

# Understanding DMAIC and Effective Root Cause Analysis

How to Apply Them to Laboratory  
Work Flow and Work Processes

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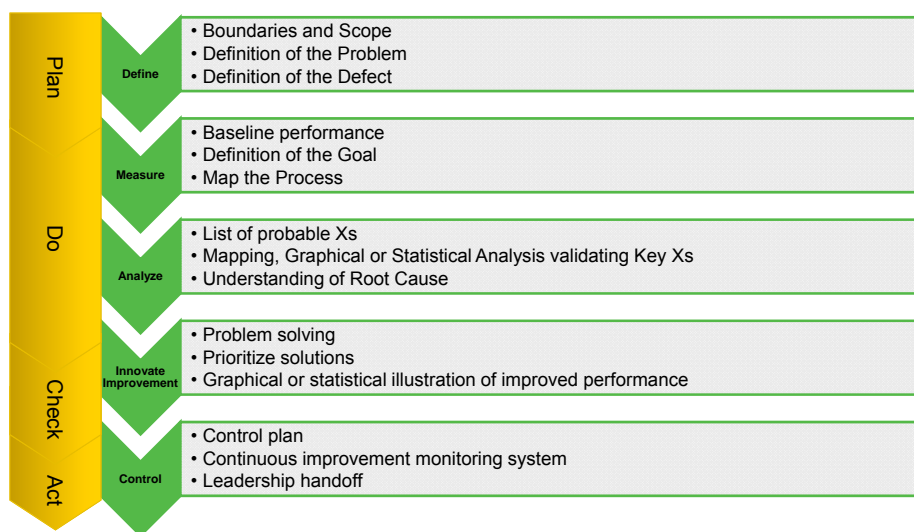
## Session Agenda

- Introduction to the Session & Objectives
- Defining the Problem
  - Overview of the DMAIC methodology
  - Illustration of how you know you have a problem
  - Using data to understand a process
  - Activity
- Defining the Root Cause
  - What is root cause analysis
  - Tools & techniques
  - Understanding cause and effect
  - Activity
- Solving the Problem
  - Implementing short-term actions
  - Understanding impact & comparing to goals
  - Activity
- Summary & Reflection
  - Key takeaways
  - Resources

## Session Introduction & Objectives

- Build capabilities of laboratory professionals in structured root cause analysis
- Understand the basics of defining and analyzing a problem. Understand how to apply root cause analysis tools to identify solutions
- Attendees will learn to:
  - identify and scope a problem,
  - apply Six Sigma and Lean techniques to analyze key input variables,
  - perform a root cause analysis,
  - implement sustainable solutions in laboratory work flow and work processes

## Defining the Problem: Overview of DMAIIC Methodology



## Defining the Problem: Boundaries & Scope

- Problem And Goal Statements
  - Description Of The Problem/Opportunity And Objectives In Clear, Concise And Measurable Terms
- Business Case
  - Why Do This Project?  
Linkage to Business Goals & Customer Needs, Expected Benefits

The term Voice of the Customer (VOC) is used to describe customers' needs and their perceptions of your product or service.

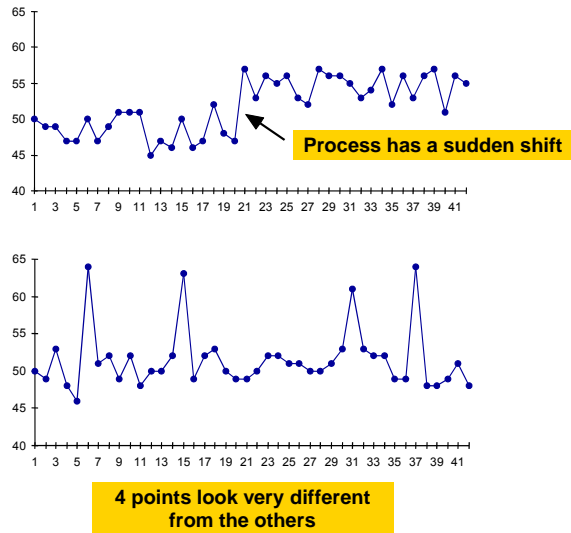


## Defining the Problem: What is a Defect?

- Failure to meet customer specification (internal or external) is called a Defect
  - Defects can be caught and “fixed” within any step in the process.
    - We generally only count defects at “the final step”.
    - However rework (additional cost and labor) can occur at all steps
  - Some defects reach the customer.
    - Often not reported
    - We learn of them when the customer leaves
  - To identify opportunities for improvement, it is important to measure all defects

## Defining the Problem: Using Data

Understanding what causes that variation helps us decide what kinds of actions are most likely to lead to lasting improvement



## Defining the Problem: Focusing Analytic Work

**Basic Question:**

The basic question focuses the analytic work, ensuring that the findings are actionable. The more specific the question the better, provided it is not so narrow that the "wrong" problem is addressed

**1 Why is it important?**

Give specific values (e.g. \$100 per day, 10 Med Tech hours per week)

**2 Who is responsible?**

Identifies primary decision maker who can affect implementation of a solution (e.g. Lab Director, Processing Manager)

**3 Criteria for success?**

What would indicate long-term success of a solution (e.g. no repeat samples for two weeks)

**4 What is included in the study?**

Indicates what will and will not be included in the study of the problem (e.g. no overtime allowed, cannot purchase any new equipment)

**5 Barriers to Impact?**

Details implementation challenges (e.g., communication practices, risk aversion)

## Defining the Problem: Example

**Basic question to be resolved:**

How can we decrease backlog by 25% over the next two weeks without sacrificing productivity, cost, or safety?

**1 Perspective/context?**

Decreasing backlog by 25% would make customers happy

**2 Stakeholders and processes?**

Following the problem solving session, we will present to the Lab Director for her approval before implementing the change.

**3 Criteria for success?**

Backlog is reduced by 25%; productivity, cost, and safety remain at current levels or improve.

**4 What is included in the study?**

We will focus on only changing the process, schedules can be changed, the SOP can be changed (with approval), additional headcount is not allowed

**5 Barriers to Impact?**

We will have 3 FTE's on vacation during the trial and will need to communicate changes to them

## Defining the Problem: Activity – “What Is Your Problem?”

**Basic question to be resolved:**

**1 Perspective/context?**

**2 Stakeholders and processes?**

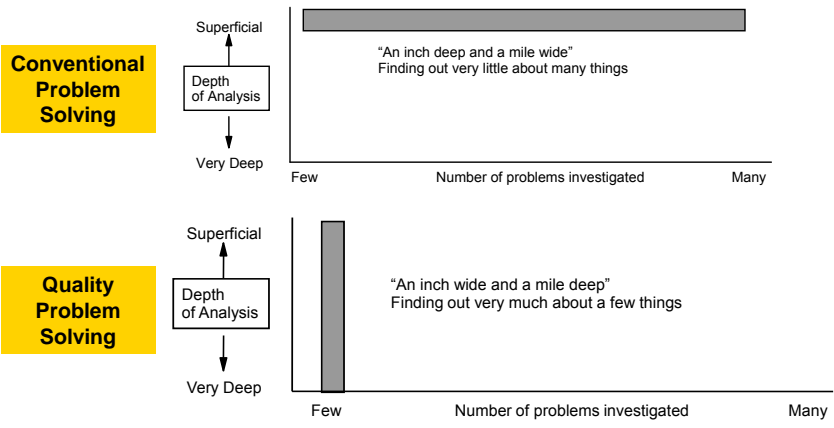
**3 Criteria for success?**

**4 What is included in the study?**

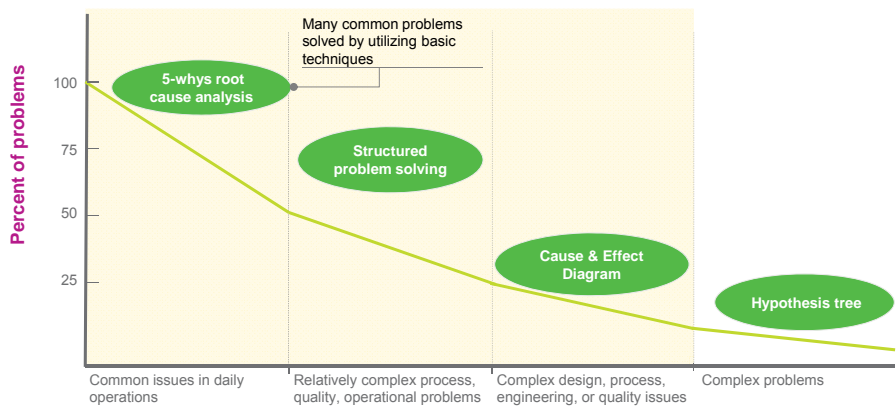
**5 Barriers to Impact?**

## Defining the Root Cause: What is RCA?

Root Cause Analysis (RCA) is the systematic analysis to determine the true root cause, and separate it from the secondary causes or symptoms.

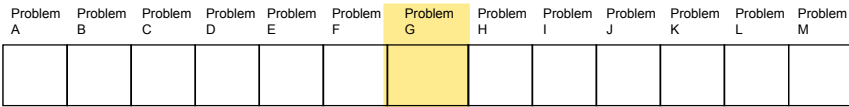


## Defining the Root Cause: Tools & Techniques

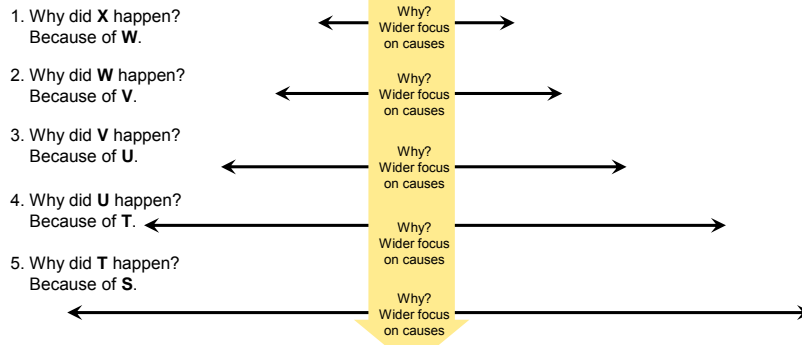


- Who:**
- All Employees
  - All Employees
  - Greenbelt
  - Supervisor/Manager
  - Blackbelt

## Defining the Root Cause: 5 Whys



“Ask the question ‘Why’ five times”

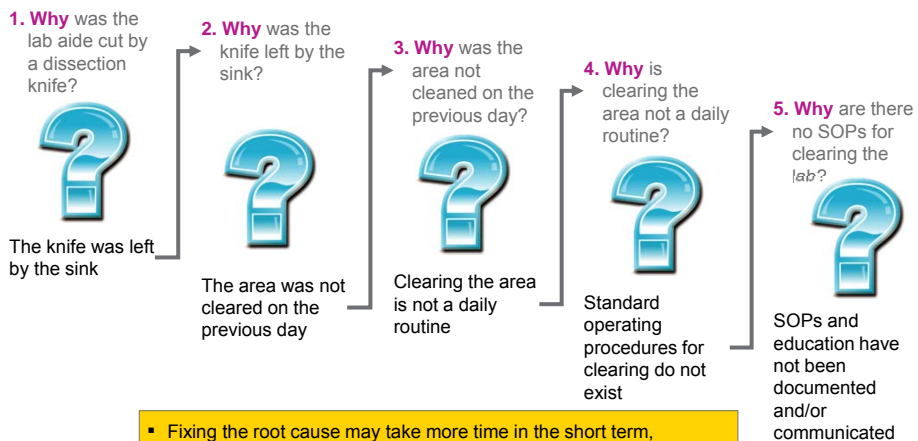


Quest Diagnostics

*Mile Deep Thinking*

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## Defining the Root Cause: 5 Whys



- Fixing the root cause may take more time in the short term, but the investment will pay off quickly as the problem never recurs
- Instituting a root-cause problem solving culture leads to higher productivity and a highly motivated workforce

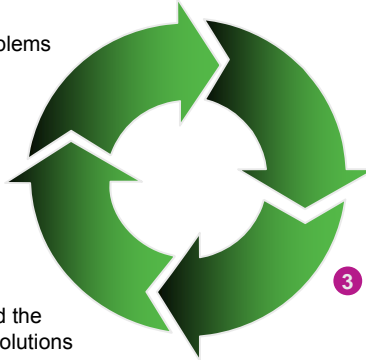
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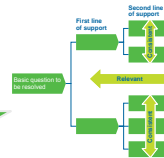
## Defining the Root Cause: Structured Problem Solving

- 1 • Select problems to improve**  
 – Define problems

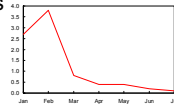
<p><b>State condition to be corrected:</b>                  The task question to cause the analysis work, ensuring that the findings are actionable. The main objective is to specify the condition to be corrected to not to define the "wrong" problem or statement.</p> <p><b>Condition of the "what/why" and "how/when" (e.g., scheduling, organization, staffing levels)</b></p> <p><b>Condition of the "what/why" and "how/when" (e.g., scheduling, organization, staffing levels)</b></p> <p><b>Condition to be corrected:</b>                  Refer to the basis on which the stakeholders will make a decision to act on the recommendations.</p> <p><b>Condition to be corrected:</b>                  Details implementation challenges (e.g., communication practices, risk aversion)</p>	<p><b>Condition of the "what/why" and "how/when" (e.g., scheduling, organization, staffing levels)</b></p> <p><b>Condition of the "what/why" and "how/when" (e.g., scheduling, organization, staffing levels)</b></p> <p><b>Condition to be corrected:</b>                  Indicate what will and will not be included in the scope of the project.</p>
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- 2 • Identify source**  
 – Identify sources of problems



- 4 • Follow-up**  
 – Understand the impact of solutions  
 – Compare with targets

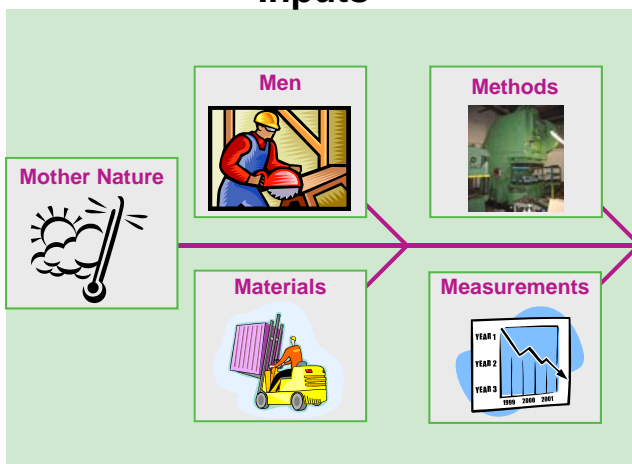


- 3 • Implement solutions**  
 – Take short-term actions



## Defining the Root Cause: Cause & Effect Diagram

### Inputs



### Output





## Defining the Root Cause: Cause & Effect Diagram

Step 1: Review the Focused Problem

Step 2: Identify Possible Causes

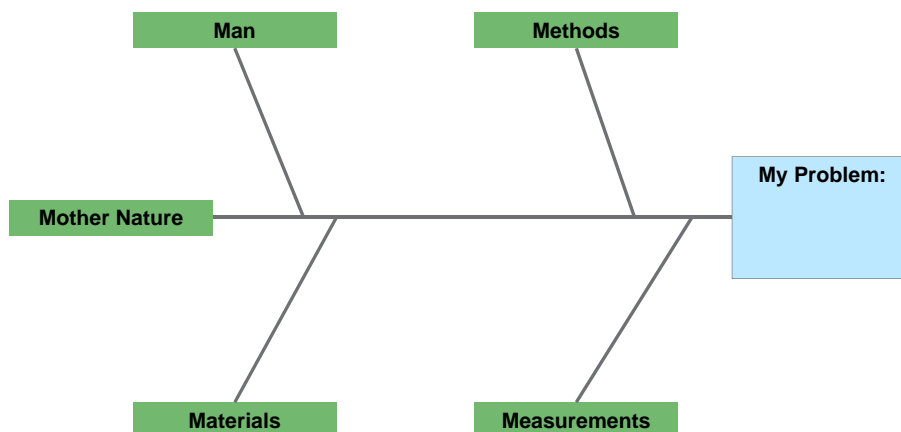
Step 3: Sort Possible Causes

Step 4: Choose a Cluster and Label Main Bone

Step 5: Develop and Arrange Bones for that Cluster

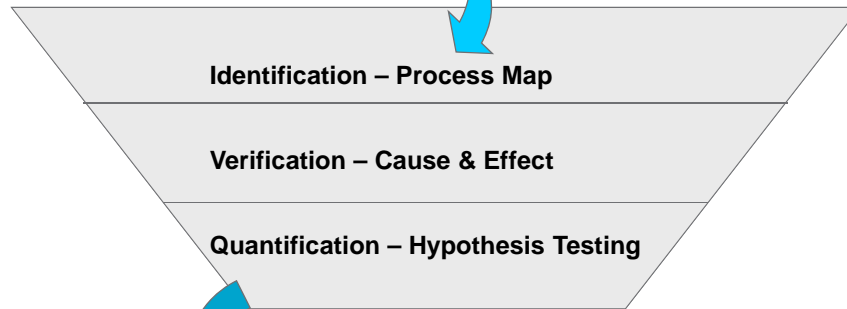
Step 6: Select Causes to Verify

## Defining the Root Cause: Activity – “Getting to The Point”



## Defining the Root Cause: Understanding Cause & Effect

$$Y = f(X_1, X_2, X_3, \dots, X_n)$$



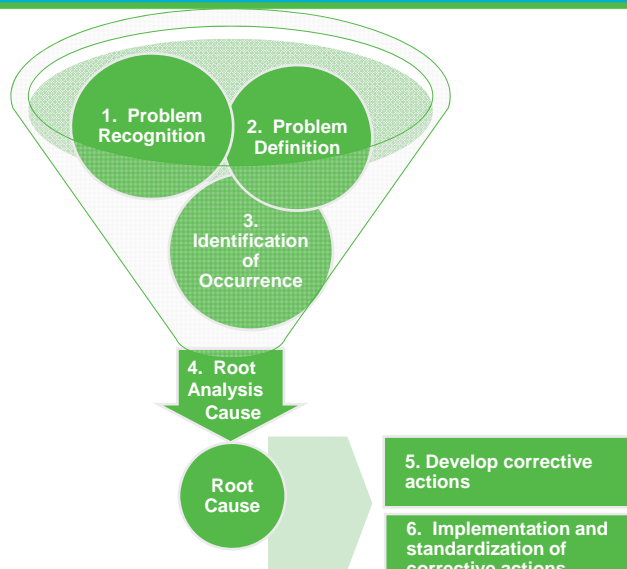
The Vital few Xs that influence Y

What vital few process and input variables (Xs) effect critical to quality process performance or output measures (Ys)?

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## Solving the Problem: Problem Solving Process



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## Solving the Problem: Characteristics of Good Problem Solving

- Uses a structured approach
  - Select a problem solving process or structure appropriate to the context audience, complexity of problem or use the method of etc., commended by our company
- Is focused on root causes
  - By not addressing root causes, we encounter the same problems repeatedly so performance does not improve
- Leads to corrective action
  - Implement counter-measures to prevent reoccurrence of the problem

## Solving the Problem: Short Term Actions

### 1. Brainstorm counter measures

- Use brainstorming to generate as many potential countermeasures as possible
- Countermeasures should focus on possible ways to address the problem

### 2. Prioritize high impact items

- Prioritize ideas to identify highest value or most likely countermeasures

### 3. Create action plans

- Create clear and concrete action plan to correct root cause of problem, specifying:
  - Specific activities
  - Owner
  - Deadline
  - Status

## Solving the Problem: Making an Impact, “A3 Template”

- One-page, A3-sized report to capture knowledge from the problem solving session
- Used to facilitate structured, concise thinking, communication and consensus building
- Focus is on clarifying issues and recommending Countermeasures
- No standard A3 template: layout is defined by context/story

<b>Problem name:</b> <i>Insert problem name as per defects notice</i>	<b>Reported by:</b> <i>Insert operator name as per defects notice</i>	<b>Date:</b> <i>As per defects notice</i>	<b>Problem #:</b> <i>As per defects notice</i>																																				
<b>1. Problem description</b> <ul style="list-style-type: none"> <li>• Describe the problem at a high level; break into sub-issues if applicable</li> <li>• Describe gap between defective state of product and target standard state</li> <li>• Describe how and where in process defect was detected</li> <li>• Specify point of cause in process (Where can/does the problem occur?)</li> </ul>	<b>3. Countermeasures / improvement actions</b> <div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>Countermeasures</b>  <i>Describe at high level prioritised list of levers to correct identified defect</i> <ul style="list-style-type: none"> <li>• ..</li> <li>• ..</li> <li>• ..</li> </ul> </div> <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th style="width: 70%;">Specific action items to implement countermeasures</th> <th style="width: 10%;">Who?</th> <th style="width: 10%;">By when?</th> <th style="width: 10%;">Status</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>			Specific action items to implement countermeasures	Who?	By when?	Status																																
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<b>2. Root cause analysis</b> <i>List potential root causes</i> <ul style="list-style-type: none"> <li>• Men:</li> <li>• Materials:</li> <li>• Machine:</li> <li>• Method:</li> <li>• Mother nature:</li> </ul> <i>Specify probable root cause:</i> <ul style="list-style-type: none"> <li>• ...</li> </ul>	<b>4. Evaluation:</b> <i>Explain how you will evaluate whether countermeasures are successful in eliminating problem</i> <div style="float: right; font-size: x-small;"> <b>Problem:</b>            Solved <input type="checkbox"/>            Partly solved <input type="checkbox"/> </div>																																						
<b>5. Standardisation:</b> <i>Explain how countermeasures could be incorporated into existing standards</i>																																							

## Solving the Problem: Activity

### “What’s Wrong With This Process?”

<b>Problem name:</b>	<b>Responsible:</b>	<b>Date:</b>	<b>Problem #:</b>																																				
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## Summary & Reflection

**"I have no particular talent.  
I am merely extremely inquisitive."  
- Albert Einstein**

### List of Resources & References

- American Society for Quality: [asq.org](http://asq.org)
- Root Cause Analysis Knowledge Base: [reliabilityweb.com](http://reliabilityweb.com)
- Institute for Healthcare Improvement: [ihi.org](http://ihi.org)
- LinkedIn- Lean Six Sigma Group: [linkedin.com](http://linkedin.com)
- Williams, PM. Techniques for root cause analysis. Proc (Baly Univ Med Cent). 2001 April; 14(2): 154-157. PMID: PMC1292997