Root Cause Analysis: The Basics

APHL QIF Call April 29, 2025

Wyoming Department of Health | PUBLIC HEALTH DIVISION | WYOMING PUBLIC HEALTH LABORATORY

What We'll Cover

- Describe root cause analysis (RCA)
- Introduce common examples of RCA tools
  - Is/Is not analysis
  - 5 Whys
  - Fishbone Diagram (Cause and Effect)
  - Pareto analysis
- Delve into 5 Whys with a real-world example

Common Terminology

Non-conforming event/ non-conformance: unplanned deviation from standard operations or expected outcomes

Correction: temporary, immediate response (ex: rerunning a failed control)

Common Terminology

Corrective Action and Preventative Action (CAPA): systematic approach in quality management to handle problems after they occur (corrective action) and identify and eliminate potential problems (preventative action)

Root Cause Analysis (RCA): a systematic, data-driven approach used to identify the underlying causes of a problem or nonconformance

Participant Question

When a problem occurs at your organization, what is your typical role in the Root Cause Analysis process?

A. I am aware of Root Cause Analysis conducted at my organization

B. I contribute information or data to help the investigation

C. I help lead or facilitate Root Cause Analysis discussions

D. I make decisions based on Root Cause Analysis findings

E. I'm not usually involved

Why do a root cause analysis?

- To drive improved outcomes through problem-solving and new solutions
- To drive quality
- To protect the safety of our colleagues
- To prevent recurrence
- To optimize operational efficiency
- To promote a culture of learning

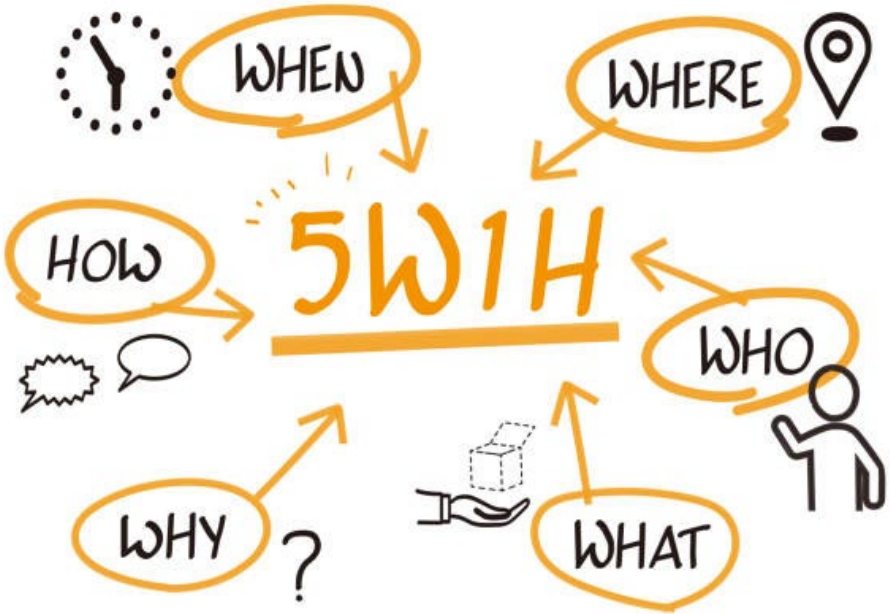
Participant Question

How are problems most often reported in your area?

A. Formal system (e.g., software, incident log, ticketing tool)
B. Informal conversation or word of mouth
C. Email or message to a supervisor
D. Paper form or manual log
E. Not sure / We don’t have a standard method

Pause… Define the Problem

- Clear problem statements focus efforts
- Clarifies what is within scope of the RCA
- Leads you towards the right RCA tool



Strategies for Information Gathering

- Interviews
- Document Review
- Data Review
- SBAR
  - S – Situation: What is happening now?
  - B – Background: What led up to this?
  - A – Assessment: What do you think the problem is?
  - R – Recommendation: What do you suggest should be done?

Root cause analysis tools

Learning objectives for this section

1) Identify 4 common tools
   - Is/Is Not
   - 5 Why's
   - Fishbone diagram
   - Pareto analysis
2) Demystify their use
3) Recognize that the complementary nature of these tools
4) Provide (very) abbreviated examples to illustrate the interplay between these tools

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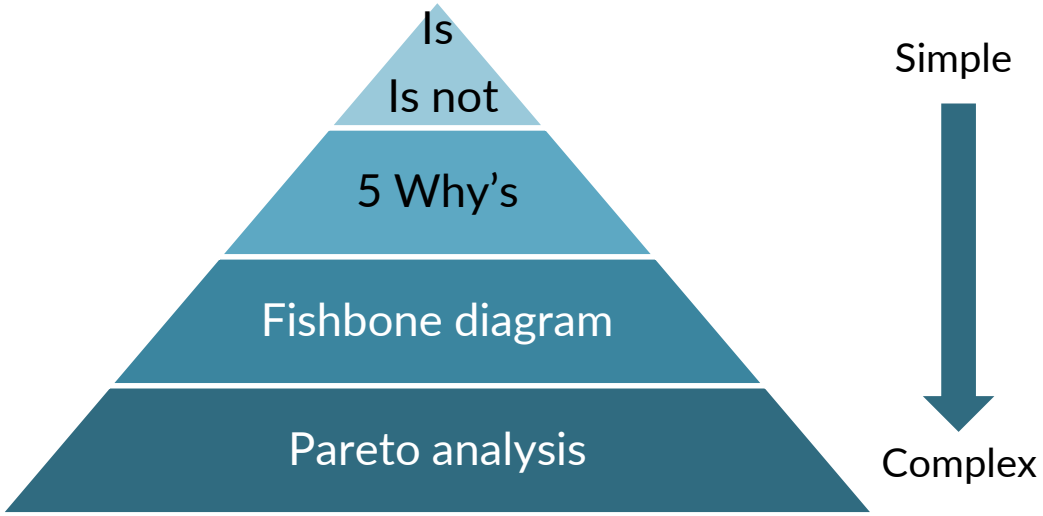
Common Ways of Framing Root Cause Analysis Work

Lists

- Is/Is not strategy
- 5 Why's
- Fishbone diagram
- Pareto analysis

Hierarchy



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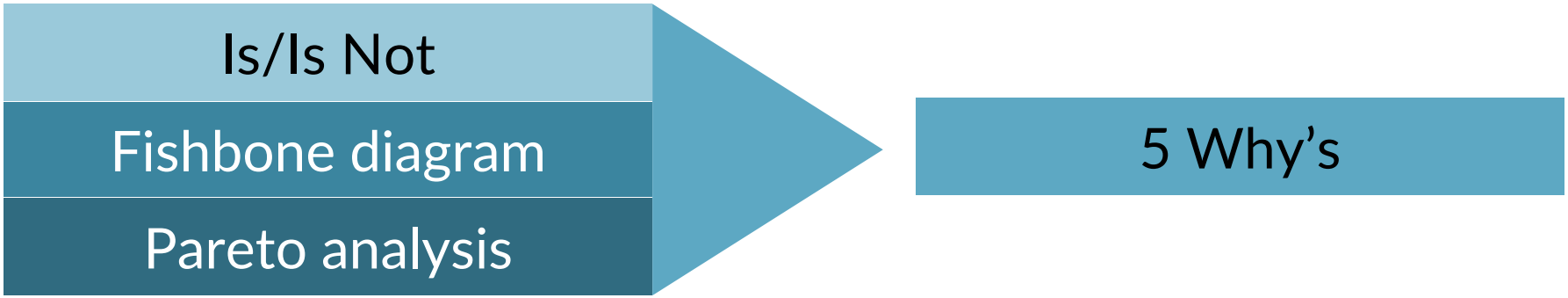
Practical Strategy for Root Cause Analysis Work

Identifying contributing factors

Driving root cause



Contributing factors are not a root cause

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Is/Is Not Strategy

Value

- To refine scope of the problem statement

Goals

- To identify if factor IS or IS NOT contributing

Steps

- Develop a problem statement
- Map Lists of Is and Is Not
- Follow up with 5 Why's

Is a contributor	Is Not a contributor

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Illustrative Vignette #1

You supervise the serology section of your laboratory. An analyst comes to you sharing that the low quality control failed.

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Illustrative Vignette #1

Use workflow.
Please walk me through what you did.

- Pulled the QC out of the fridge.
- Samples warm to room temperature.
- Aliquoted the low QC using the 100 ul pipet.
- Aliquoted the high QC using the 200 ul pipet.
- Aliquoted the samples using the 200 ul pipet.
- Vortexed & incubated samples for 1 hour.
- Loaded on to the machine.

May be a contributor	May be Not a contributor

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Illustrative Vignette #1

Use workflow.
Please walk me through what you did.

- Pulled the QC out of the fridge.
- Samples warm to room temperature.
- Aliquoted the low QC using the 100 ul pipet.
- Aliquoted the high QC using the 200 ul pipet.
- Aliquoted the samples using the 200 ul pipet.
- Vortexed & incubated samples for 1 hour.
- Loaded on to the machine.

May be a contributor	May be Not a contributor
Fridge temp?	
Samples not warmed?	
Pipettor calibration?	
Pipettor at wrong volume?	
Improperly vortexed?	
Machine improperly calibrated?	

Illustrative Vignette #1

Use workflow.
Please walk me through what you did.

- NO: Pulled the QC out of the fridge.
- NO: Samples warm to room temperature.
- Aliquoted the low QC using the 100 ul pipet.
- Aliquoted the high QC using the 200 ul pipet.
- Aliquoted the samples using the 200 ul pipet.
- NO: Vortexed & incubated samples for 1 hour.
- NO: Loaded on to the machine.

May be a contributor	May be Not a contributor
	Fridge temp?
	Samples not warmed?
Pipettor calibration?	
Pipettor at wrong volume?	
	Improperly vortexed?
	Machine improperly calibrated?

Illustrative Vignette #1

Further discussions with the analyst reveal that they pulled the pipettor from a drawer. Examination of that pipettor (used only for the low QC control) was that it hadn't been calibrated in over 3 years.

THIS IS NOT A ROOT CAUSE.

5 Why's

Value

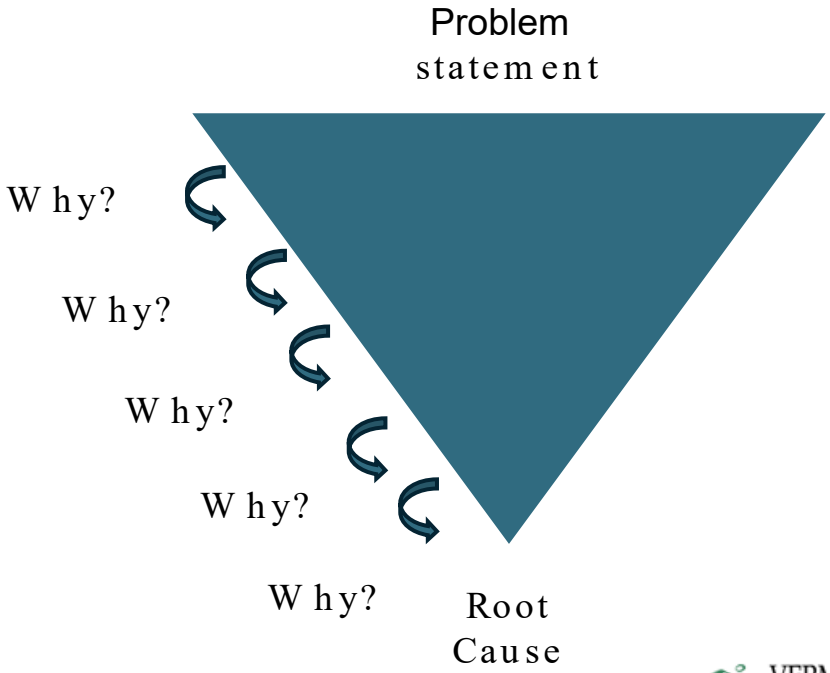
- To deepen understanding of the problem

Goals

- To identify an actionable statement that you can control

Steps

- Repeatedly ask why is response to efforts to solve RCA



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Illustrative Vignette #1

Discussion abbreviated for simplicity.
5 Why's is a central tool
and will be revisited.

I pulled a pipettor from the drawer.

There wasn't any on the bench.

One was needed in the food lab.

We don't have enough calibrated pipettors.

We don't calibrate all the pipettors when the vendor comes onsite.

Root cause: We don't have a designated storage area for 'out of commission' pipettors.

Action: Designate a storage area for pipettors.

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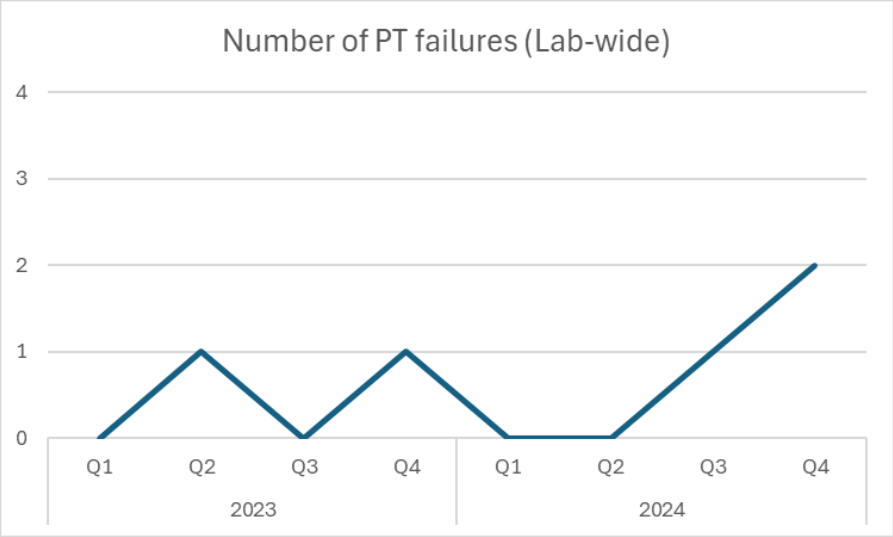
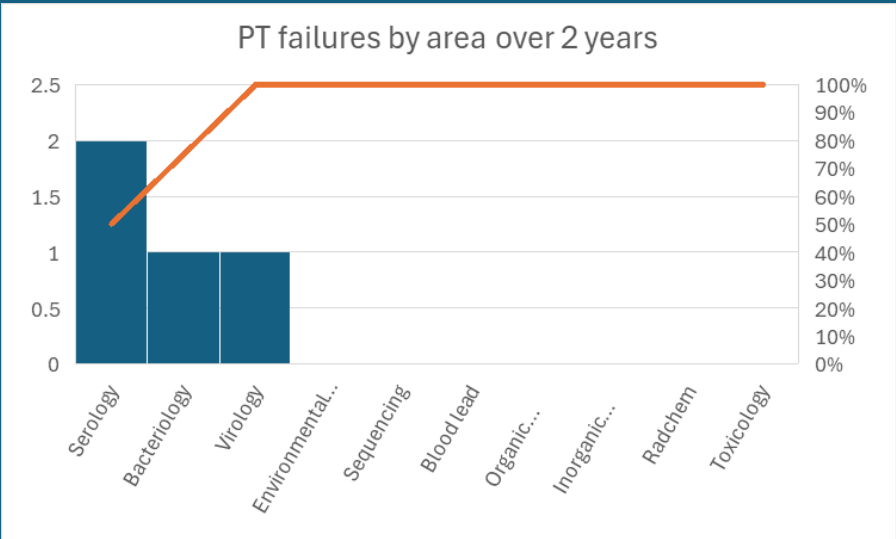
Illustrative Vignette #2

You are the laboratory director. Your quality manager is reviewing proficiency tests results from the year and has noticed an increase in proficiency test failures. You ask some data to understand this observation better.

Illustrative Vignette #2





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Pareto analysis

Value

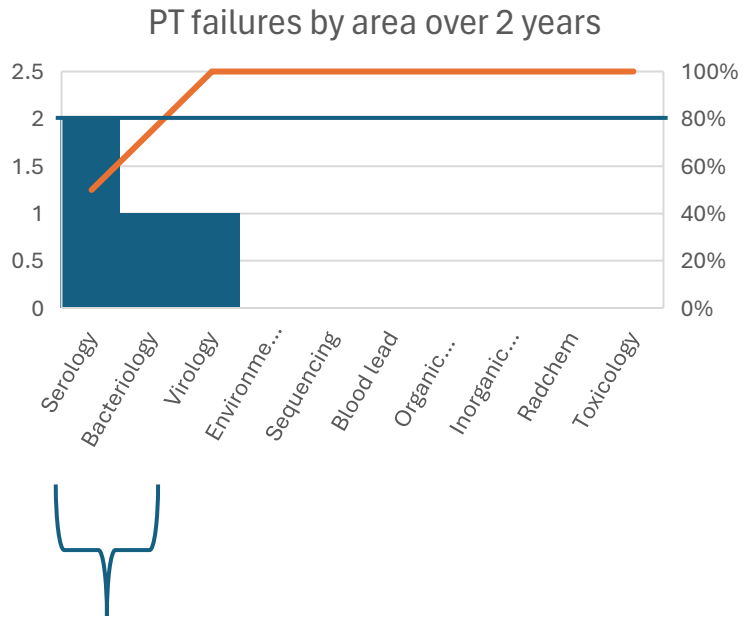
- To identify important contributing factors (Pareto Principle of 80/20 rule)

Goals

- To drive an evidence-based approach

Steps

- List factors with relative contributions
- Identify factors that contribute to the 80%
- Follow up with 5 Why's



Two programs account for 80% of failures

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Illustrative Vignette #2

As you are reviewing this, your supervisor over serology comes in to share that they had their second failure in one test. Given the severity of this, along with the data you've seen, you ask for a comprehensive approach to this failure.

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Fishbone Diagrams

Value

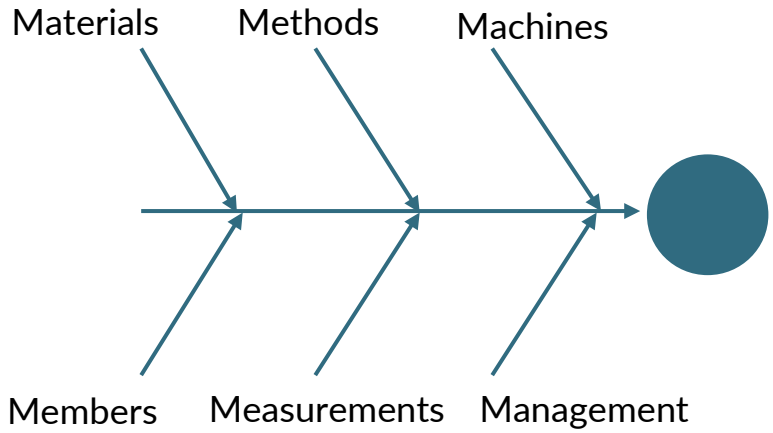
- To address complex problems or where there may be biases or assumptions

Goals

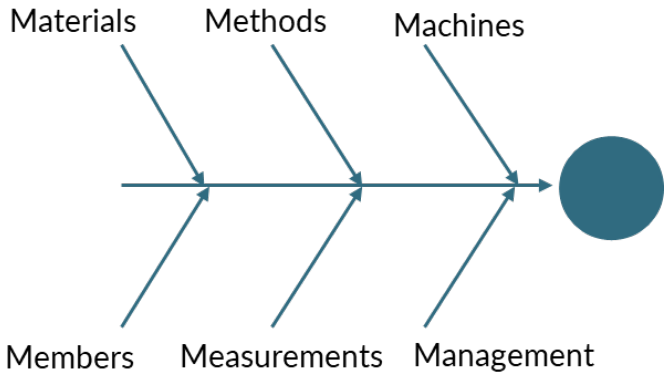
- To consider all aspects of evaluation

Steps

- Establish the categories
- Seek recent changes or consider workflow
- Follow up with 5 Why's



Fishbone diagram (list form)



Possible contributing factors

1. Supplies
2. Processes
3. Personnel
4. Equipment
5. Calculations
6. Policies

Materials
Methods
Members
Machine
Measurements
Management

Referred to as the 6 M's

Illustrative Vignette #2

Category	Any recent change
Material	No
Methods	No
Members	Yes – new staff (within last 6 months)
Machine	No
Measurements	No
Management	Yes – added automated temperature monitoring system

Tips

- *Listing specific items for each category can be helpful.*
- *This approach can be combined with use of workflow mapping.*

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Combining a fishbone diagram and 5 Why's

Material

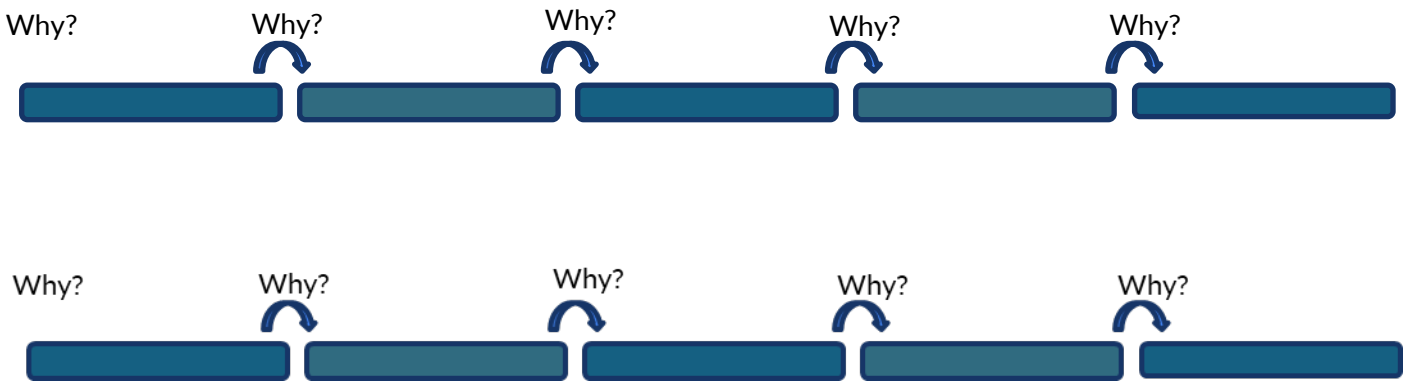
Methods

Members

Machine

Measurements

Management



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Illustrative Vignette #2

Multipronged analysis reveals that the refrigerator in the serology section was left off the list when the new temperature monitoring system was introduced. Further, the new staff was storing calibrators and controls in the same box in the same fridge.

Root cause: A failing fridge degraded the QC and calibrators

Contributing factors:

- Calibrators and controls were stored together
- Routine checks of the fridge were missed

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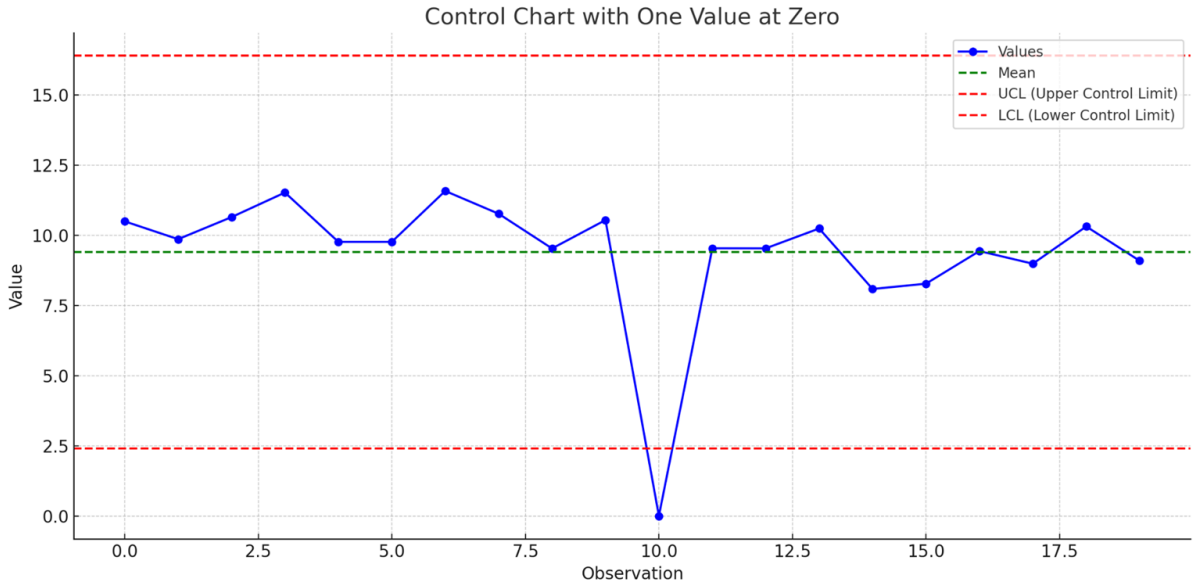
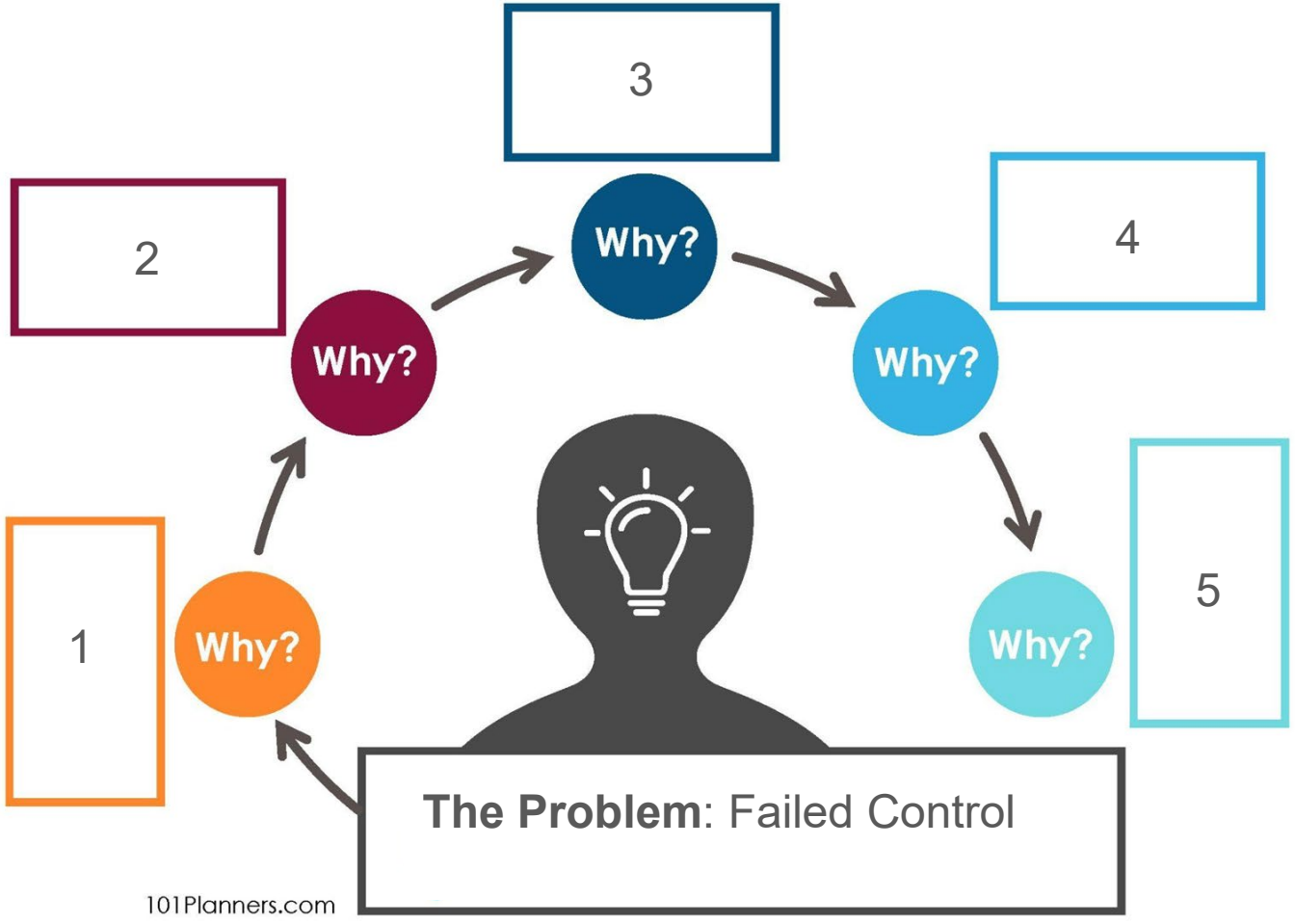
5 Whys: In the real world

- Situation: A positive control showed no analyte.
- Background: The Chemical Testing Program produced positive controls as part of its daily drug analysis runs. On June 32, the positive control showed no analyte during analysis. All other run controls showed appropriate levels and meet all metrics
- Stakeholders: Analysts, Lab Manager, QA Officier




3
2
Why?
4
Why?
Why?
1
Why?
5
Why?
The Problem: Failed Control
101Planners.com

The Problem: Failed Control

1. **Why?:** The control value was zero. This is outside the acceptable range.
2. **Why?:** The analyte wasn't present in the sample.
3. **Why?:** The analyst reports not remembering pipetting the standard into solution.
4. **Why?:** The analyst developed a list of solutions to generate, however, failed to verify the list while making the solutions.
5. **Why?:** There is not system to record the solutions during the production process.

Check the Final Why

- To ensure appropriateness, verify the final why against the problem statement
  - Does the final why statement answer that can be answered by the problem?
- Why did the control fail?
  - There is not system to record the solutions during the production process.

The Root Cause

- The root cause is a proposed solution to the final why
- There is not system to record the solutions during the production process.
  - Proposed solutions
    - Retrain staff on laboratory notebook techniques
    - Develop a checklist to use in conjunction with the SOP
    - Your organizational solution

Valuable reference:
https://www.aphl.org/aboutAPHL/publications/Documents/QSA-2021-PHL-Model-Practices-QMS11-A.pdf

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