COLLEGE of AMERICAN PATHOLOGISTS

Root Cause Analysis (RCA)
From blame to gain

Rich Becker
Frank Schneider

Objectives

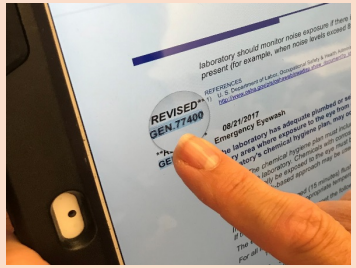
- Recognize key steps in an RCA and corrective action methodology that meets the requirements of international quality standards such as ISO 15189
- Recognize how RCA changes the quality culture of a laboratory
- Recognize tools available through the CAP to assist with RCA

Agenda

Scene 1 – What is RCA?

Scene 2 – Why we don't do RCA

Scene 3 – True stories



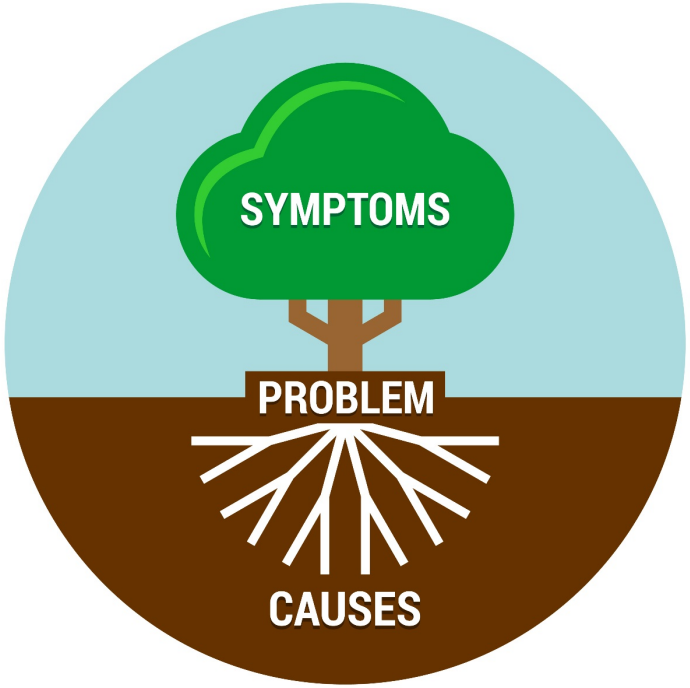
Scene 4 – RCA Toolkit

	Step					
Project	1	2	3	4	5	6
A						
B						
C						
D						
E						

What is RCA?

What is root cause analysis?

- Looking deeply into problems to find out why they are happening
- Uncovering causes that are not obvious



Root Cause Analysis

Methodology to make sure we're taking the right corrective action

Corrective Action

Set of steps to make the problem go away

What happens when we don’t do root cause analysis?

- Blaming individuals
- Telling people to “Pay closer attention”
- Requiring people to be retrained

Four RCA Tools

- Five why's
- Fault tree
- Detailed process map
- Fishbone diagram

Five why's

Why?

Why?

Why?

Why?

Why?

Event/Problem: Repeat blood draws happen frequently on the 5th floor.

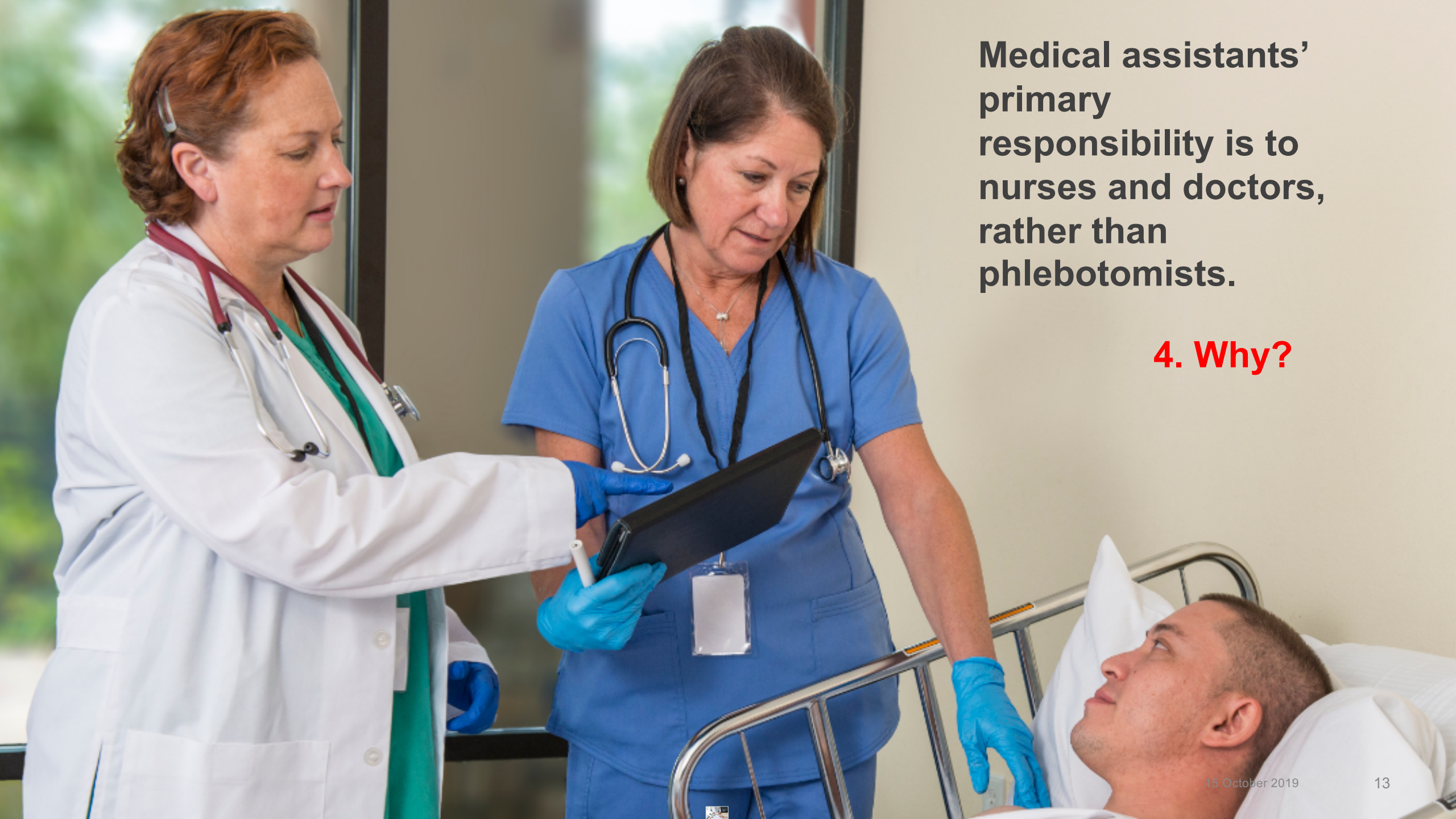
1. Why?

Medical assistants are not available to help phlebotomists with difficult patients (eg, patient is delirious).

2. Why?

Assistants have many responsibilities and often respond to other requests

3. Why?



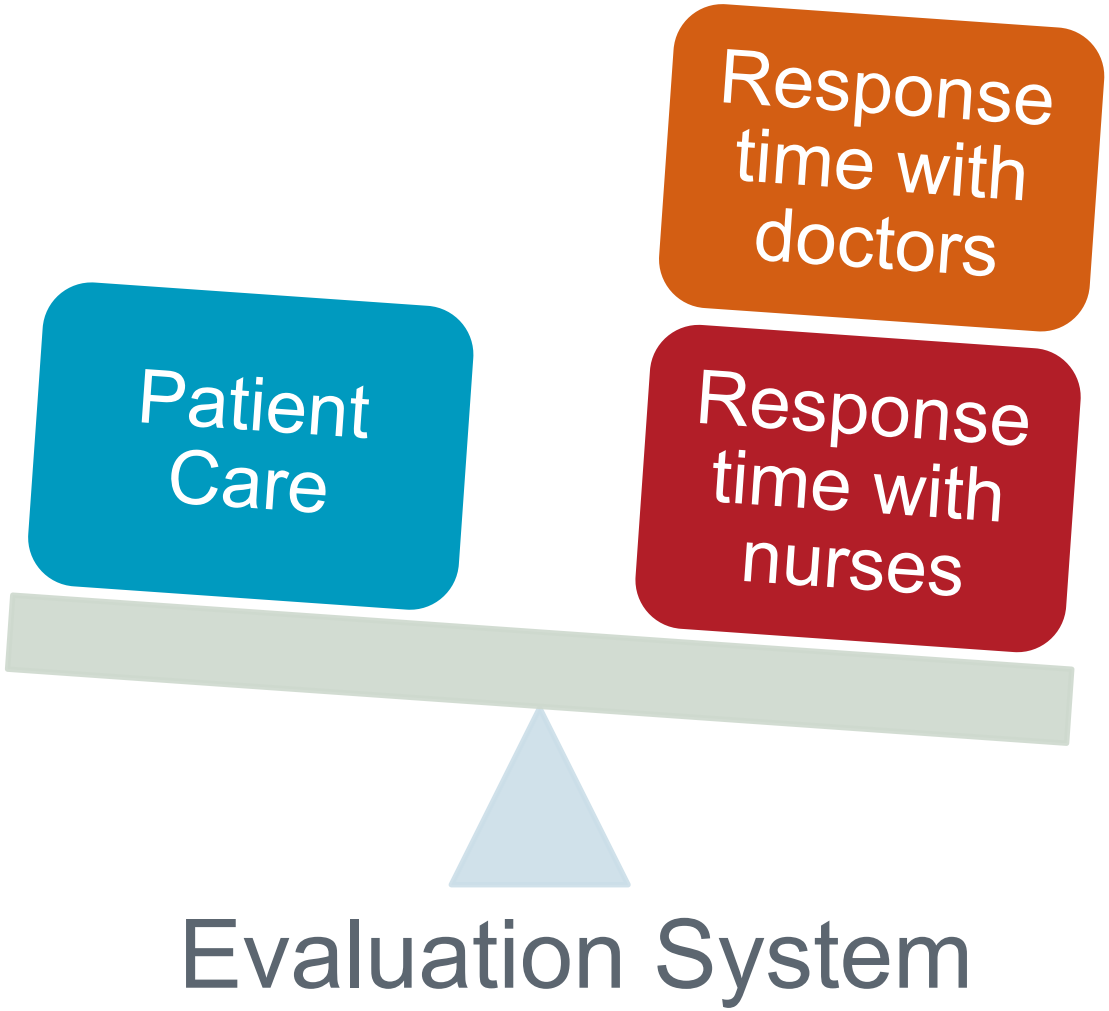
Medical assistants' primary responsibility is to nurses and doctors, rather than phlebotomists.

4. Why?


They are concerned about their performance evaluations.
5. Why?

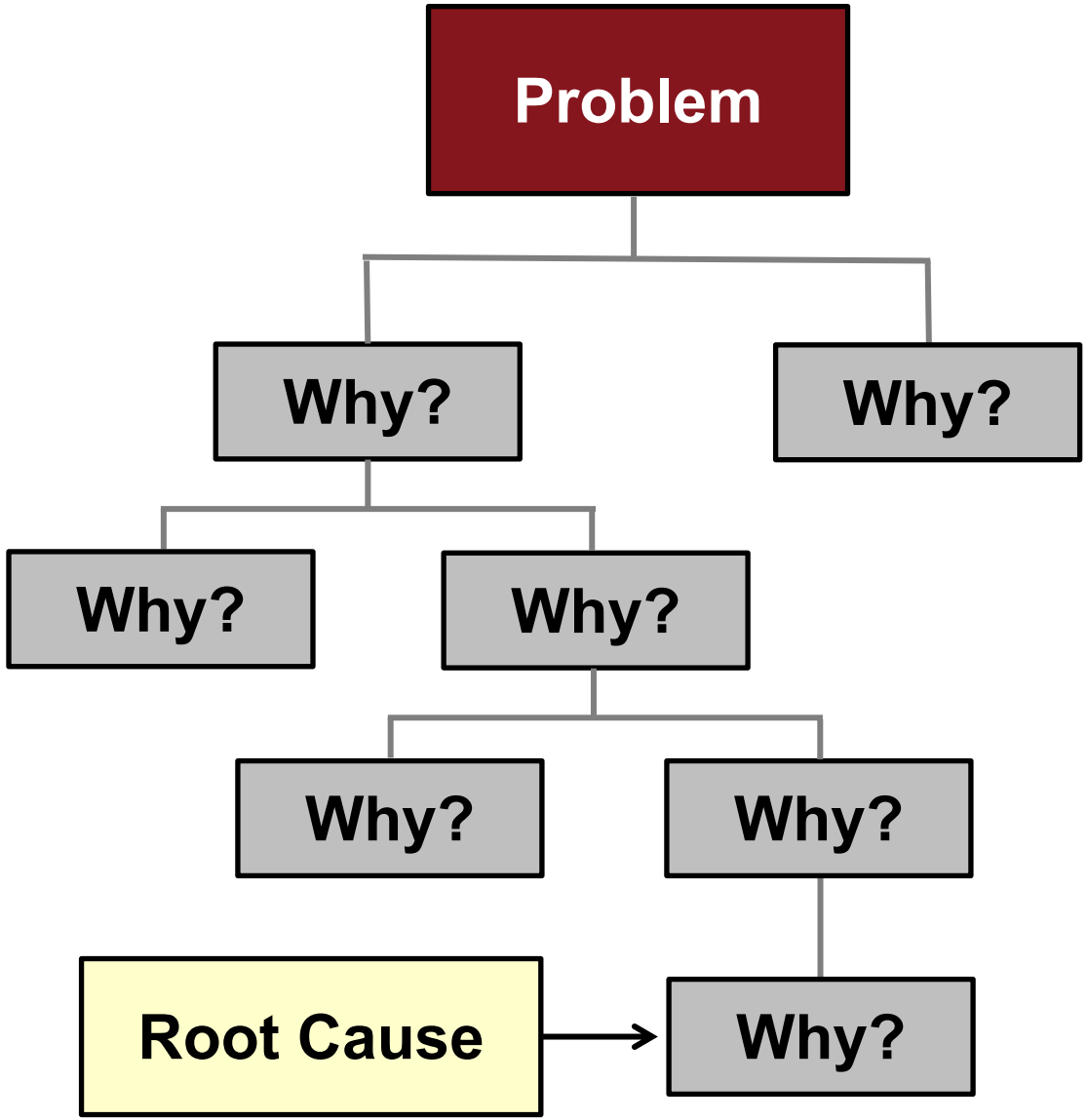
Possible Root Cause:

Performance evaluation system is flawed – does not promote good patient care.



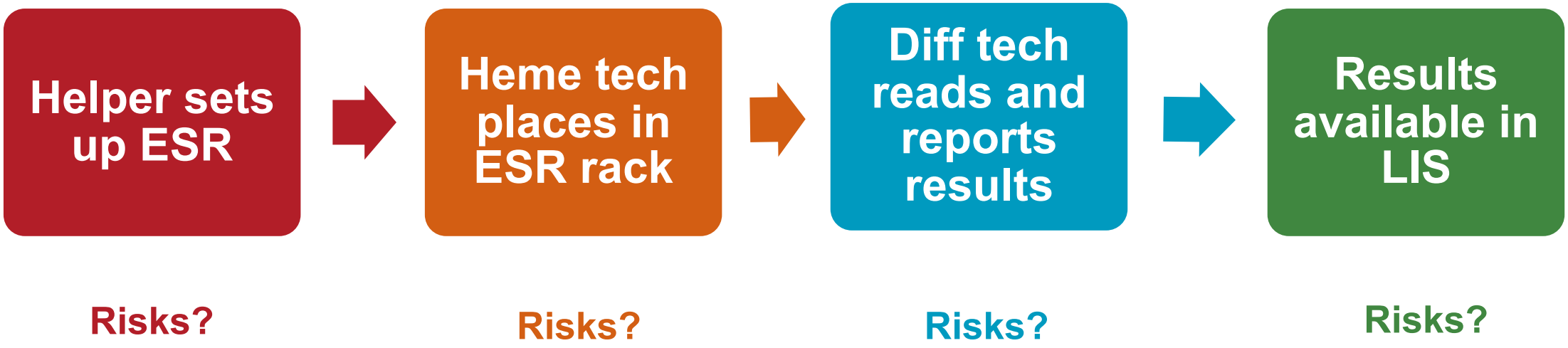
Fault Tree

- Like 5 why's, but go down multiple paths

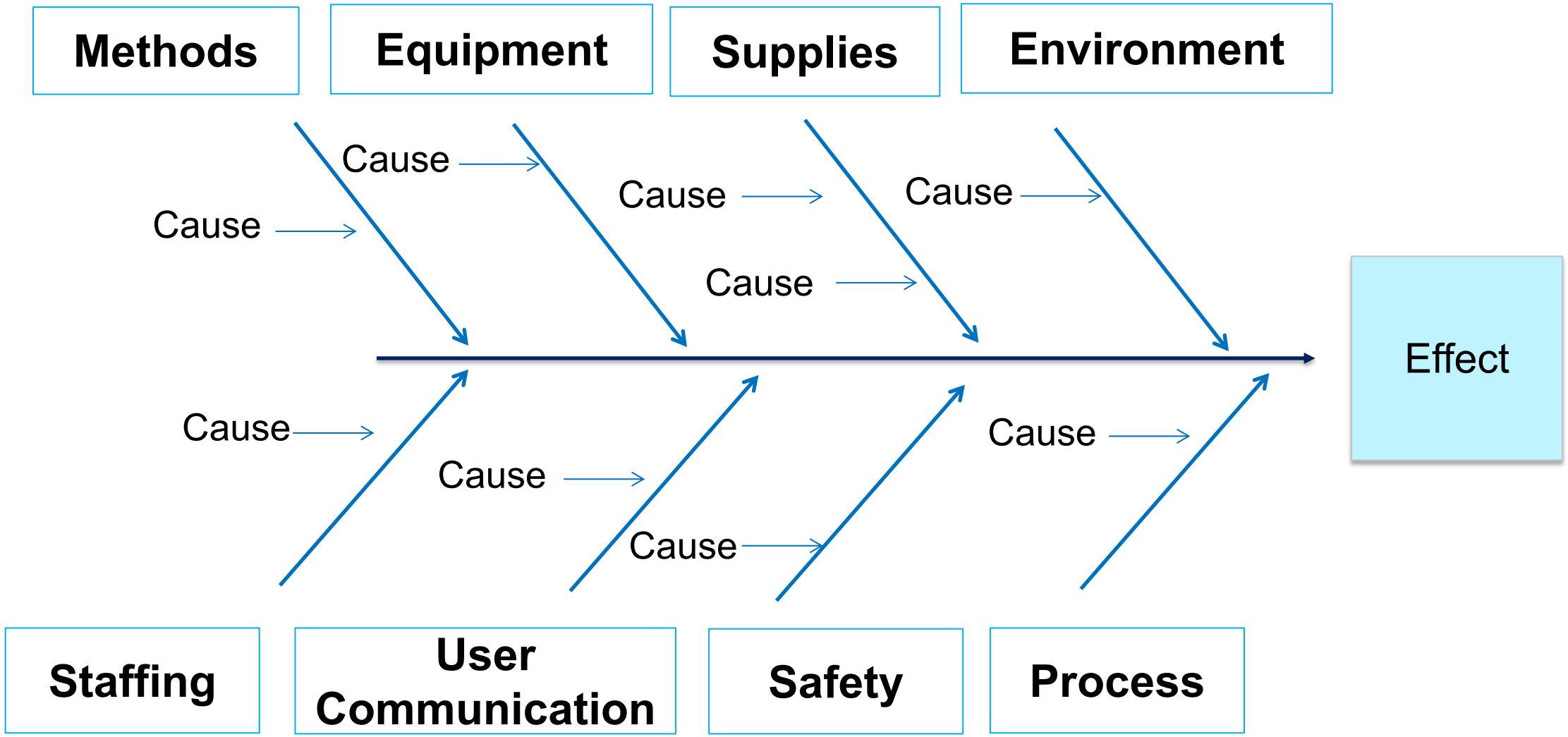


Detailed Process Map

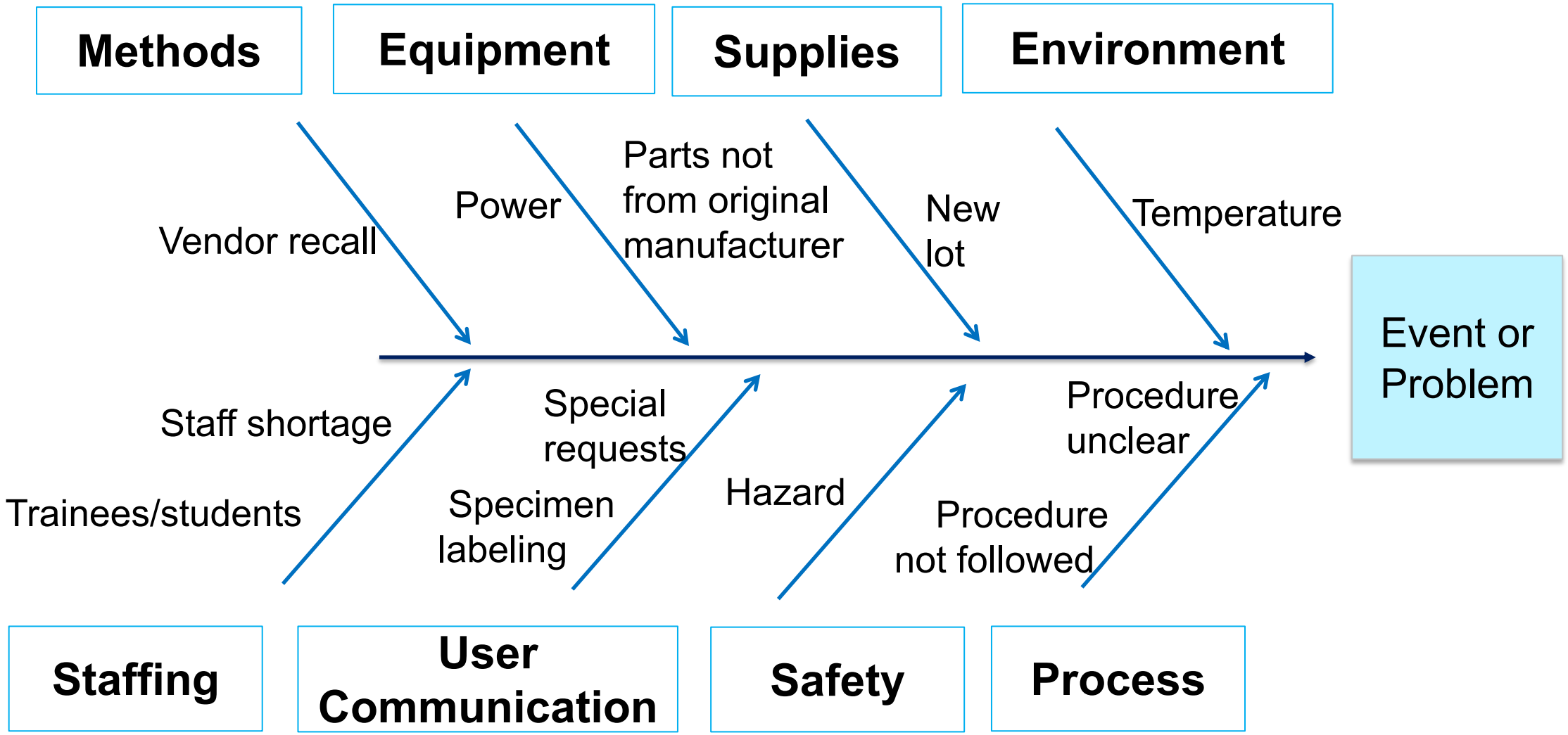
- Treat each step as a potential source of the problem.
- Ask, “What could go wrong at this step?”
- a.k.a. Failure Mode and Effects Analysis (FMEA)



Fishbone Diagram



Fishbone Diagram for Medical Laboratories

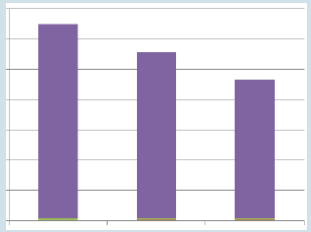


Choosing root cause analysis methods

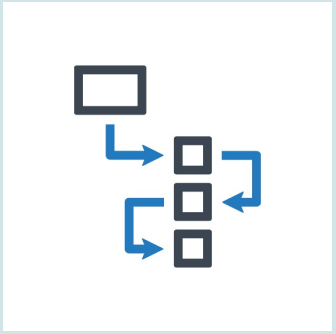
Tool	Good for…
Five Why's / Fault Tree	Analyzing a chain of underlying causes
Flowcharting	Finding error-prone steps in a complex sequence
Fishbone Diagram	Providing a systematic look at multiple factors, some of which might get overlooked

To be effective, RCA tools need to be embedded in problem solving steps…

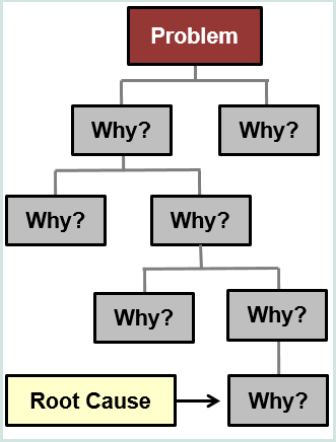
1. Define the Problem



2. Map the Process



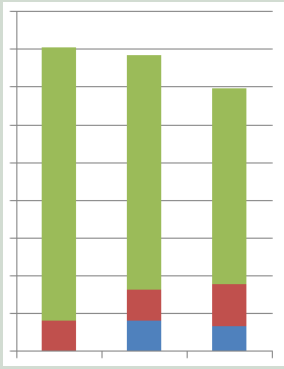
3. Find Root Cause



4. Develop Solution

5. Implement Solution

6. Assess Effectiveness



Pitfalls

1. Define the Problem	2. Map the Process	3. Find Root Cause	4. Develop Solution	5. Implement Solution	6. Assess Effectiveness
• Define the problem in terms of a solution • Let one confident person make the decisions	• Trust the SOP • Jump to conclusions about what the process is	• Use the same tool every time • Jump to conclusions	• Use a “weak” solution	• Ignore stakeholders and possible sources of resistance	• Assume it will work • Fail to set up an assessment approach

Why we don’t do RCA

Top reasons for not doing RCA

1. The cause of the problem is typically clear
2. I don't have time
3. I don't know how to do RCA
4. Not sure it's worth the investment of time
5. Doesn't apply to the kind of problems I face
6. Not sure how to start the project and get the right people
7. It's easier to just retrain the people involved
8. What we discover may be awkward to report

1. The cause of the problem is clear

- Sometimes this is true – no need to create a big project

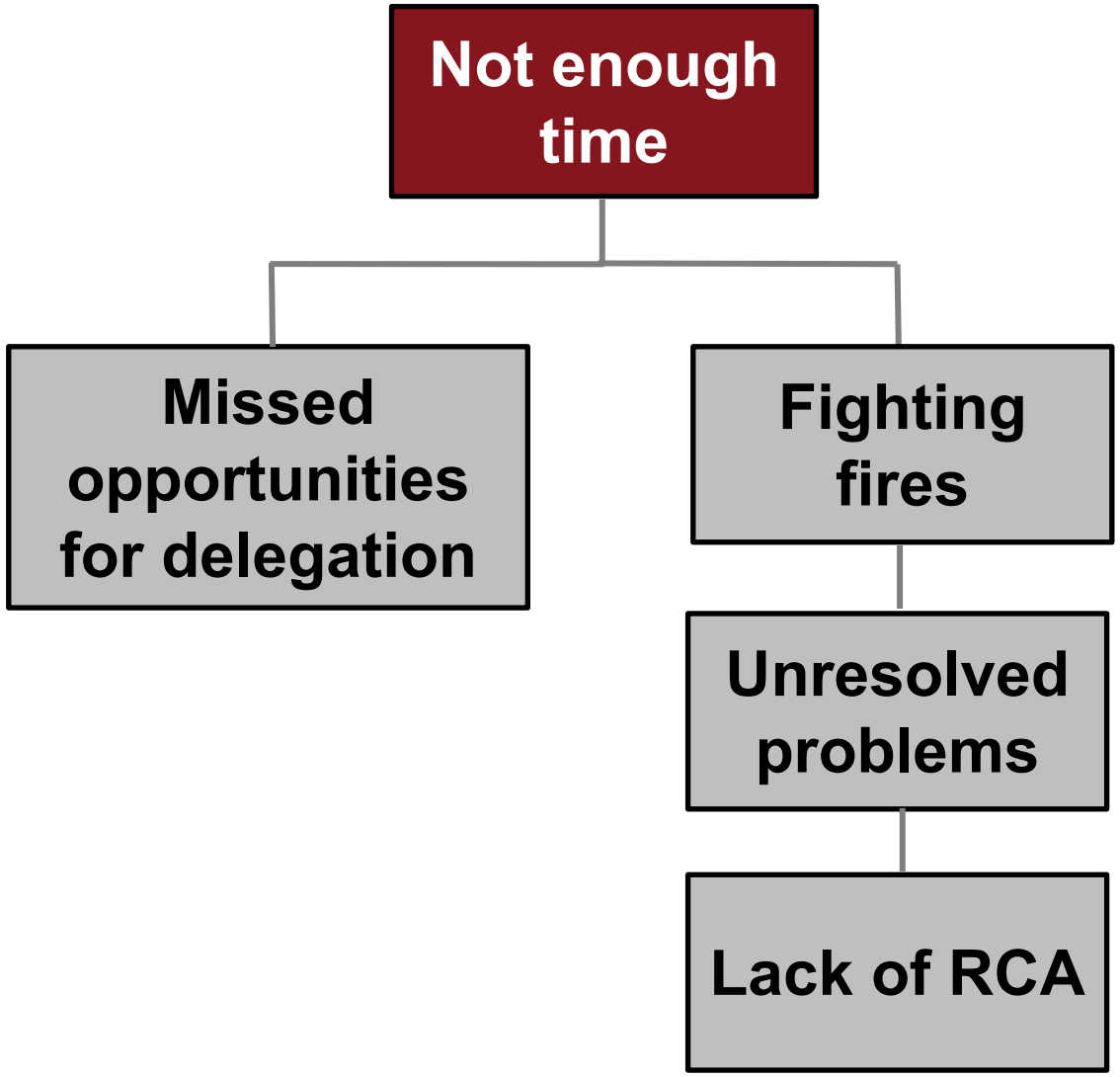
The cause of the problem is clear

- Sometimes this represents blaming
- Unconscious inclination when something happens → Look to the “Who?”

“The cause of the problem is obvious – it’s Bob”

2. Not enough time

- I’m too busy
- My staff is too busy



3. I don’t know how to do RCA

- I’ve heard the word, but I’ve never done this before
- Somebody else in quality department does this.

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https://cap.enspire.com/course/coursemenu

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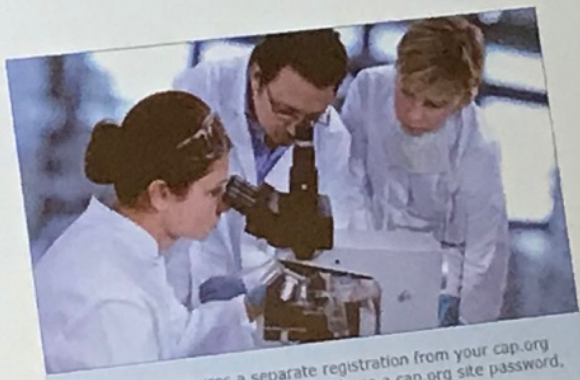
PURCHASE OPTIONS

Courses Available

15189 Walkthrough
Price: $395
An overview of the intent and requirements of the ISO 15189 standard.
More Info

QMS Implementation Roadmap
Price: $395
The key steps in planning and building a sustainable quality management system.
More Info

Root Cause Analysis
Price: $695
Methodology and actual examples from medical laboratories.
More Info



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sustainable quality management system.

More Info

Root Cause Analysis

Price: $695

Methodology and actual examples from medical laboratories.

More Info

Root Cause Analysis

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Course Map

Demonstration – ESR Results

This section provides a demonstration of Step 1 – Define Problem.

Wolfe-Christopher Hospital provides inpatient, outpatient, diagnostic, surgical, rehabilitative, behavioral, kidney dialysis, emergency, and outreach services.

Currently, the rheumatology department is participating in a study with Investigation Drug Services.

General Problem Description

The erythrocyte sedimentation rate (ESR) was chosen as a test variable for monitoring the response of a medication in patients undergoing a multi-centered study. Registered nurses (RNs) in rheumatology need the test results before they can order the medication from Investigation Drug Services. The director of the rheumatology department has expressed her dissatisfaction with the laboratory services, explaining that their patients often have to wait a long time for their medication because it takes too long to get ESR results.

Laboratory Data

TAT expectation is 95% ESR <80 minutes

Root Cause Analysis course - Testimonial

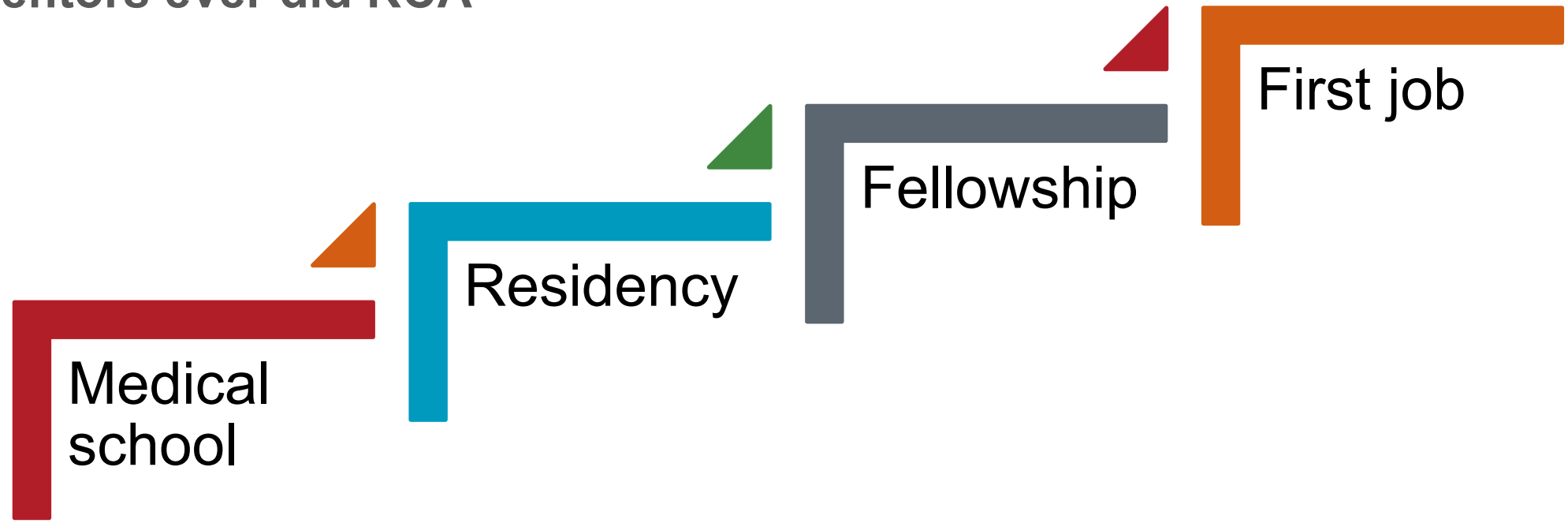
"After going through the RCA course and studying the examples, I felt like I could perform at a professional level.

"I knew what I was doing."

Justin Caron, MD, FCAP
UCLA Hospital Laboratories

4. Not sure it's worth investment of time

- None of my teachers or mentors ever did RCA



An RCA wasteland…

…No RCA projects or resulting benefits in sight


Henry Ford Health System
Henry Ford Hospital
Improving Efficiency in Core Lab Processes to Achieve a Best in Class One Touch to the Line Laboratory
ABSTRACT
PLAN: PROBLEM BACKGROUND
With over 12 million tests performed annually the laboratories of Henry Ford Health System are constantly looking for ways to improve and innovate change to gain efficiencies, reduce variability and improve the quality of laboratory testing. The 7 deadly wastes still exist within the current processes
Waiting
Overproduction
Transportation
Inventory
7 Types of Waste
Motion
Defects
Rework
PLAN: AIM
With a goal of one touch to the line:
If we implement an automation line then we will :
Reduce specimen handling
Reduce variation in the specimen delivery process
Reduce human motion
Remove the human touch
Mistake proof the current condition
Implement visual controls
Identify defects to improve standard work
PLAN: CURRENT STATE
CURRENT LAYOUT
Motion
Before Automation
Daily Steps Traveled
72,405
Daily Miles Traveled
41.1 miles
Daily Time Spent in Motion
20.11 hours
Specimen Handling
Touches Per Barcode Ready Specimen
Touches Per Non-Barcode Ready Specimen
Before Automation-Hematology
26
28
Before Automation-Basic Chemistry
17
19
Before Automation Basic Chemistry Shared between 2 analyzers
34
36
MODELING
DATA REVIEW
CHECK: RESULTS
NEW LAYOUT = 159 FT. OF AUTOMATION
After Automation
Daily Savings
Daily Steps Traveled
27,051
45,345 steps
Daily Miles Traveled
15.4 miles
25.8 Miles
Daily Time Spent in Motion
7.5 hours
12.6 hours
Before Hematology & Coagulation Spaghetti
After Hematology & Coagulation Spaghetti
KEYS TO SUCCESS
CONCLUSION
Pathology and Laboratory Medicine
ELCOME

5. Doesn't apply to the kinds of problems I face

- RCA is only relevant to catastrophic events, and the documentation is onerous
  - Wrong blood type
  - False negative test result
  - Instrument malfunction – HIV in eye
  - Needle stick

Catastrophic

Voluminous documentation

Scrutiny

Sentinel event

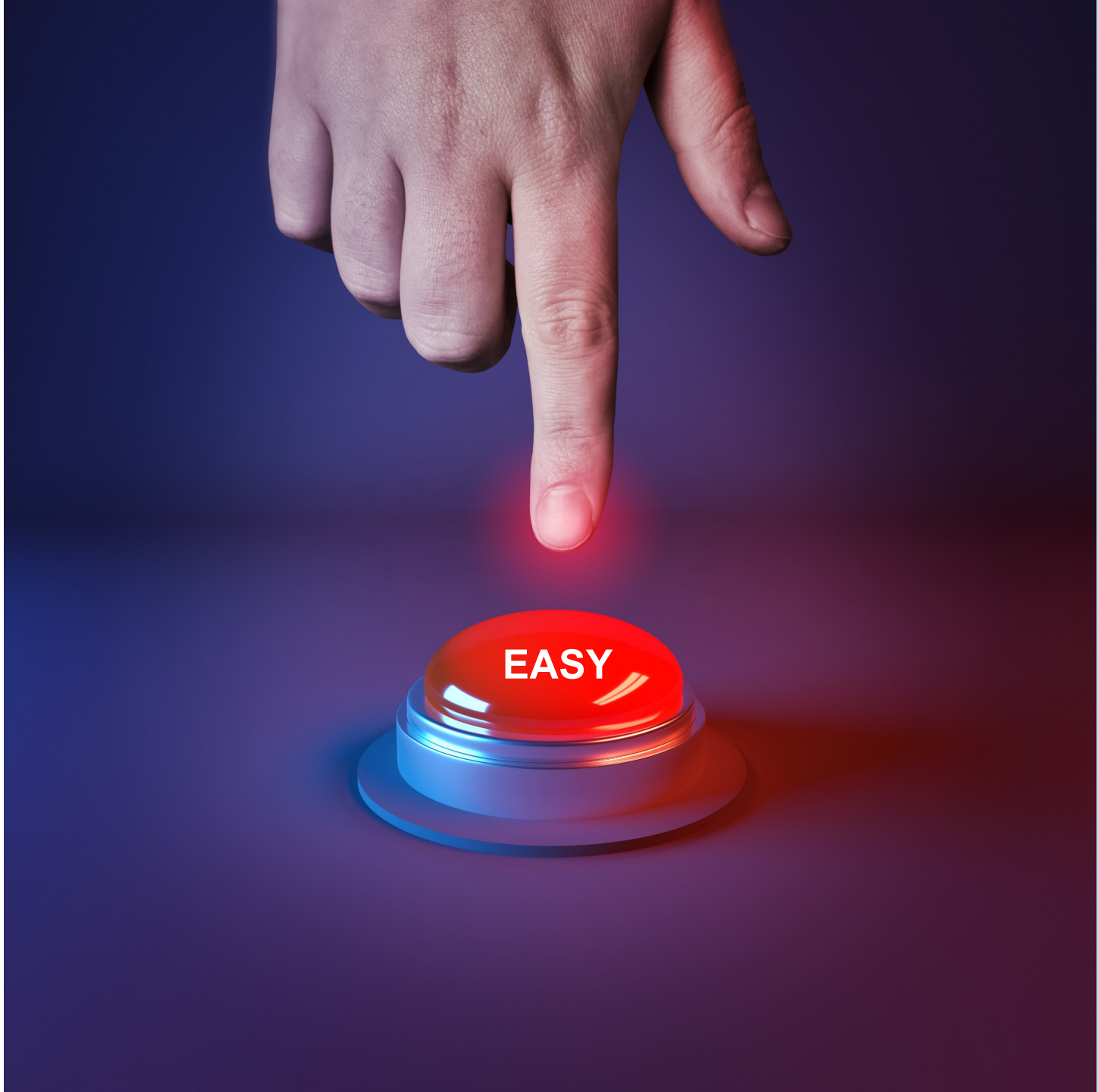
Big deal

6. Not sure how to start the project and get the right people

- I'll never get the project approved
- When and how exactly is this going to happen?

7. It’s easier just to retrain people

- “What harm could possibly come from retraining?”



8. What we discover may be awkward to report

- The RCA might single out a person or area with responsibility.

Beyond awkward…

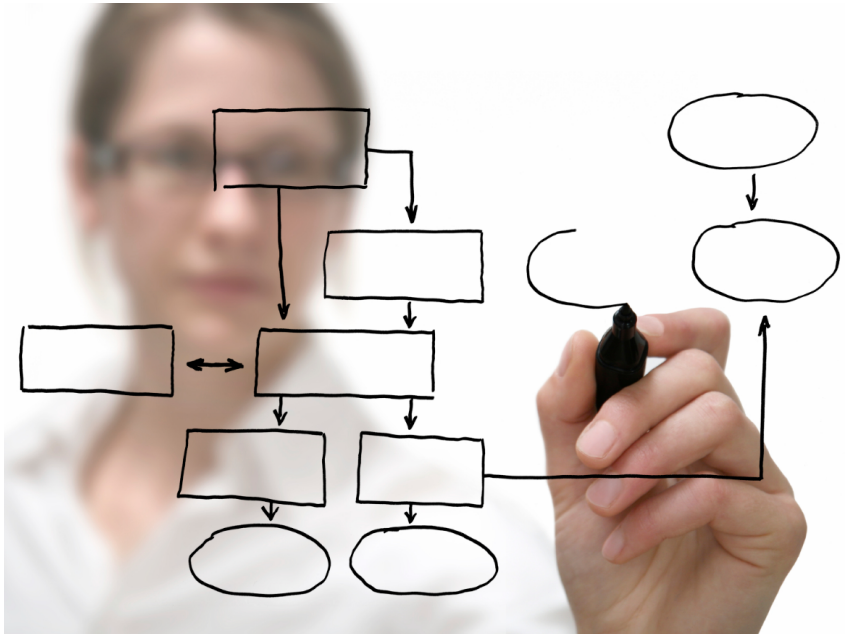
- If we look into the problem – if we get into the detail – I may look bad.
- Might cause guilt – I may have caused patient issue.
- I'm only allowed to have three corrective actions – then it affects my bonus.
- The unspoken message I get at leadership staff meetings is, "Everything's perfect." I wouldn't want to look out of place.

True stories of RCA and culture change

As laboratory matures…

Process Orientation

- Ask, “How did it happen?” rather than “Who did it?”
- Respond to mistakes by looking for a system cause



Transparency

- Report errors and near misses to supervisors and managers
- Support staff and encourage them to escalate errors

Teamwork and Involvement

- Include front line staff in problem solving and decision making

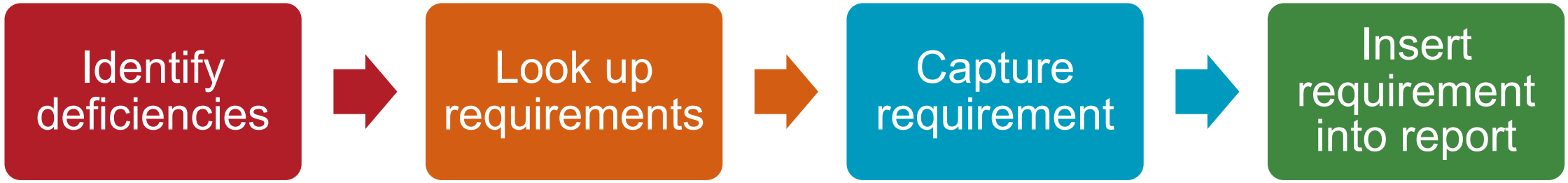
Inspector Summary Report (ISR) Project

Situation

- Transcription errors in ISRs
- Errors cause problems for the technical LAP staff and require roughly 20 steps to fix.

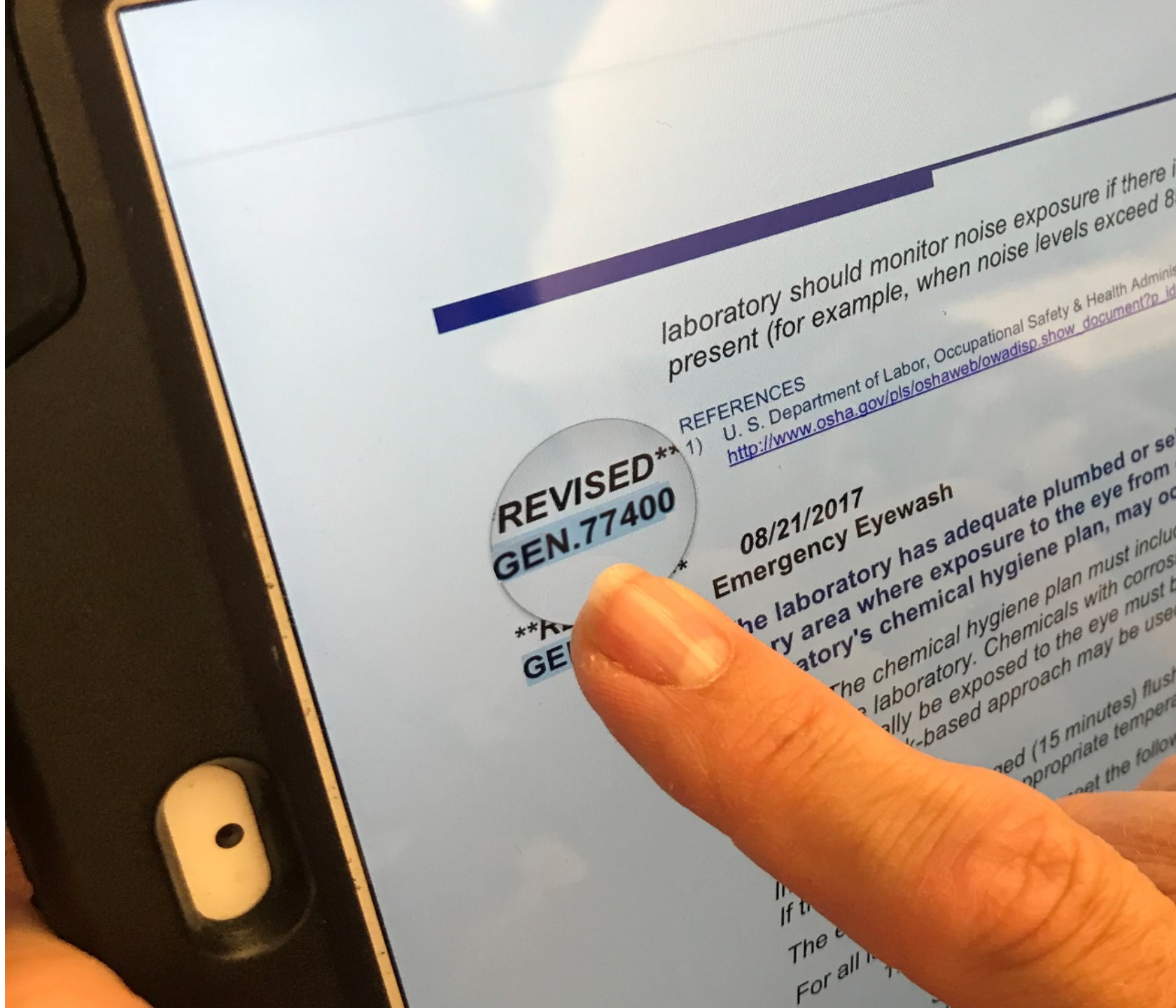
Jean Ball
Inspection
Services Manager

“Before” Process Map

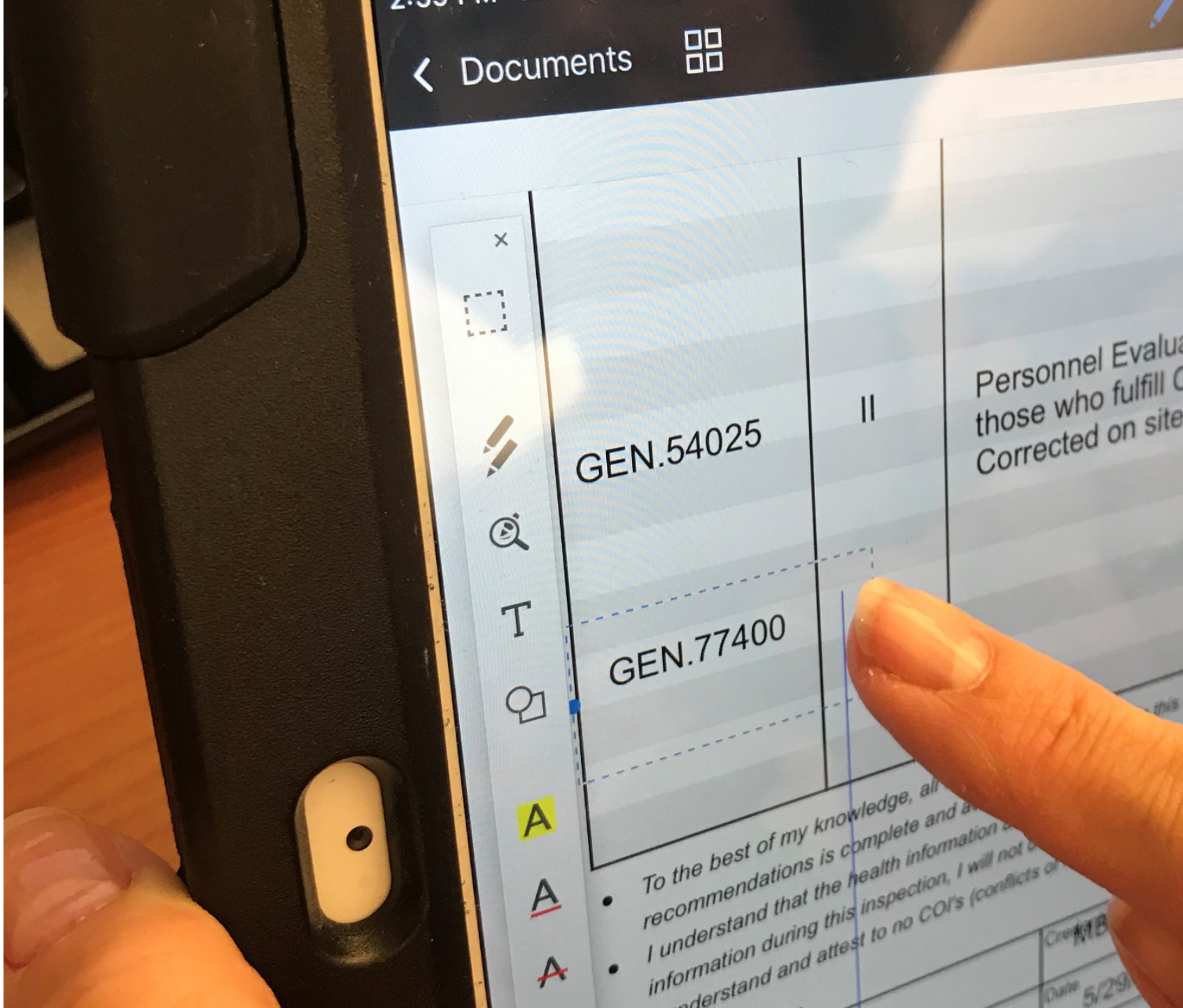


Electronically copy it → **Paste it in**

Use fingers on tablet surface to copy…



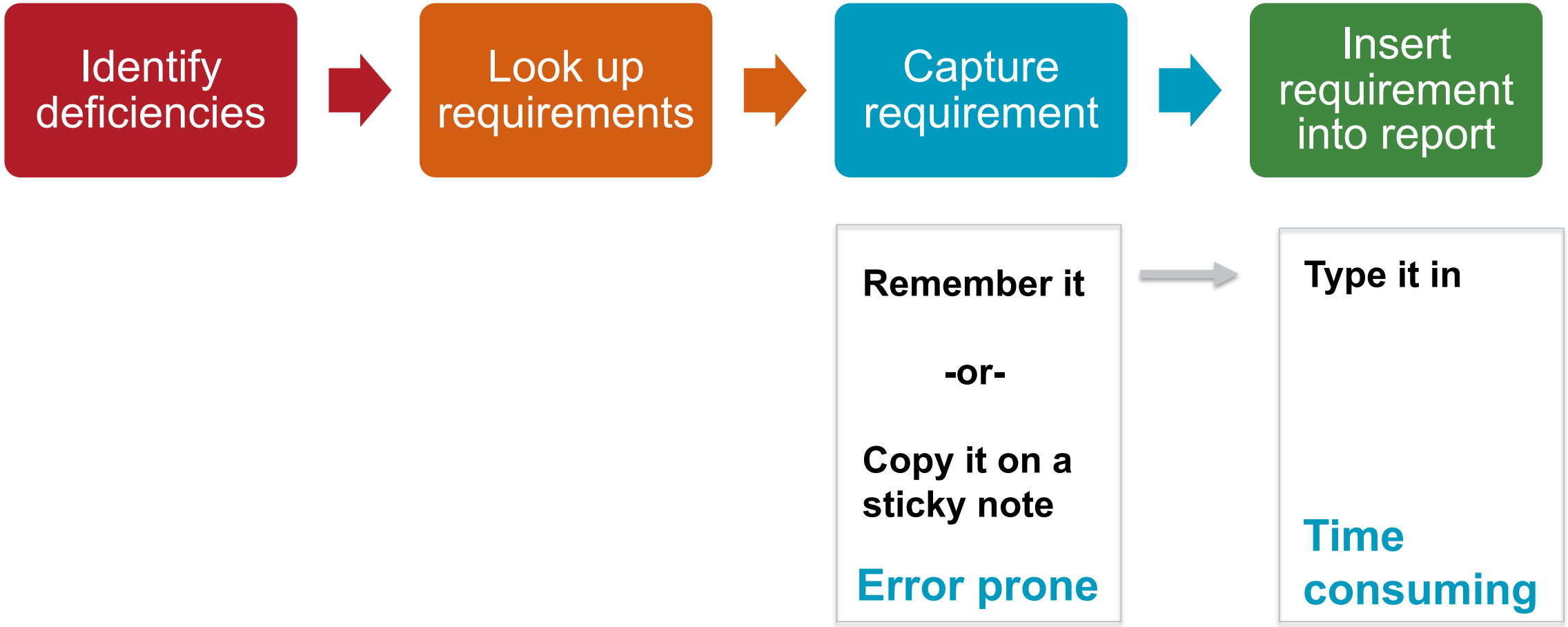
Then paste … then reposition … then try to align with table…



Problems

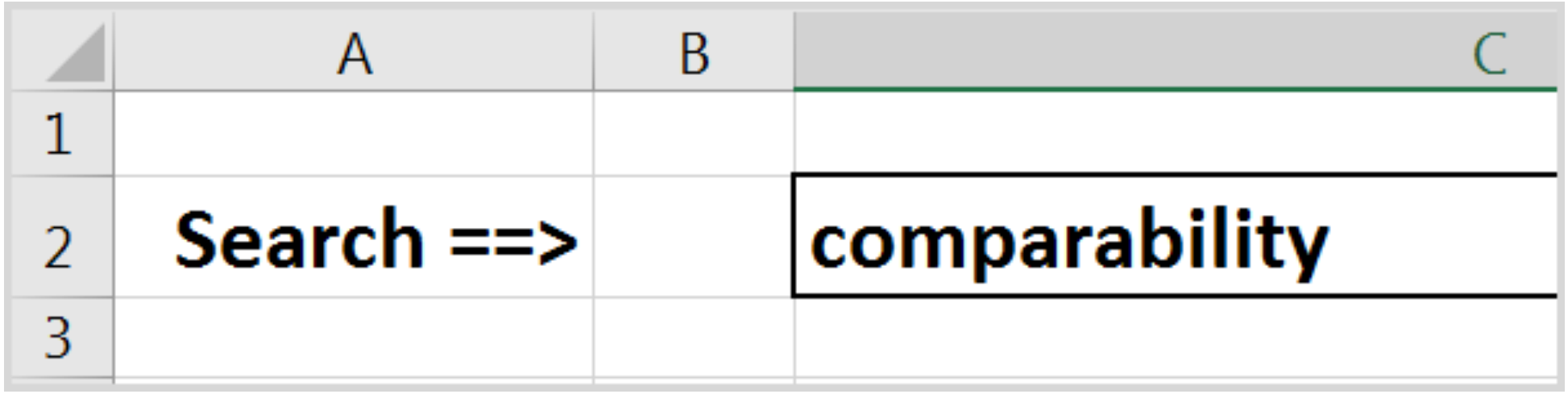
- Process is…
  - Mechanically difficult
  - Time-consuming
- Resulting in…
  - Fatigue, overtime, and frustration
  - Opportunity cost

“Before” Process Map – other options



New process: Create Excel tool

1. Search for phrase representing the requirement



	A	B	C
1			
2	Search ==>		comparability
3			

New process (continued)

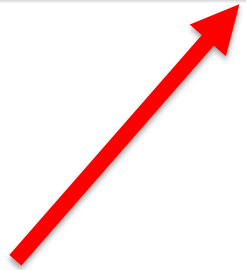
2. Select the requirement and its associated number

Req ID	Ph	Requirement, Note
COM.04250	2	If the laboratory uses more than one nonwaived instrument/method at least twice a year for comparability of results. NOTE: This requirement applies to tests perfor med on the same o requirement is to evaluate the relationship between test results usi for nonwaived instruments/methods accredited under a single CAP
COM.04300	2	Acceptability criteria are defined for comparability of nonwaived inst criteria are not met. NOTE: Statistically defined acceptability limits should be used for (
POC.03810	2	The POCT program follows manufacturer's instructions for all test s NOTE: Changes in the specimen type, collection device, or intende instructions" in the Definition of Terms as found in the All Common

New process (continued)

3. Type in notes and recommendations

	A	B	C	
				Deficiencies
	SU Name	Req ID	Ph	Comments
	1327419 Chemistry & Special Chemistry	COM.04250	2	not being compared every 6 months



New process (continued)

4. **When all deficiencies and notes are complete…Click a button.**
   - **Sorted, aligned, correct, complete**

Requirement ID	Phase	Inspector Comments
		☐ This laboratory section has no deficiencies
COM.04250	2	Beckman analyzers were not compared every 6 months in 2018. Only one comparison that year.
COM.01200	1	Activity menu does not include all testing at contiguous campuses.
COM.01400	2	Person signing PT attestation statement for high complexity is not qualified to sign.

Perspective of staff inspector

"Investigating the Inspector Summary Report (ISR) errors made a difference in our culture.

"Management was willing to listen to our concerns, get our perspective, and involve us in looking for process causes rather than just saying, 'Pay closer attention.'

"This was significant to us."

Nancy Sheffer
CAP Inspection Analyst

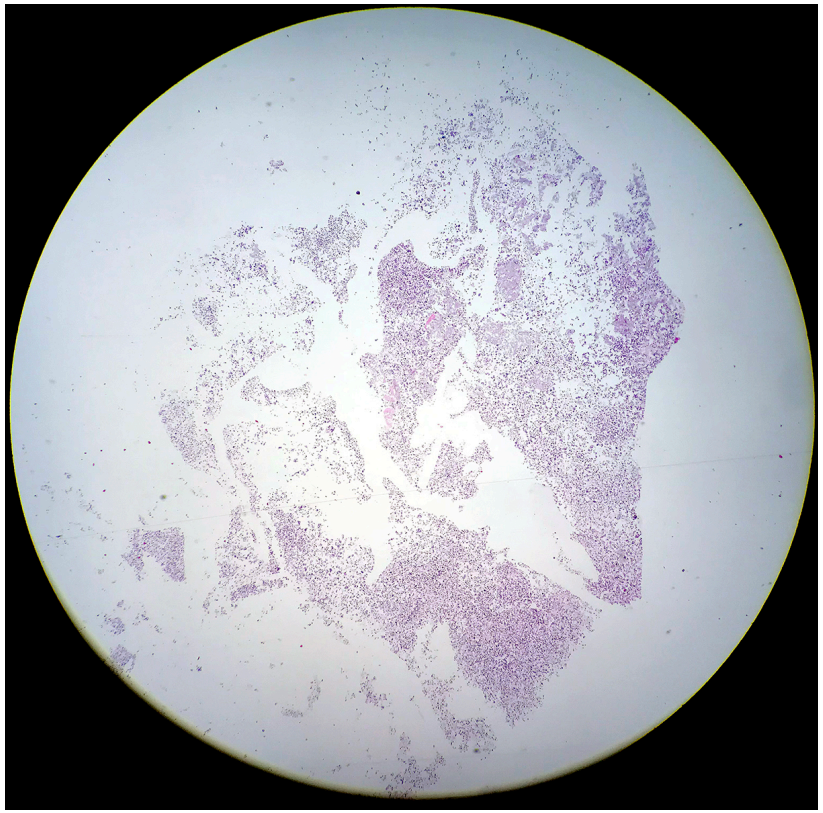
Time Comparison

Scenario: 15-page ISR report with 5 deficiencies

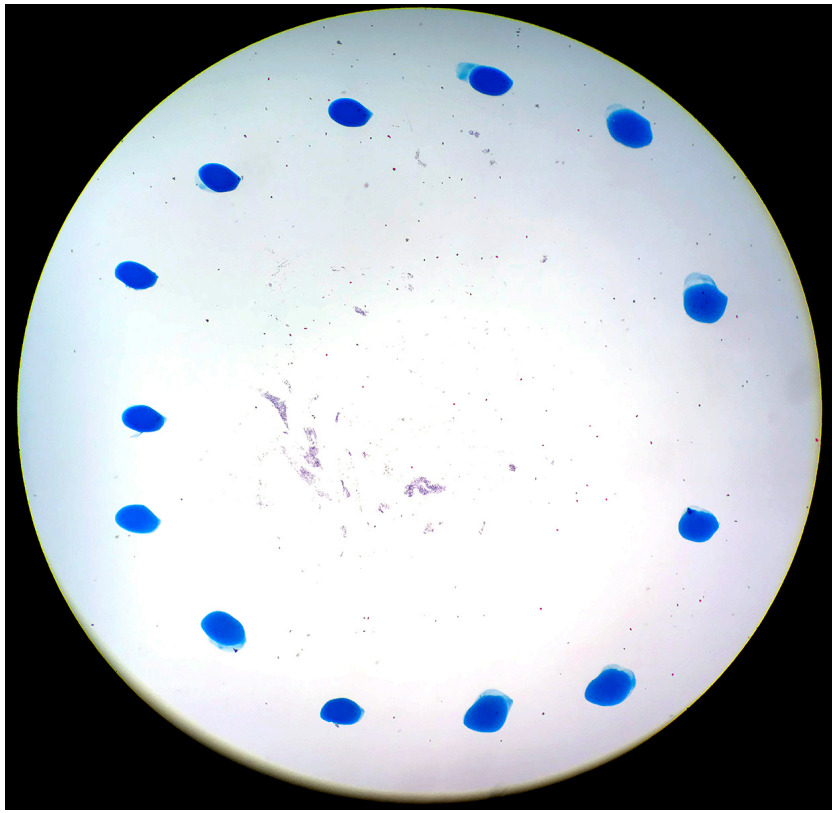
Task	Old Method	New Method
Transfer requirement numbers, phases, and descriptions to ISR	20 minutes	5 minutes
Apply credentials and inspection date to each page of ISR report (5 stamps per page)	10 minutes	<1 minute
Sequence and sort requirements (so all GEN, CHEM, COM, etc. are together) Recheck requirement numbers based on notes of deficiency	10 minutes	0 minutes
Total	40 minutes	6 minutes

Other things staff inspectors could be doing in the evening, when on the road…

Example: Preventing unnecessary re-biopsy



Have you been asked to run molecular testing on a block



and this is all that was left…?

Problem: Unstained slides were not prepared at the same time as the initial H&E sections

1. Why?

Sample not accessioned under correct specimen class

2. Why?

Accessioning staff did not know it was a lung mass

3. Why?

Clinical history field was not completed on requisition

4. Why?

Radiologist not aware that oncologist needed testing

5. Why?

Physician order entry does not transfer to radiology paper

Unstained slides not prepared in histology traced back to test ordering…

… this is a known and recurrent problem.

6. Why? Adverse event reporting cumbersome; oncologist does not have the time, change rarely happens

Possible root causes

Organizational culture characterized by inertia	IT group not responsive enough to user needs	Disconnect between departments resulting in lack of feedback and learning

Example: Staff Turnover

Do you feel like you post too many of these flyers…?

Please

Join us in the Hallway

Outside Histology on

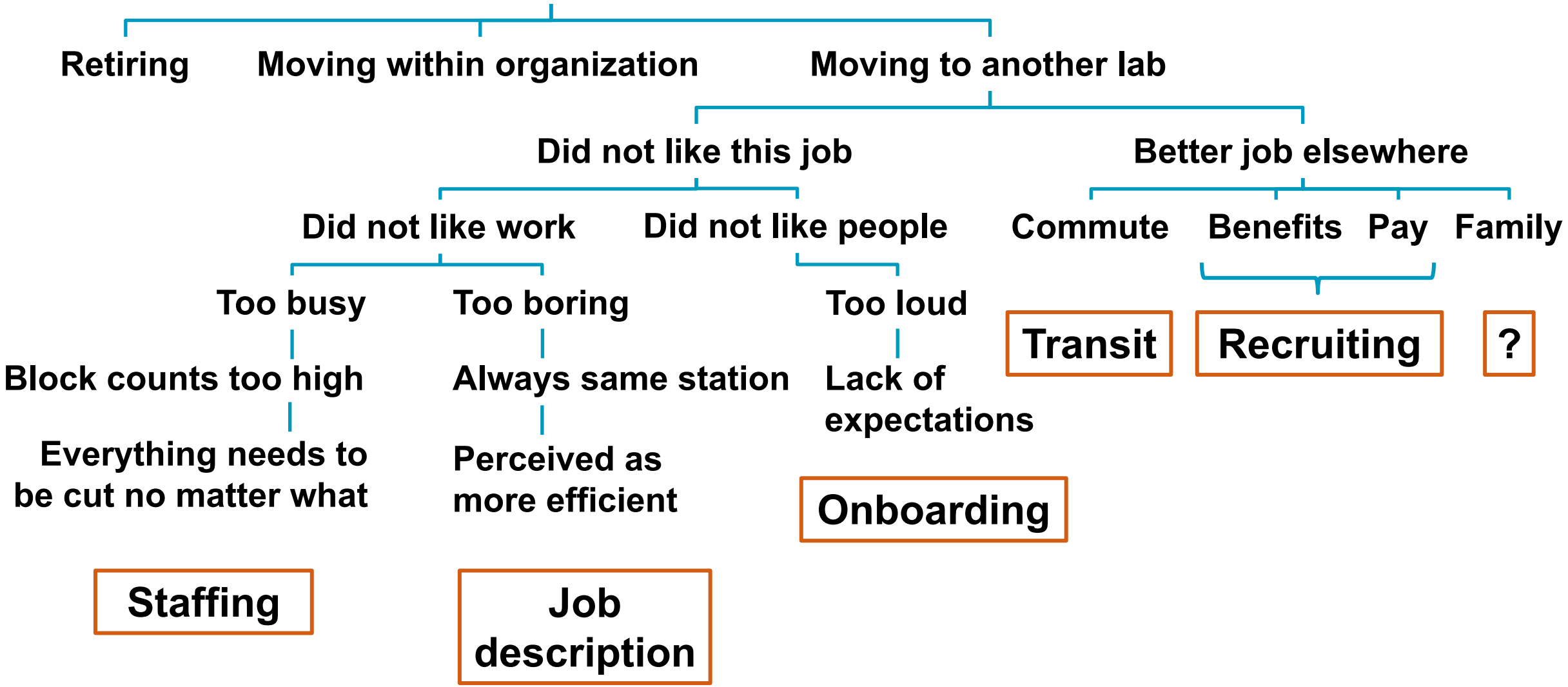
Wednesday, July 17th 1 pm

To say

"Fond Farewell and Best Wishes"

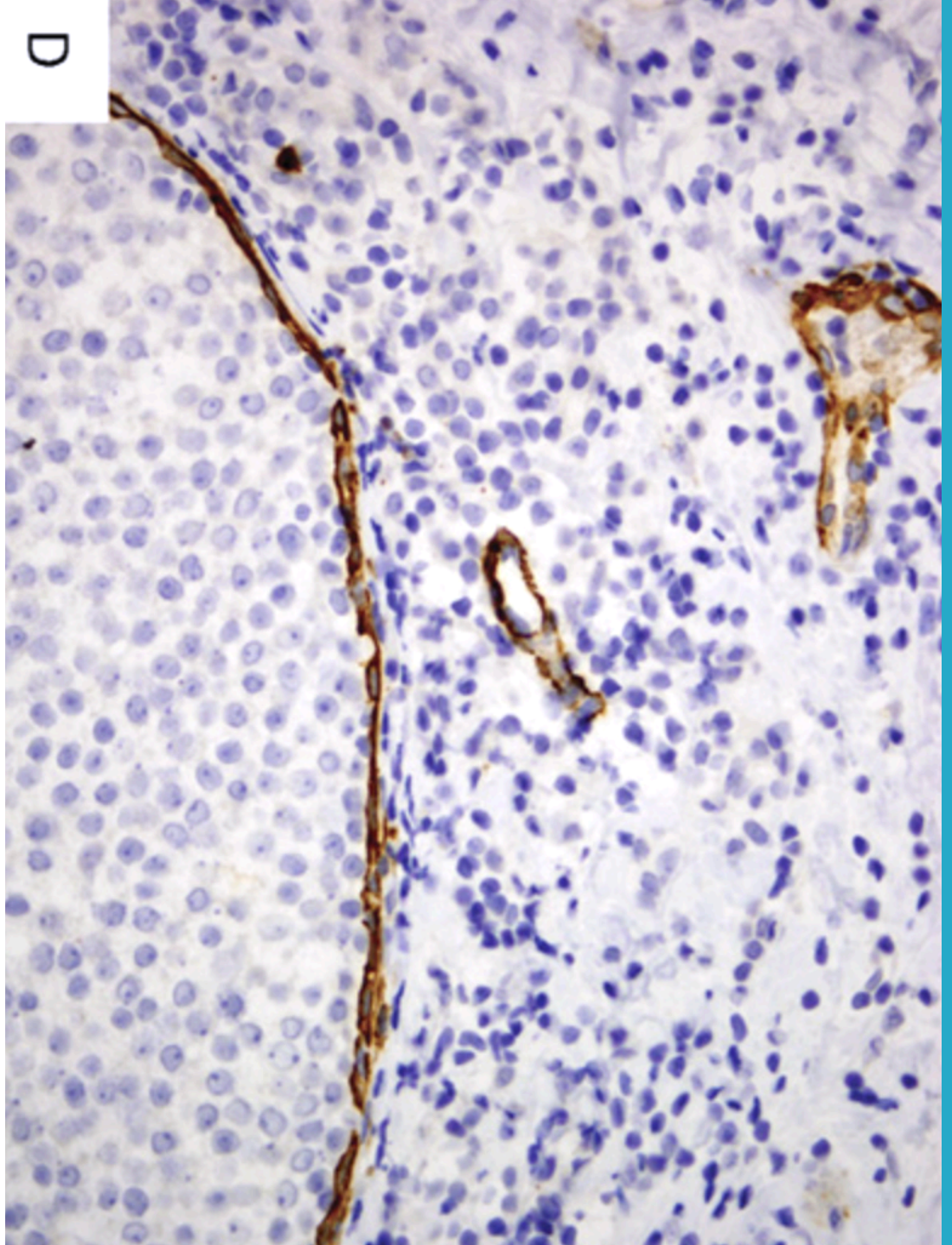
To

Problem: Histotechs are leaving

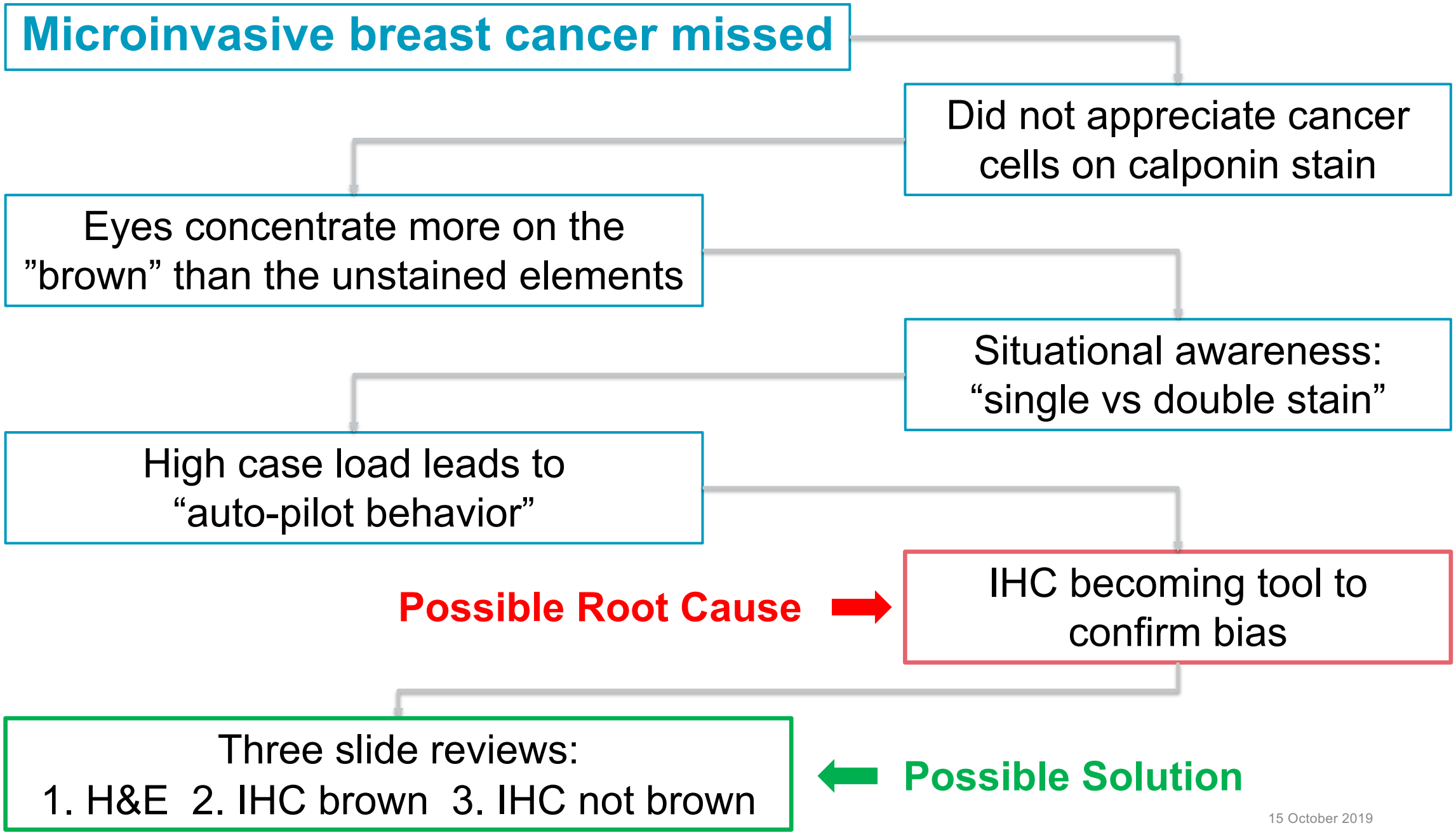


Example: Personal Diagnostic Errors

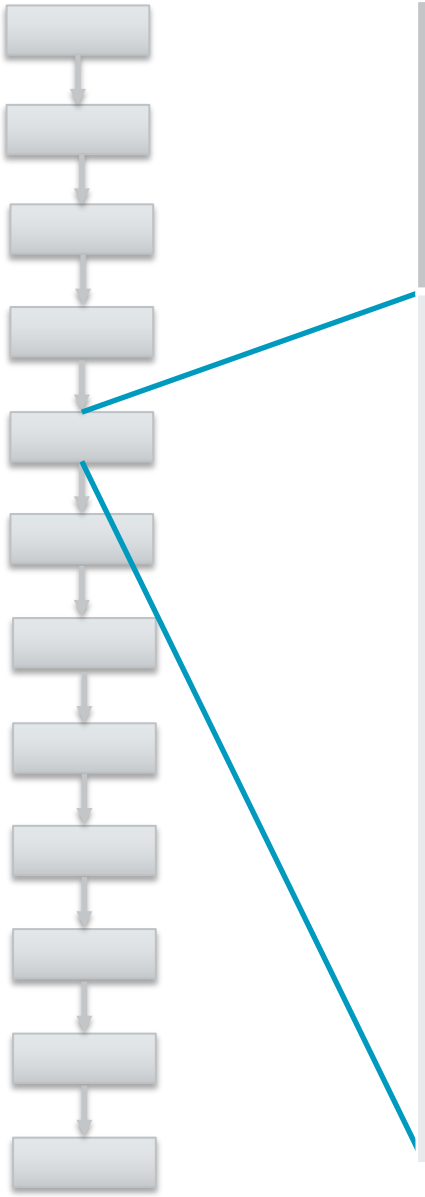
Have you reported a wrong diagnosis and later wondered what happened…?



Am J Surg Pathol 2011;35:750-756


Microinvasive breast cancer missed
Did not appreciate cancer cells on calponin stain
Eyes concentrate more on the ”brown” than the unstained elements
Situational awareness: “single vs double stain”
High case load leads to “auto-pilot behavior”
Possible Root Cause
IHC becoming tool to confirm bias
Three slide reviews:
1. H&E 2. IHC brown 3. IHC not brown
Possible Solution

Example: Erroneous tissue on slides



Function	Failure Mode	Effect	Severity	Cause	Frequency	Current Controls	Priority
Embedding	Tissue stuck to forceps	Another patient's tissue in block	8	Serrated tip forceps	2	Wiping forceps with tissue paper	high
	Incorrect orientation	Diagnosis difficult or impossible	5	Side of block not labeled with instruction	3	None	medium
	Cannot find a minute biopsy piece	Loss of biopsy	9	No lenspaper or tea bag used	1	None	high

Example: Use events to promote culture change

By Ben Sutherly,
Posted Jul 1, 2013 at 12:01 AM
Updated Jul 1, 2013 at 10:48 AM

Worker inexperience and a flawed clinical laboratory information system caused mishaps that cost **your hospital's name here** Medical Center nearly $1 million. Those details were gleaned from a government-mandated analysis of **your PT provider name here** 's mishandling of six proficiency-test samples that was conducted by and obtained by **local or national newspaper name here.**

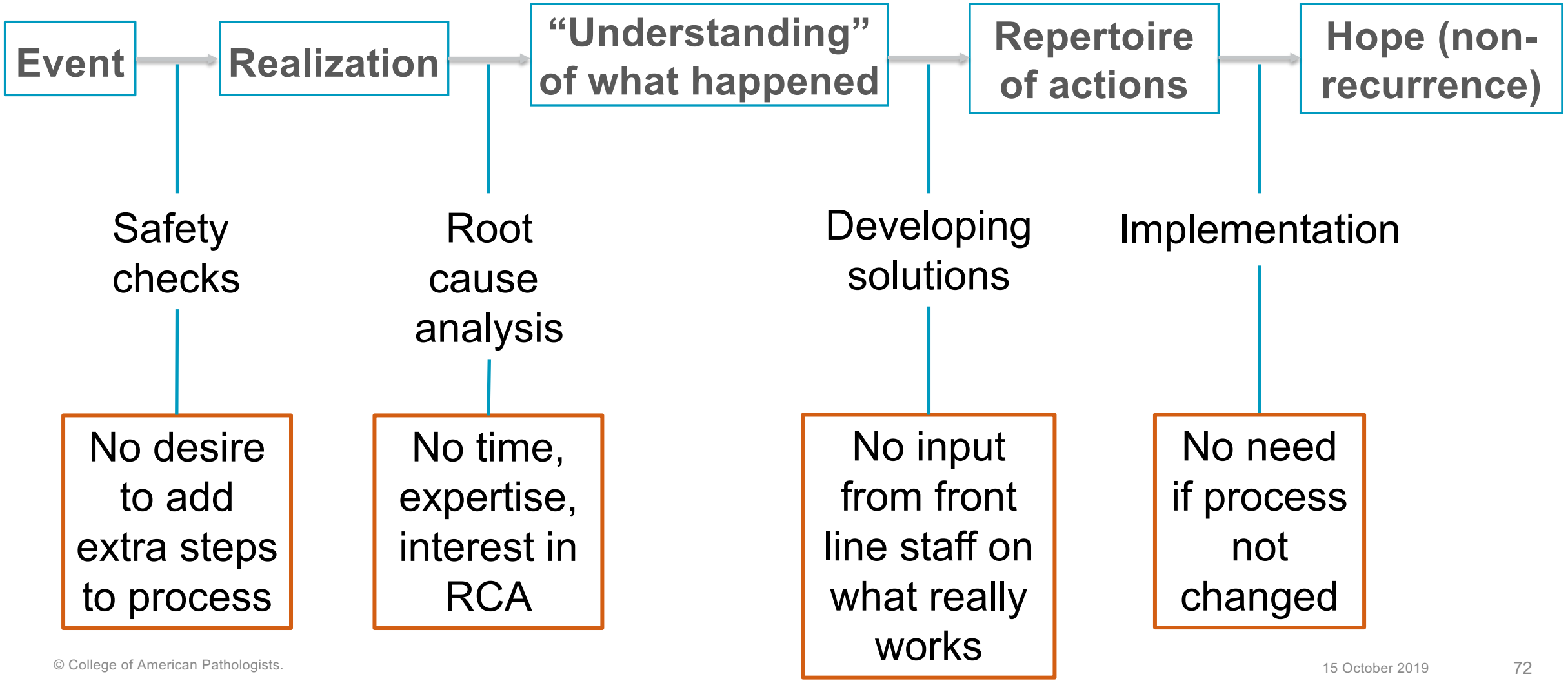
“Before” Behaviors

1. Someone brings the news that a mishap occurred
2. Everyone gets quiet and tries to think hard and fast whether “they did it”
3. Try to give impression that this is a minor random glitch that will not happen again
4. Generate feel-good atmosphere by reassuring everyone that no serious harm was done
5. Suggest that no further workup necessary because person “who did it” now fully aware of the problem
6. Everybody back at work ten minutes later as if nothing happened, except for person “who did it” who feels bad all week

Problems

- Understanding handling of PT samples beyond “like patient samples”
- Not appreciating the opportunity for improvement
- Lack of time to work anything up beyond “try not to do that again”
- Not realizing that if it had not happened to that one person, it would have happened to another
- Unwillingness to celebrate mistakes openly
- Skewed perception: for every mishap, a 1000 things go right

Root Causes



Solution

- Create an easy access event log and incentivize contributions
- First of all, congratulate those involved in a mistake/error/mishap, because they helped uncover a weakness in the system
- What I do as medical director: Look the one “who did it” in the eyes and tell them that if it had not happened to them, it would have happened to me (I usually follow up with something I screwed up that week…)
- Do ad-hoc five-why root cause analysis at the workbench, no scheduled meeting and no meeting room (my staff does not do well when removed from their home turf…)
- Empower staff and ask THEM for solutions (no rush, we want the best solution and not the quickest solution; but follow up on this)

“After” Behaviors

1. Someone brings the news that a mishap occurred
2. Someone says “Oh no, we should solve that”
3. Focus is on the steps of what we did, and not on who did it
4. We all realize that RCA is not as easy as presented at the CAP meeting
5. Staff translates ideas and solutions from one process to another

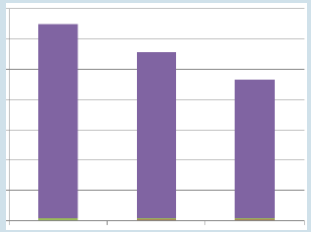
RCA Toolkit

Performance Tool

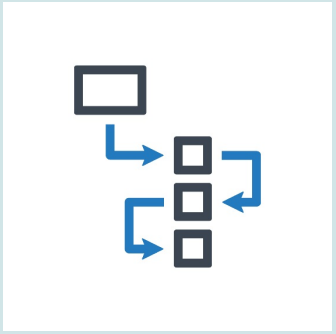
Microsoft Excel Worksheet

- Provides prompts that guide users through the six steps
- Provides a place to document results of each step

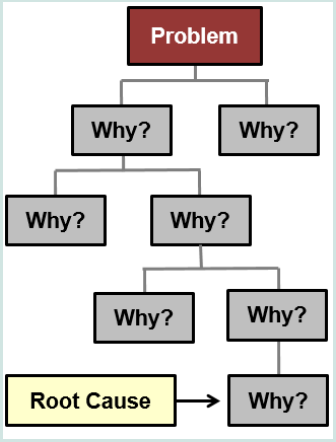
1. Define the Problem



2. Map the Process



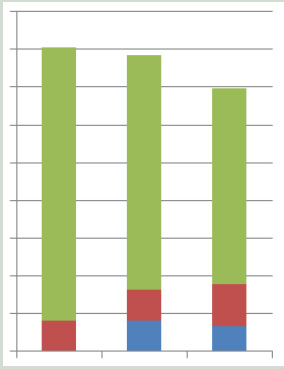
3. Find Root Cause



4. Develop Solution

5. Implement Solution

6. Assess Effectiveness



Performance Tool

Contents: Six Key Steps

1. Define the Problem

What to Do:

* Assemble the team
* Review the data
* Develop problem definition

Team Composition / Individuals Consulted:

John Doe, Jane Doe

Problem Definition / Statement of Non-Conformity:

There are documents located throughout the laboratory that are not in Document Control/Master Control.

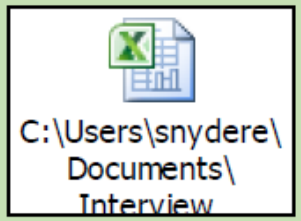
2. Map Current Process

What to Do:

* Interview individuals doing the work
* Review laboratory documents
* Create and/or expand flowcharts (or simply list the steps)

Flowcharts / Steps:

1. A process is created or adjusted 2. Supervisor or assigned staff member creates documentation reviewing the process or pocess changes 3. Documentation is provided to staff which is then left within the department.



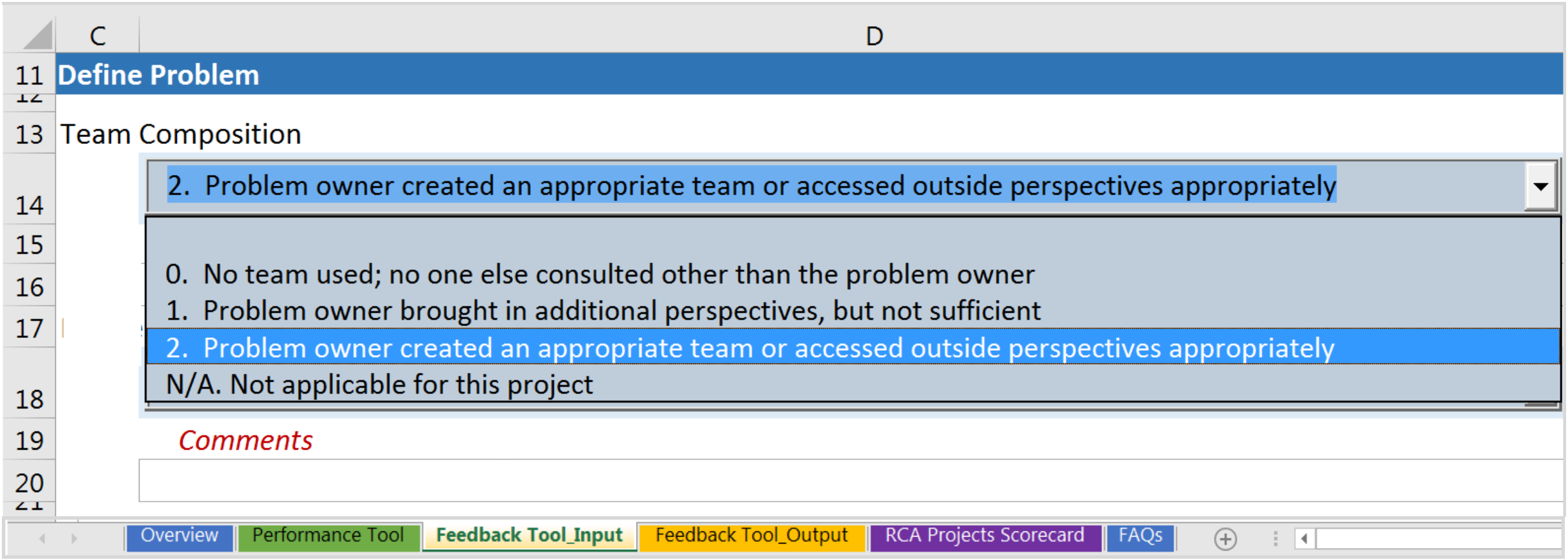
Overview | Performance Tool | Feedback Tool_Input | Feedback Tool_Output | RCA Projects Scorecard | FAQs

Feedback Tool, Projects Scorecard

- Makes it easy to evaluate the work and give feedback on each step
- Makes evaluation criteria transparent – no surprises

Feedback Tool - Evaluation

- 0,1, or 2 evaluation of each key step, plus space for comments



Feedback Tool – Output

- Scorecard ratings are familiar and easy to interpret

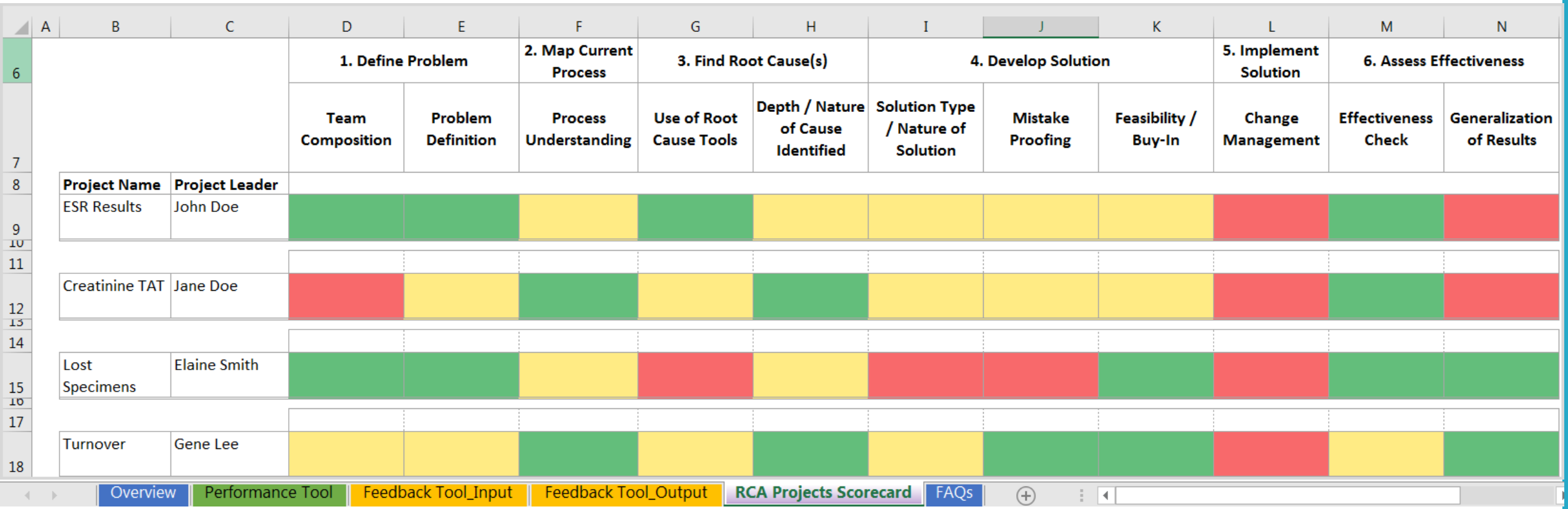
Project: ESR Results

Step	Sub-Step	Assessment	Comments*	Raw Score (0-2)	Points
1. Define Problem	Team Composition	2. Problem owner created an appropriate team or accessed outside perspectives appropriately	The team used lab techs, supervisors and vendors. Good mix of perspectives	2	10
	Problem Definition	1. Problem defined inadequately, or in terms of a preconceived solution	The problem was defined, but framed in terms of a solution.	1	6.67
2. Map Current Process	Process Understanding	0. No attempt to understand the current state/process	Documentation is missing information about current processes (analytic process, shift hand-off process, purchasing process)	0	0
3. Find Root Cause(s)	Use of Root Cause Tools	2. Use of root cause tools to address key aspects of the problem	Excellent fault-tree analysis	2	5
	Depth / Nature of Cause Identified	1. Analysis explores why the person or equipment failed, or why the condition was present	Analysis explored why the analytic procedure was failing (shallow volume of reagent because of wide reagent vial) but does not explore general issue, such as purchasing process.	1	3.33
4. Develop Solution	Solution Type / Nature of Solution	1. Intermediate - Provide info at the point of need; redesigning training to make it more effective	Team put permanent instruction on caroussel to check reagent depth, but did not redesign process.	1	6.67

Overview | Performance Tool | Feedback Tool_Input | Feedback Tool_Output | RCA Projects Scorecard | FAQs

Projects Scorecard

- Allows comparison of multiple projects; helps identify common weaknesses



		1. Define Problem		2. Map Current Process	3. Find Root Cause(s)		4. Develop Solution			5. Implement Solution	6. Assess Effectiveness	
Project Name	Project Leader	Team Composition	Problem Definition	Process Understanding	Use of Root Cause Tools	Depth / Nature of Cause Identified	Solution Type / Nature of Solution	Mistake Proofing	Feasibility / Buy-In	Change Management	Effectiveness Check	Generalization of Results
ESR Results	John Doe											
Creatinine TAT	Jane Doe											
Lost Specimens	Elaine Smith											
Turnover	Gene Lee											

Overview | Performance Tool | Feedback Tool_Input | Feedback Tool_Output | RCA Projects Scorecard | FAQs

RCA Toolkit

"The RCA Toolkit has turned our corrective action up multiple levels."

"I'm using it in meetings with other team members. I'm using it to push team members to do better – to challenge them."

"I look forward to these meetings now."

Nancy Levin
Quality and regulatory manager for Mayo Clinic Eau Claire Laboratory

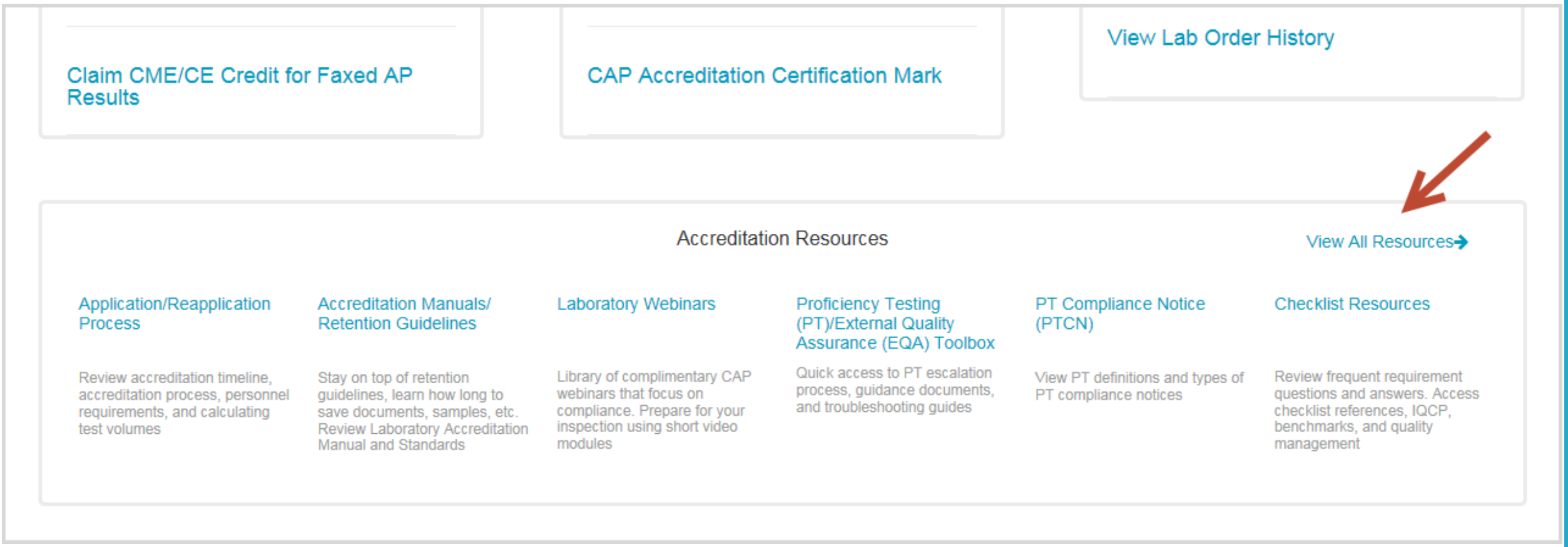
From left: Tracy Williamson (MT), Nancy Levin (MT), and Jennifer Dalhoe (MLT)

“We love it.”

Vipul Trivedi, M.D., FCAP
Chair of Mayo Clinic Division of Community Laboratory Medicine and Pathology

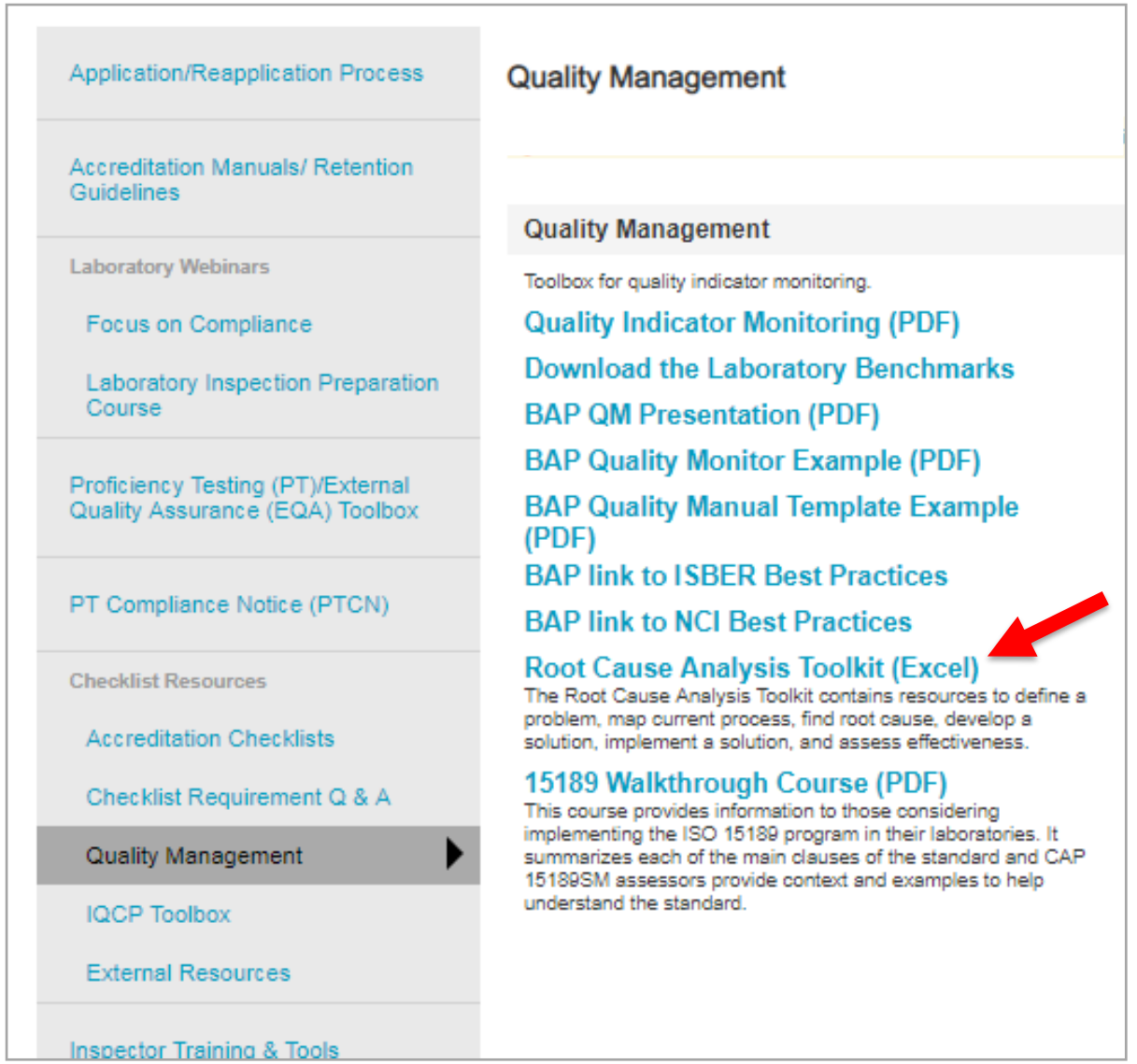
Where to find RCA Toolkit in eLab Solutions

1. **Scroll down to Accreditation Resources**
2. **Click View All Resources**



Where to find RCA Toolkit in eLab Solutions

3. Click Quality Management
4. Select Root Cause Analysis Toolkit



COLLEGE of AMERICAN PATHOLOGISTS

Resources for Further Study

- College of American Pathologists. CAP Quality Management Education Resources. *Root Cause Analysis* [online course]. 2010. http://www.cap.enspire.com

- Okes, Duke. *Root Cause Analysis: The Core of Problem Solving and Corrective Action*. Milwaukee, WI: Quality Press; 2009.

- Schneider, Frank, MD. “ISO 15189.” In *Quality Management in Anatomic Pathology,* edited by Qihui ‘Jim’ Ahai and Gene P. Siegal, 185-194. Northfield, IL: CAP Press, 2017.