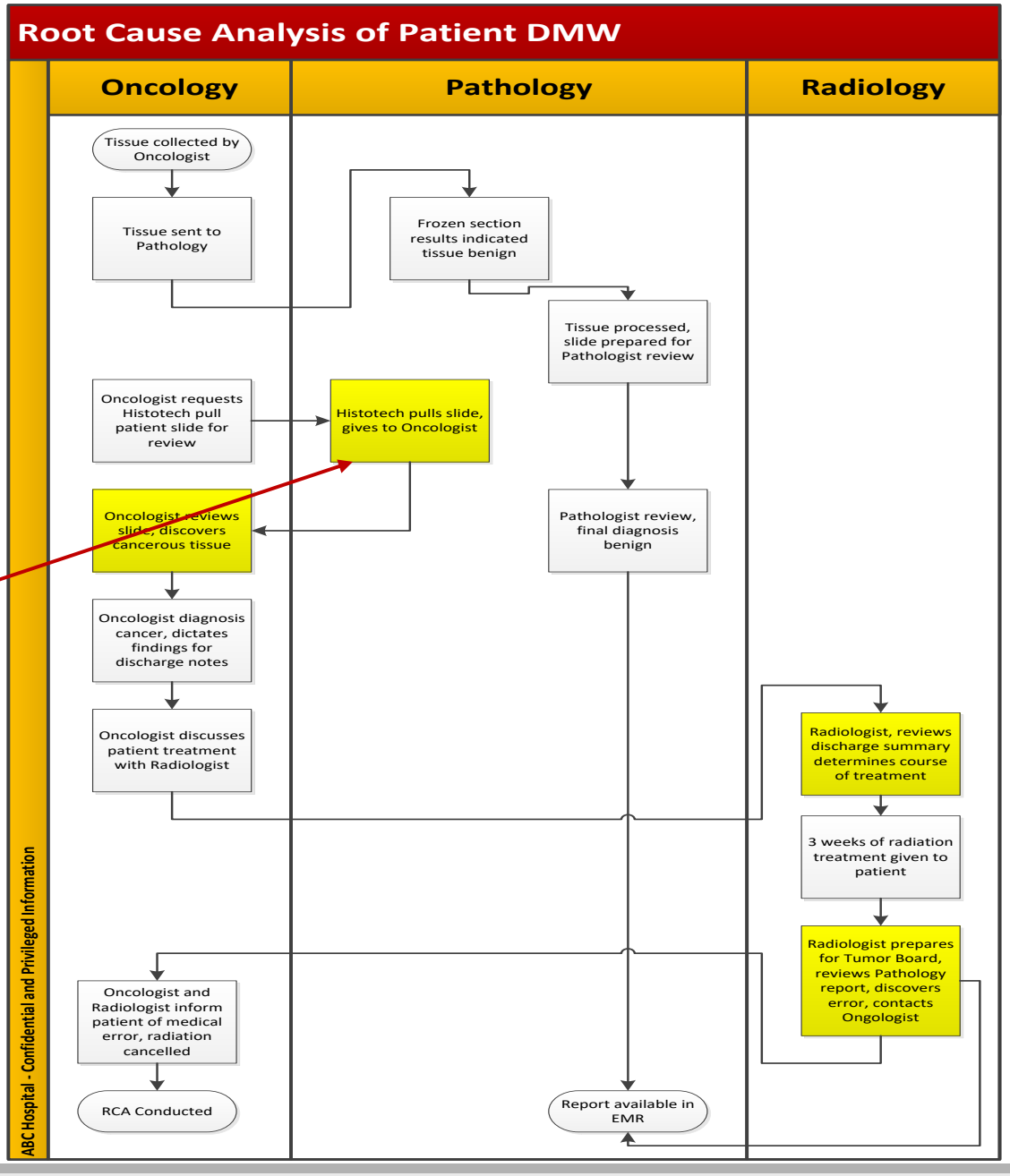


Brainstorm possible causes then identify the primary "pain points."

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

Step 3: Find Root Cause

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

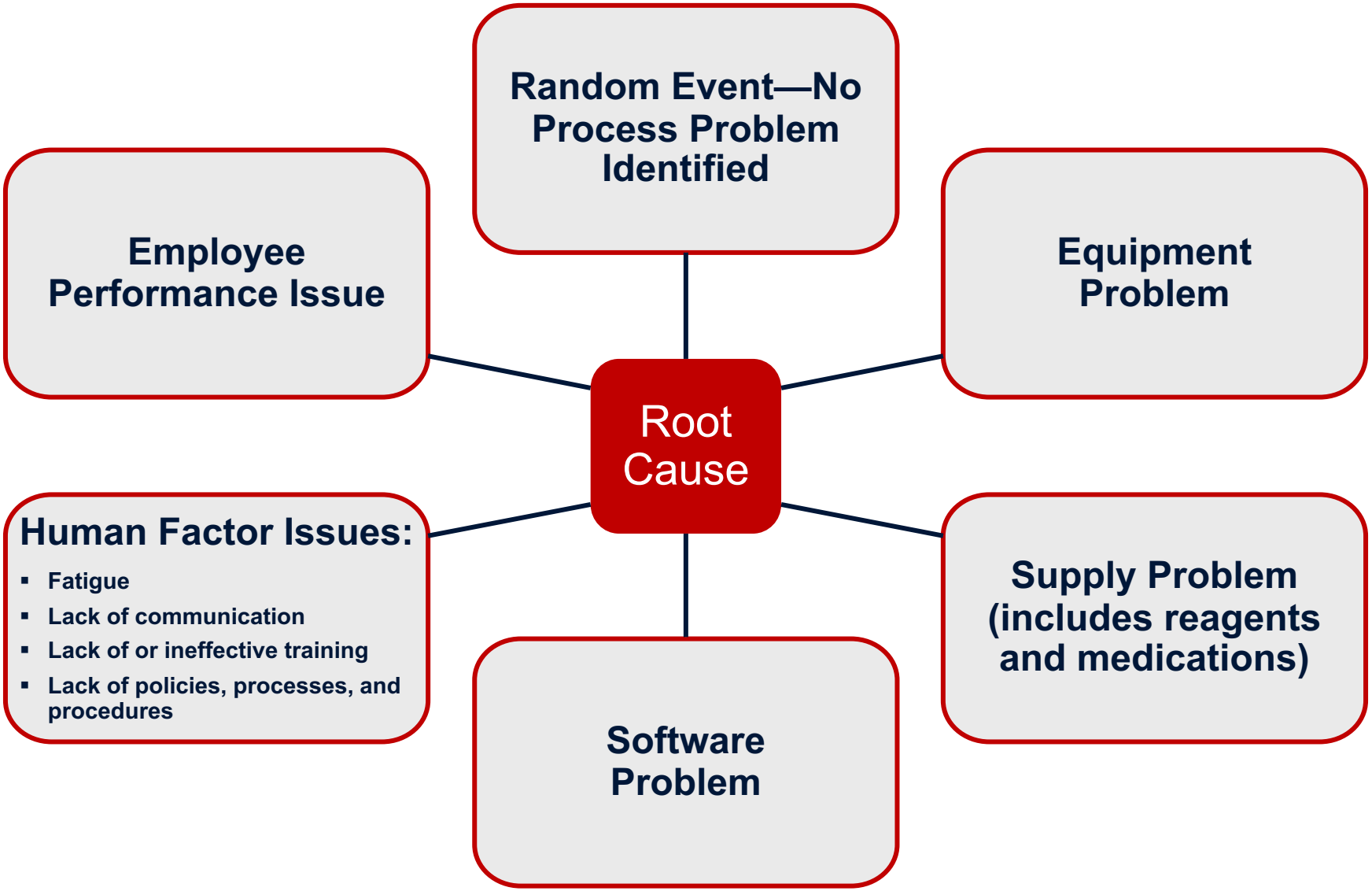


Step 3: Find Root Cause

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.
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.

Identify possible causes at each level.
Tool: 5 Whys

Commonly Identified Root Causes

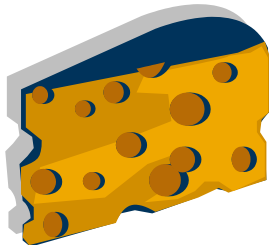


Step 4: Develop Solution(s)

Identify & prioritize solution(s) for each root cause.

Tool: Brainstorming

Step 5: Implement Solution(s)

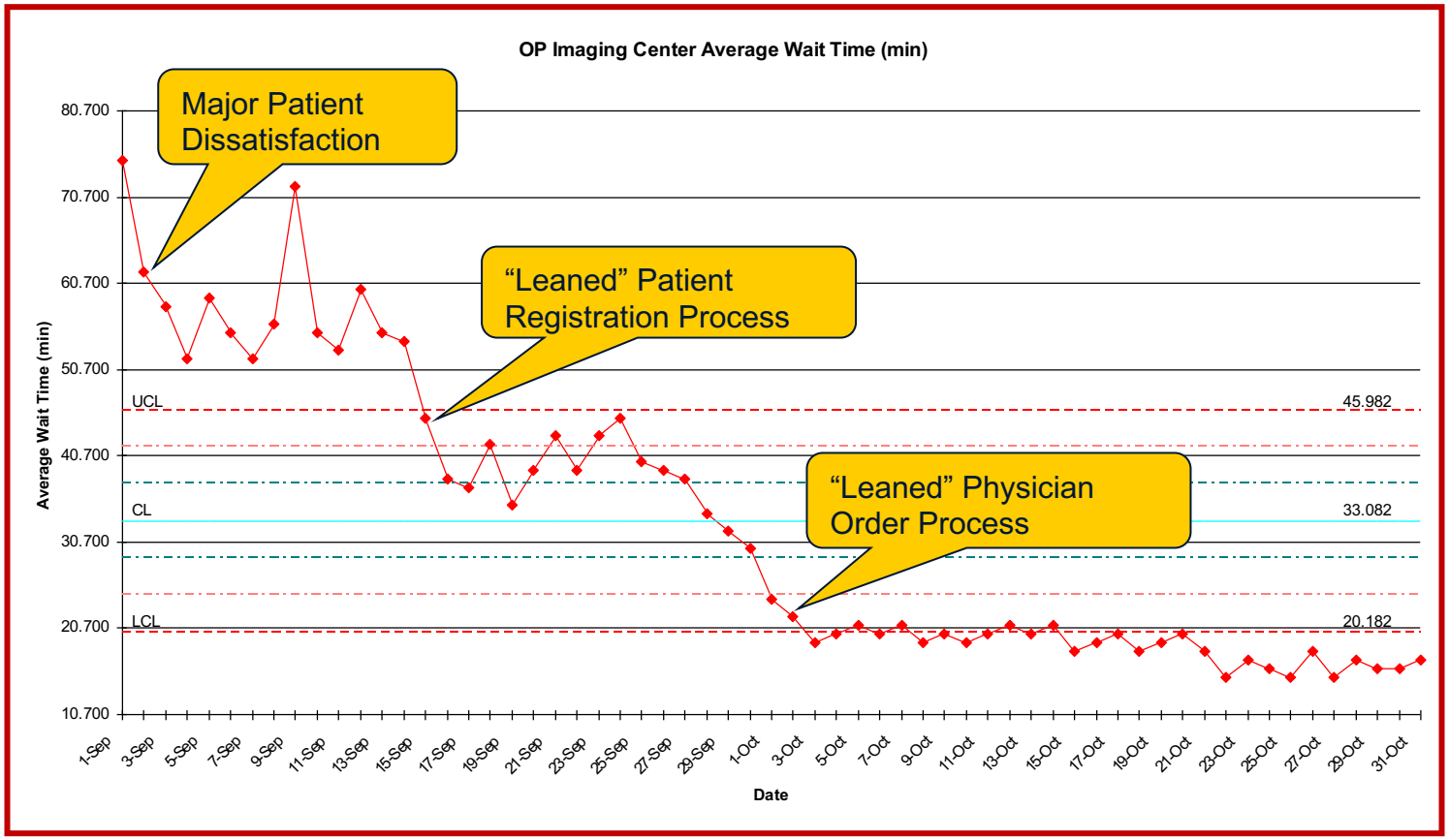


- Pathology:
  - Two critical patient identifiers were added to all slides.
  - Slide and writing tool changed to improved products.
  - Preliminary report printed for all physician slide review requests.
- Oncology:
  - Discrepancy in diagnosis discussed with pathologist.
  - Final pathology report reviewed with discharge summary.
- Radiology:
  - Final pathology report reviewed prior to start of treatment.
  - Case review within one week of treatment start, published schedule, back-up radiologist used if needed.

Document at minimum what, who, and by when

Tool: Corrective Action Plan

Step 6: Assess Effectiveness

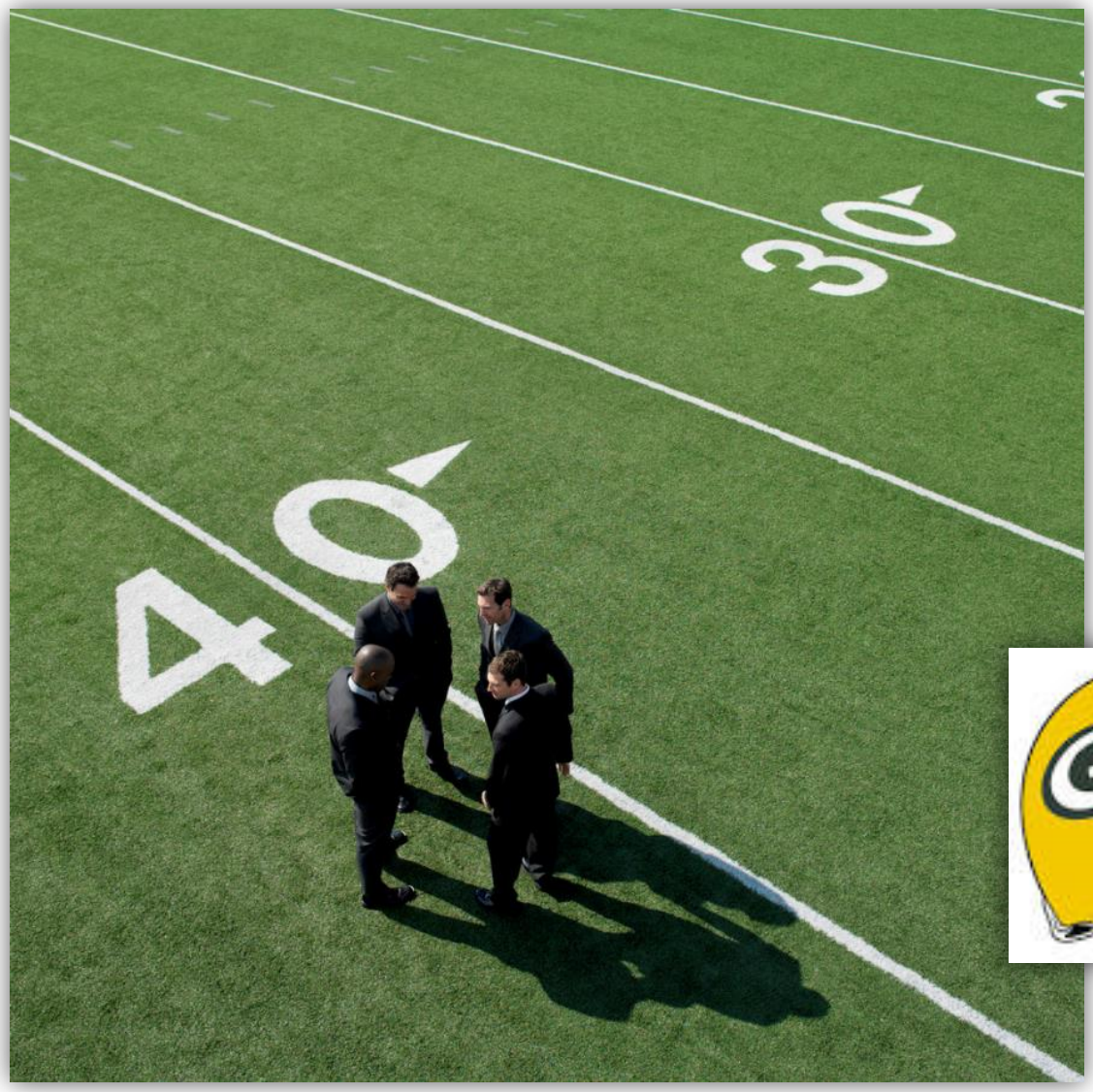


Outcome: Reduced Outreach Imaging Center Patient Wait Time

Monitor process primary performance metric

Tool: Run Chart – can vary depending on process

Develop Immediate Strategies to Address Common Pitfalls



Creating a "Just Culture"

- Just culture recognizes that most nonconformances should not lead to employee discipline.
- Just culture classifies behavior in three categories:
  - Unintended, honest human error.
  - At-risk behavior.
  - Reckless behavior.

Without a "Just Culture,"
root cause identification may not occur.

Resource: CLSI, QMS11 *Nonconforming Event Management,* 2nd Ed., 2015

Pitfalls to Avoid

- Address staff *FEAR*:
  - "I don't want to rat on my co-worker!"
  - "Will I lose my job?"
  - Keep people informed of investigation.
- Avoid using negative descriptors in communication (e.g., "poor," "inadequate," "bad").
- Use a systematic approach to RCA.
  - Need to understand all the details. Caution: analysis by paralysis.
- Assess effectiveness of corrective action and monitor compliance over time if needed.

Focus on process, not people!

Essential Steps Summarized

STEP	ACTION	TOOL
1	Define the Problem	Interview
2	Map Current Process	Process Map
3	Find Root Cause	Cause-and-Effect Diagram Process Map 5 Whys
4	Develop Solution(s)	Brainstorming
5	Implement Solution(s)	Corrective Action Plan
6	Assess Effectiveness	Run Chart (Tool depends on process)

Twenty Years Later, the Rest of the DMW Story…

Celebrated 70 years of marriage at 95 and 91!

General Discussion

Anne T. Daley
MS, MT(ASCP)DLM, CSBB(ASQ)CMQOE
ARUP Quality Officer
anne.daley@aruplab.com