# Lab Quality Confab 2013

# Understanding and Using Six Sigma's Most Powerful Tools

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# Course Objectives

- Recognize the most important tools to ensure a good project has been chosen.
- Recognize the most important tools to move through an improvement project.
- Understand tool usage and the outcomes of proper usage

# Seven Basic Tools of Quality

## (source: Wikipedia)

"A designation given to a fixed set of graphical techniques identified as being most helpful in troubleshooting issues related to quality. They are called *basic* because they are suitable for people with little formal training in statistics and because they can be used to solve the vast majority of quality-related issues.
The seven tools are:

Cause-and-effect diagram (also known as the "fishbone" or Ishikawa diagram)
Check sheet
Control chart
Histogram
Pareto chart
Scatter diagram
Stratification (alternately, flow chart or run chart)

The designation arose in postwar Japan... It was possibly introduced by Kaoru Ishikawa who in turn was influenced by a series of lectures W. Edwards Deming had given to Japanese engineers and scientists in 1950. At that time, companies that had set about training their workforces in statistical quality control found that the complexity of the subject intimidated the vast majority of their workers and scaled back training to focus primarily on simpler methods which suffice for most quality-related issues."

# Great, and

- How do we select the right project?
- How do we know what data to collect to use with those tools?
- How do we know what to do with the outcomes of those tools?
  - Answers
  - More questions
- How do we close the project and ensure successful handoff?

# Six Sigma Roadmap

- Disciplined group of steps always used in sequence to identify root cause and decrease process variability
  - DMAIIC
    - Define
    - Measure
    - Analyze
    - Innovative Improvement
    - Control

Small or large – use the roadmap as a guide to increase QI success rate.

# Project Selection and Chartering

# Project Identification

- Value stream map – waste and variation
- Recurring "fires"
  - What are you constantly solving?
- Process initiation
  - Do it right the first time
- High "priced" issues
  - Quality
  - Productivity
  - Materials
  - Reputation – customer confidence

Document to ensure you always have a good business case to justify QI time and projects.

# Project Charter

- Documentation of agreement between management and project team on project goals, budget and timeline.
- Elements
  - **Champion(s)**
  - **Problem description**
  - **Project scope**
  - **Stakeholders**
  - **Goal(s)**
  - **Current state metrics**
  - **Team members**
  - **Budget**
  - **Deadline**
  - **Milestones**

| Lean Six Sigma Project Charter | | | | |
|---|---|---|---|---|
| Project Name | | | Start Date | |
| Project Leader | | | | |
| Champion (Project Sponsor) | | | | |
| Other Executive Support | | | | |
| Project Description (Problem Statement and Business Case) | | | | |
| Project Scope (What is IN? What is OUT?) | | | | |
| Stakeholders | | | | |
| Project Goal(s) | Key Performance Indicator (KPI) | | | |
| | Metric | Baseline | Goal | Stretch |
| | | | | |
| | | | | |
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| | | | | |
| Team Members | Signature | | Date | |
| | | | | |
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| | | | | |
| Other Support Required (ad-hoc) | | | | |
| Budget | | | | |
| Deadline / Timeline Directive | | | | |
| | | | | |
| Milestone Events | Target | Actual | Notes | |
| Define complete | | | | |
| Measure complete | | | | |
| Analyze Complete | | | | |
| Innovative Improvement Complete | | | | |
| Control Complete | | | | |
| Project Closed | | | | |
| Hand-off to: | Signature | | Date | |
| | | | | |

# Project Charter
# Project Description

- Problem statement
  - Specifically what is happening?


- Business case
  - Data!!
  - What are the outcomes of the process today?
  - What are the current expectations
  - How are expectations not being met?

# Project Charter

## Project Description & Goal Cautions

- Beware of the following
  - A proposed solution
  - Third hand anecdotes of issues or impacts
  - Listing likely causes

# Project Charter Resources and Timeline

- Think from the beginning about timing and who will be involved
  - During project - team and ad hoc resources
  - Sustaining the solution.
- Recognize this is not an on-going project or "forever team"

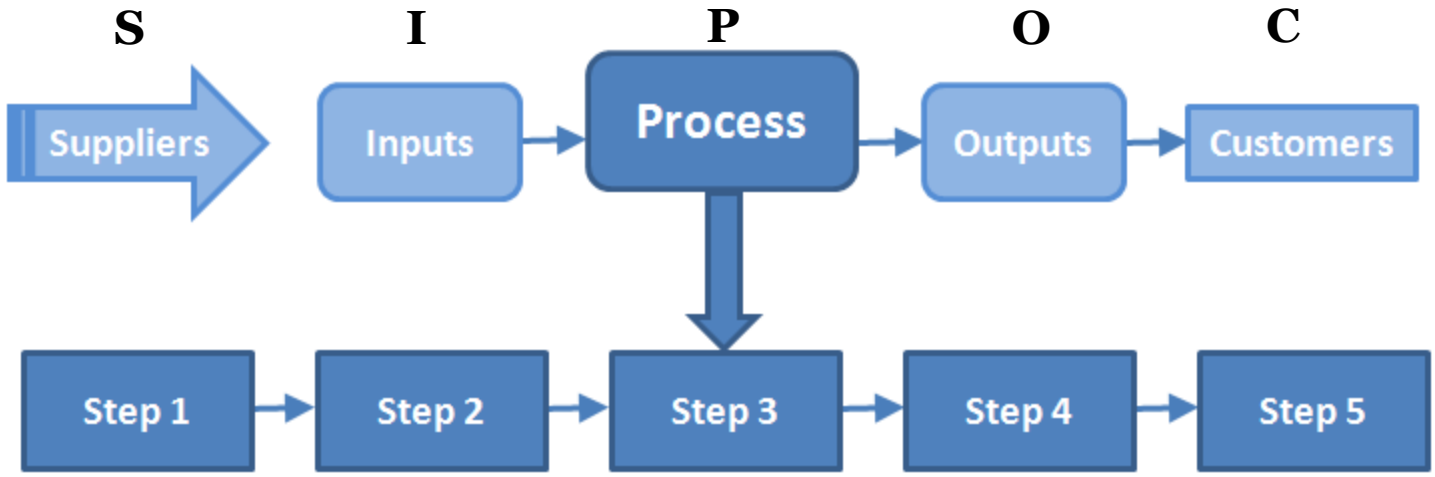
# Important Basic Concepts and Tools from the DMAIIC Roadmap

# High Level Process Map - SIPOC

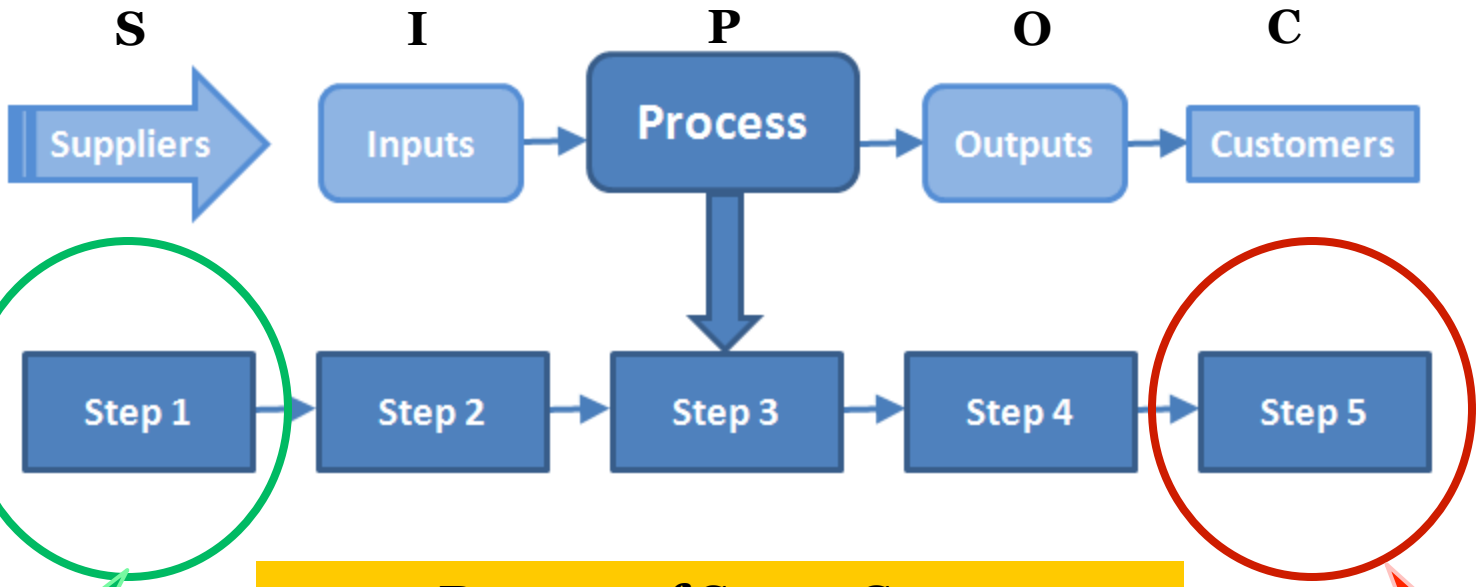
- Creates a picture of the process at a high level
- Identifies the key process steps
- Provides a place to begin using preliminary process data
- Identifies high level x's (process inputs)
- Identifies high level y's (process outputs)
- Documents key customers of the process

# SIPOC

- Start with the process – the focus of your project
- Minimal process steps (4-7)
- Inputs directly impact the process
- Outputs are a direct result from the last process step
- Customers are those directly affected by process output



# Project Scope




**Beginning of scope**

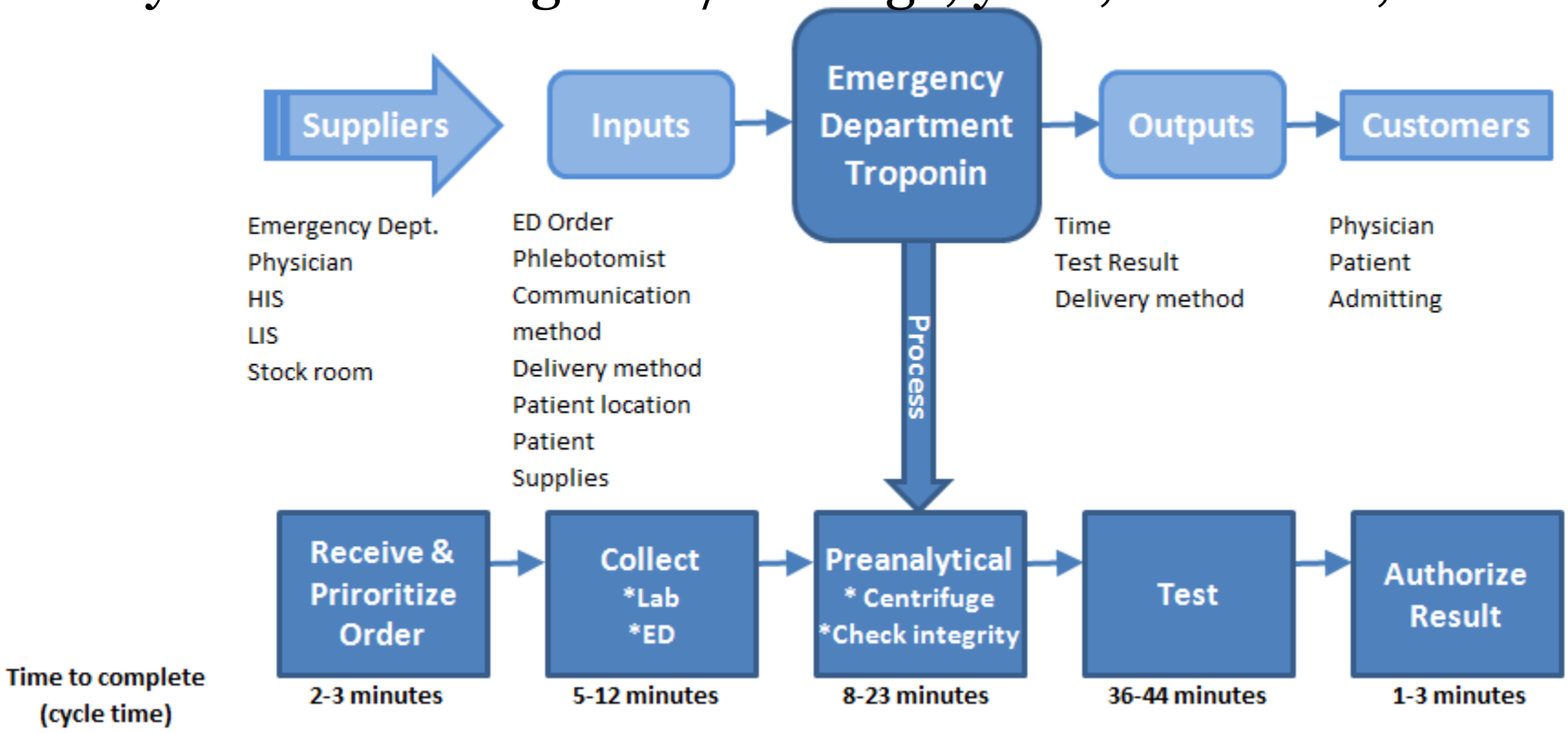
**End of scope**

**Beware of Scope Creep**

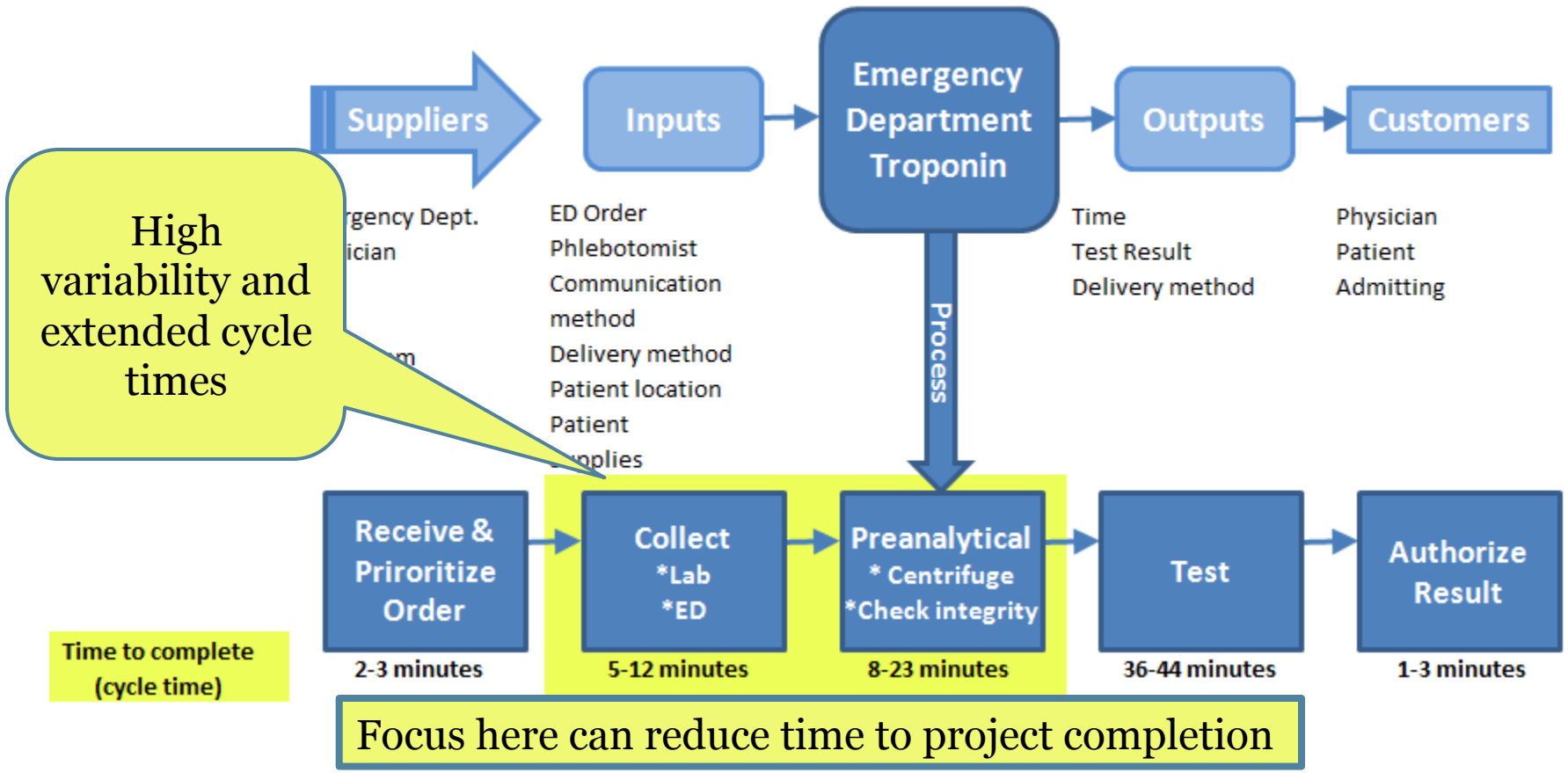
1. Going outside the boundaries set here
2. Adding categories of data within these boundaries.
    1. New department, analyzer, personnel type, etc.

# Narrowing the Scope

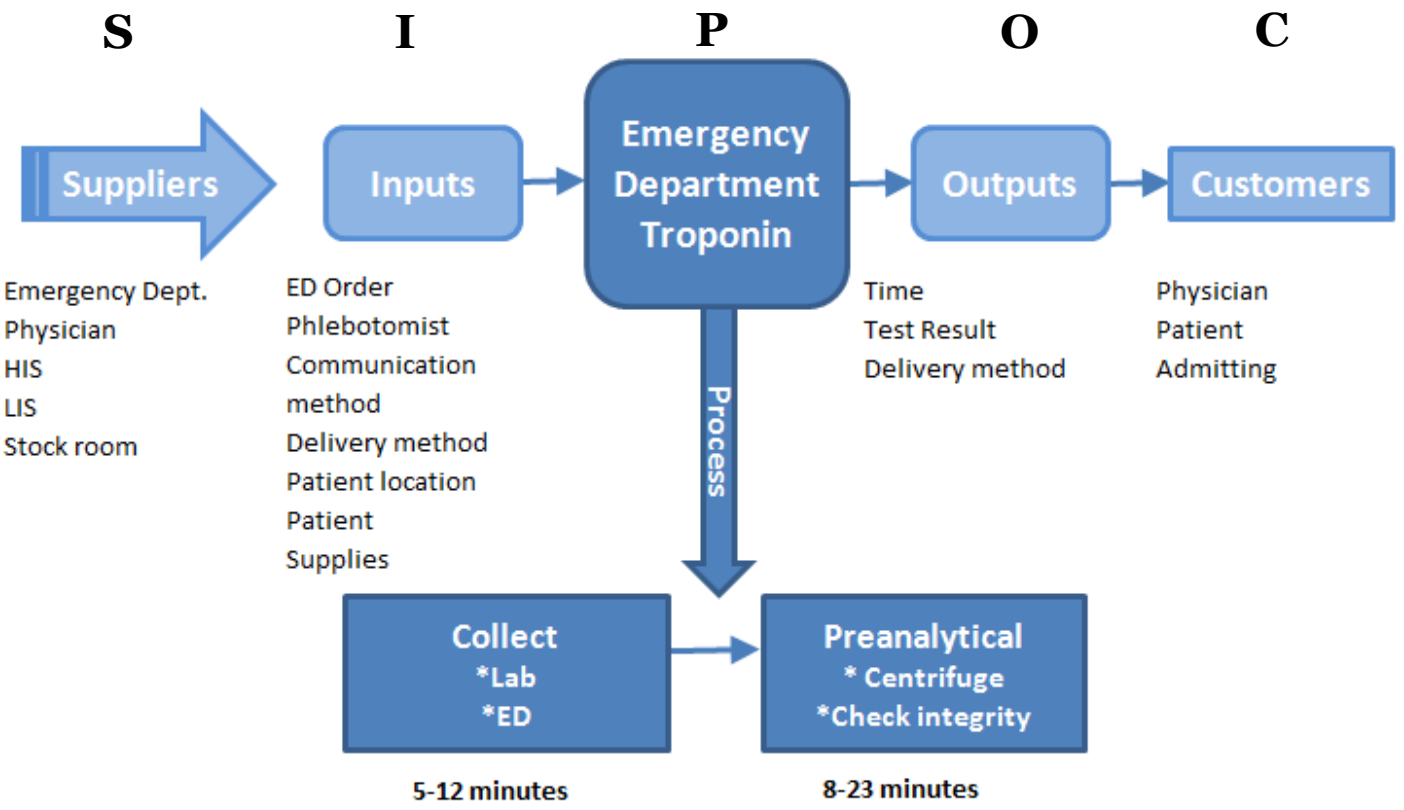
- Make early decisions based on current data
- Cycle time average and/or range, yield, error rate, etc.



# Narrowing the Scope



# SIPOC - Refined



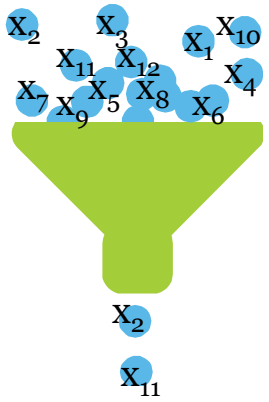

These steps could be broken into 4-7

# Caution!

- Resist the urge to go from project identification to immediate data collection or analysis of historical data
- How do you know what data to collect or pull from history?

# Funneling Potential Causes

- Measure
  - Identify all potential causes (x's)
  - Begin to funnel to critical x's
  - Collect data on identified critical x's

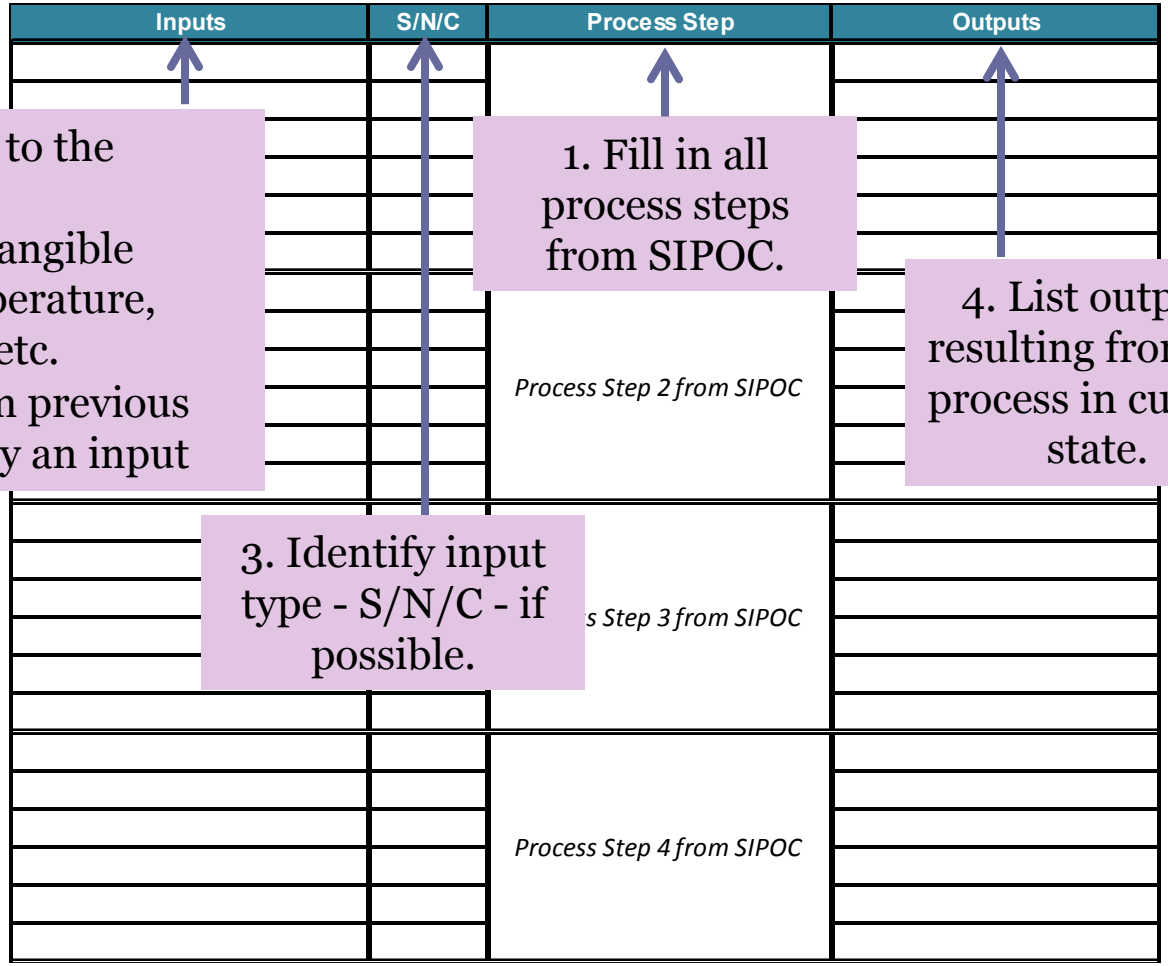


# Linear Process Map

- Process identified on SIPOC
- Detailed identification of inputs (x's)
- Identification of outputs (y's)
- Presented in simple linear format
- Value added and non value added steps can be identified

Not a flowchart

# Linear Process Map




2. List all inputs to the process.
•Don't forget intangible inputs , i.e. temperature, time, humidity, etc.
•The output from previous step is commonly an input

1. Fill in all process steps from SIPOC.

4. List outputs resulting from the process in current state.

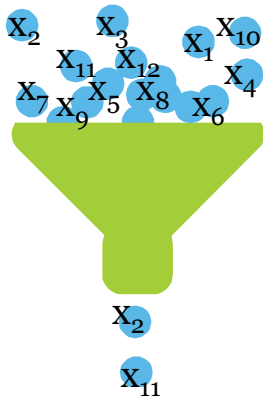
3. Identify input type - S/N/C - if possible.

# Example Process Map with VA/NVA

| | Process Step | |
|---|---|---|
| **Inputs** | **VA Mandatory NVA NVA** | **Outputs** |
| Supplier Delivery | Receive Airbills from Courier<br>Scan Airbill for Courier Manifest<br>Sort Airbills by Priority | Airbill Packages<br>Airbill Manifest |
| | Cut open Airbill | |
| | Remove Requisition and Specimen | |
| | Discard Empty Airbill Packaging | |
| Airbill Packages | Unfold & Verify Req for Accuracy | Printed Batch Chain of Custody |
| Requisition | Verify Specimen for Min Volume, Seal Integrety and Damage | Batched Requisitions |
| Processor (Employee) | Sign and Date Req Chain of Custody | |
| Specimens | Enter Req Information into LIS | Labeled (Barcoded) Specimen |
| Label | Assign Batch # / Location to Specimen | |
| Computer Terminal | Print Barcoded Labels | Batched Specimens |
| Workstation | Apply Barcodes to Req and Specimen | |
| Barcode Printer | Add Specimen to Batch (Inventory) | Electronic Specimen ID Information |
| | Add Requisition to Paperwork Batch | |
| | Print Batch Chain of Custody | |
| | Deliver Specimen Batch and Req Batch to Inventory Rack | |
| Batched Requisitions | Pull Batch from Inventory | |
| Printed Batch Chain of Custody | Transfer Req Batch to Verifier | |
| Electronic Specimen ID Information | Cut Specimen Seals | |
| Aliquoter (CV-1000) | Load Specimen Racks onto CV-1000 Instrument (Inventory) | Batched Aliquots |
| Batched Specimens | Fill Instrument w/ Aliquot Tubes & Racks | |
| Operator | Enter Batch Information into LIS | Printed Aliquot Batch List |
| Computer Terminal | Start Aliquot Run | |
| Aliquotting Disposibles | Collect Finished Samples / Specimens | Verified Requisitions |
| Hitachi Sample Trays | Place Aliquot Racks onto Inventory Tray | |
| Printer | Print Aliquot Batch Chain of Custody | |
| | Deliver Aliquot Batch and Batch List to Screens Department | |
| Batched Aliquots<br>Printed Aliquot Batch List | Screens Department Tests Batch | Screened Specimen Results |

# Prioritization Matrix

- Use all inputs – potential critical x's – identified in process map
- Use identified requirements of the process/product (CTQs)
- Begin funneling x's with a prioritization matrix
  - Funnel to critical few to focus data collection efforts




| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Output | Output | Output | Output | Output | Output | Output | Output | Output | Output | Output | Output | Output | Output | Output | |
| | Customer Priority | | | | | | | | | | | | | | | | |
| Process Step | Process Input | | | | | | | | | | | | | | | | Total |
| | | | | | | | | | | | | | | | | | 0 |
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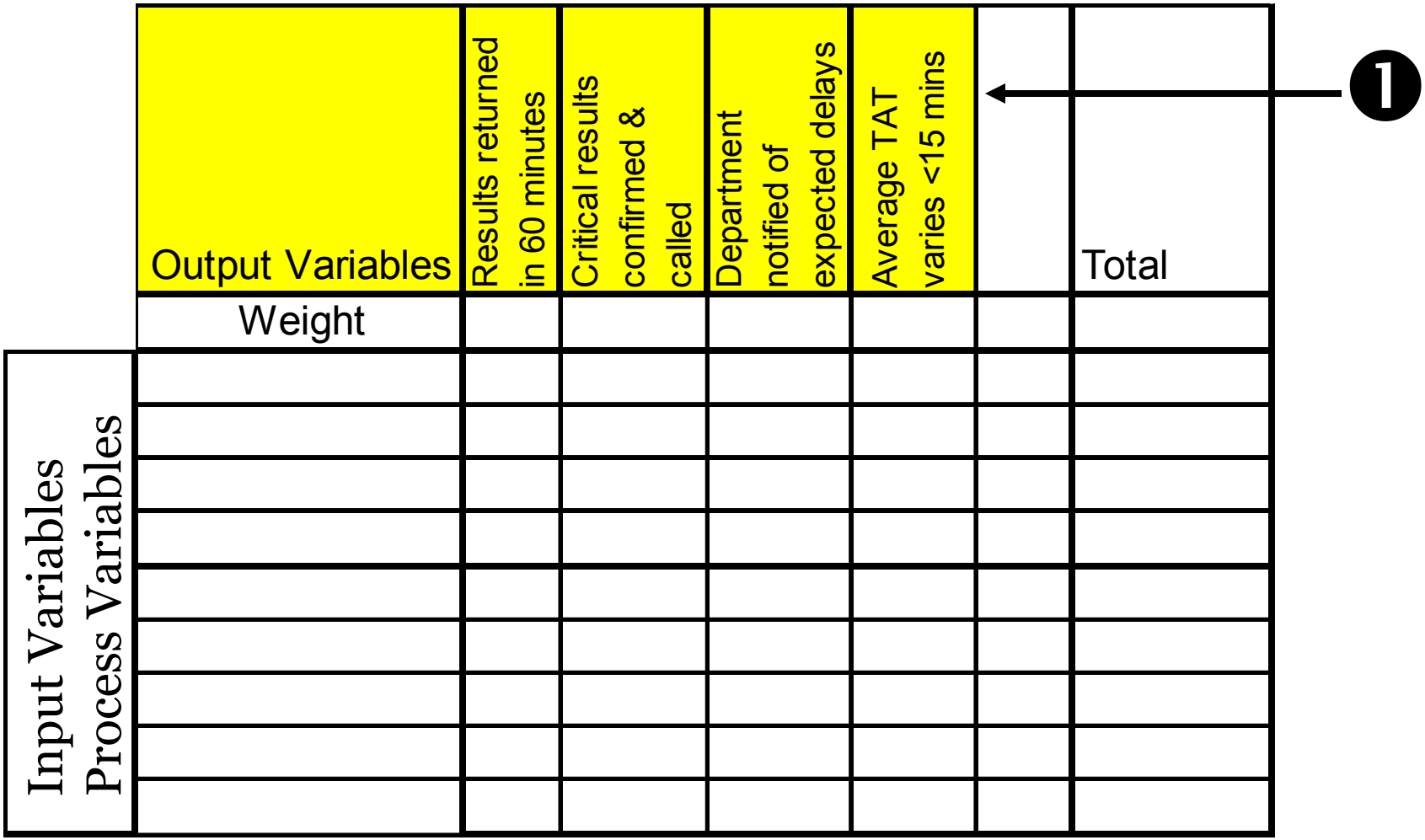
# List All CTQs



| | Output Variables | Results returned in 60 minutes | Critical results confirmed & called | Department notified of expected delays | Average TAT varies <15 mins | | Total |
|---|---|---|---|---|---|---|---|
| | Weight | | | | | | |
| Input Variables Process Variables | | | | | | | |
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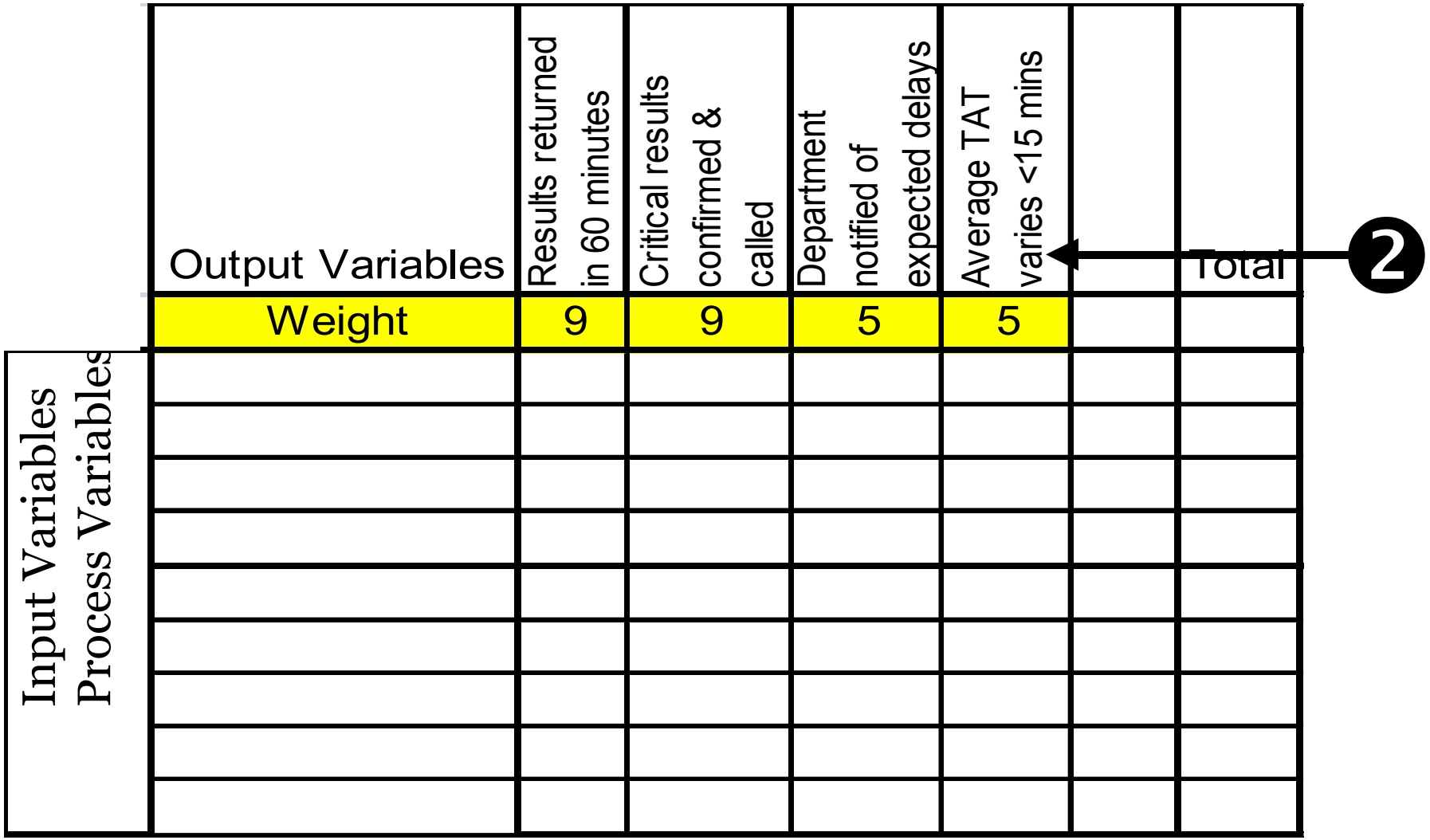
# Rank and Weight the CTQs



| Input Variables / Process Variables | Output Variables | Results returned in 60 minutes | Critical results confirmed & called | Department notified of expected delays | Average TAT varies <15 mins | | Total |
|---|---|---|---|---|---|---|---|
| | Weight | 9 | 9 | 5 | 5 | | |
| | | | | | | | |
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# List All Input and Process Variables

| | Output Variables | Results returned in 60 minutes | Critical results confirmed & called | Department notified of expected delays | Average TAT varies <15 mins | | Total |
|---|---|---|---|---|---|---|---|
| | Weight | 9 | 9 | 5 | 5 | | |
| Input Variables Process Variables | Test requisition | | | | | | |
| | Ordering location | | | | | | |
| | Phlebotomy | | | | | | |
| | Testing staff | | | | | | |
| | Department staff | | | | | | |
| | Analyzers | | | | | | |
| | Time of day | | | | | | |
| | Test type | | | | | | |
| | | | | | | | |

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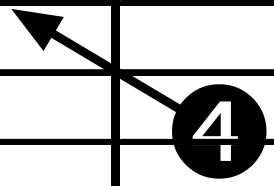
# Evaluate the Relationship Between CTQs and Input/Process Variables

| | Output Variables | Results returned in 60 minutes | Critical results confirmed & called | Department notified of expected delays | Average TAT varies <15 mins | | Total |
|---|---|---|---|---|---|---|---|
| | Weight | 9 | 9 | 5 | 5 | | |
| Input Variables Process Variables | Test requisition | 9 | 1 | 1 | 5 | | |
| | Ordering location | 5 | 1 | 1 | 1 | | |
| | Phlebotomy | 9 | 1 | 5 | 1 | | |
| | Testing staff | 9 | 9 | 9 | 1 | | |
| | Department staff | 1 | 5 | 5 | 1 | | |
| | Analyzers | 5 | 1 | 1 | 9 | | |
| | Time of day | 5 | 9 | 5 | 5 | | |
| | Test type | 9 | 1 | 1 | 9 | | |
| | | | | | | | |



# Cross-Multiply Weight and Rank

| | Output Variables | Results returned in 60 minutes | Critical results confirmed & called | Department notified of expected delays | Average TAT varies <15 mins | | Total |
|---|---|---|---|---|---|---|---|
| | Weight | 9 | 9 | 5 | 5 | | |
| Input Variables Process Variables | Test requisition | 9 | 1 | 1 | 5 | | 120 |
| | Ordering location | 5 | 1 | 1 | 1 | | 64 |
| | Phlebotomy | 9 | 1 | 5 | 1 | | 120 |
| | Testing staff | 9 | 9 | 9 | 1 | | 212 |
| | Department staff | 1 | 5 | 5 | 1 | | 84 |
| | Analyzers | 5 | 1 | 1 | 9 | | 104 |
| | Time of day | 5 | 9 | 5 | 5 | | 176 |
| | Test type | 9 | 1 | 1 | 9 | | 140 |
| | | | | | | | |

5

# Highlight the Critical Few Variables

***Ask: "Does this make sense?**

Common sense is critical as you make your way through the DMAI²C roadmap

| | Output Variables | Res in 6 | Crit con call | Dep noti exp | Ave vari | | Total |
|---|---|---|---|---|---|---|---|
| | Weight | 9 | 9 | 5 | 5 | | |
| Input Variables Process Variables | Test requisition | 9 | 1 | 1 | 5 | | 120 |
| | Ordering location | 5 | 1 | 1 | 1 | | 64 |
| | Phlebotomy | 9 | 1 | 5 | 1 | | 120 |
| | Testing staff | 9 | 9 | 9 | 1 | | 212 |
| | Department staff | 1 | 5 | 5 | 1 | | 84 |
| | Analyzers | 5 | 1 | 1 | 9 | | 104 |
| | Time of day | 5 | 9 | 5 | 5 | | 176 |
| | Test type | 9 | 1 | 1 | 9 | | 140 |
| | | | | | | | |

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# Prioritization Matrix

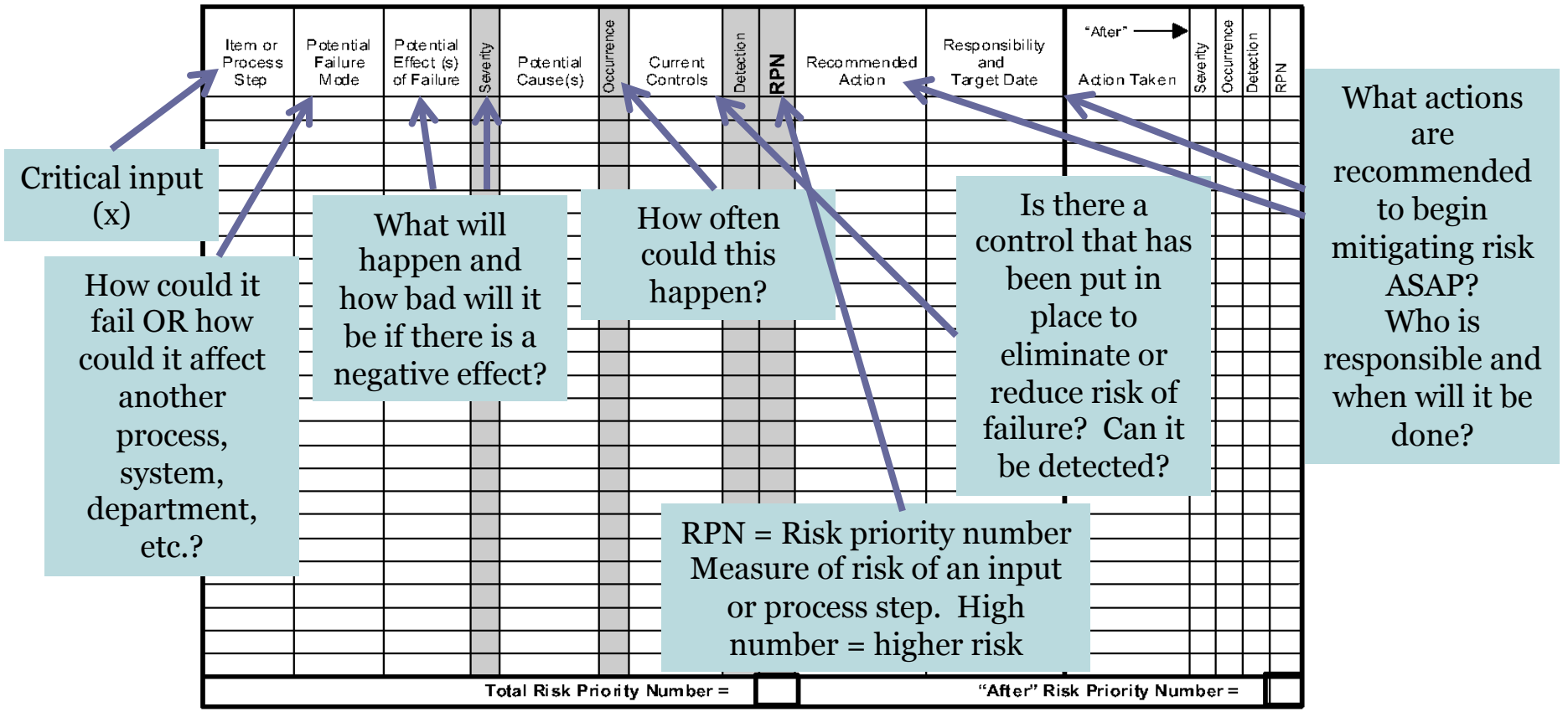
- Identify inputs (x's) most likely to be contributing to the root cause of the problem.
- Now what?
- Determine need for risk analysis
  - Failure modes and effects analysis
- Project focused on critical area or process
- Project including multiple x's with associated risk
- If risk not an issue move to data collection plan

# Failure Modes and Effects Analysis (FMEA)

- Focuses x's critical to satisfying the CTQs.
- Structured approach to identifying, estimating, prioritizing, and evaluating risk.
- Aims at failure prevention.
- Identifies things that could be fixed right away
- Evaluates the impact, frequency, and ability to detect a process failures.
- Used again in Innovate and Improve phase used to limit the risk involved in implementing changes.

# Failure Modes and Effects Analysis (FMEA)

- Assess potential risks of identified solutions BEFORE the pilot.



# FMEA Terminology

- Potential Failure Mode:  Any way the input or process could fail
- Potential Effect of Failure:  How the failure affects the customer
- Severity:  A numerical score of the seriousness of a specific effect from one of the failure modes (higher score is worse)
- Cause:  How the failure mode could occur, described in terms of something that can be corrected or controlled

# FMEA Terminology

- Occurrence:  A numerical score of the likelihood that a specific cause would occur  (higher score is worse)
- Controls:  Any efforts that are already in place to identify the failure mode before it affects the customer
- Detection:  A numerical score of the vulnerability of current controls in allowing the failure mode to reach / affect the customer (higher score is worse)
- RPN = Risk Priority Number:  The product of the Severity, Occurrence and Detection scores  (S x O x D)

# Drawbacks of RPN

- Remember RPN is a number based on subject matter expertise that's still highly subjective.
- Use common sense and ask questions before jumping into action.
  - Example:

| RPN | Failure Mode | Sev | Occ | Det |
|---|---|---|---|---|
| 160 | A | 10 | 4 | 4 |
| 200 | B | 4 | 10 | 5 |

  - Though both failure modes might require action, Mode A requires immediate action to prevent injury.
  - Ease of implementation should also be considered; don't delay identified quick fixes just because they have a low RPN.

# FMEA Scales

- Scales for severity, occurrence, and detection can be adjusted if necessary.
- Before you use the standard scales, make sure they are in line with the organization.

# Severity Rating Scale Example

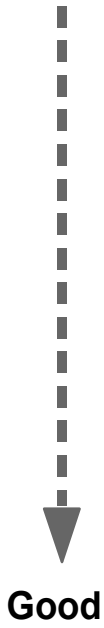
Severity = impact of the potential failure on the customer

| | Rating | Criteria: A failure could… |
|---|---|---|
| Bad | 10 | Injure a customer or employee |
| | 9 | Be illegal |
| | 8 | Render the product or service unfit for use |
| | 7 | Cause extreme customer dissatisfaction |
| | 6 | Result in partial malfunction |
| | 5 | Cause a loss of performance likely to result in a complaint |
| | 4 | Cause minor performance loss |
| | 3 | Cause a minor nuisance; can be overcome with no loss |
| | 2 | Be unnoticed; minor effect on performance |
| Good | 1 | Be unnoticed and not affect the performance |

Source: www.fmeainfocenter.com

# Severity Rating Scale Example

Severity = impact of the potential failure on the organization

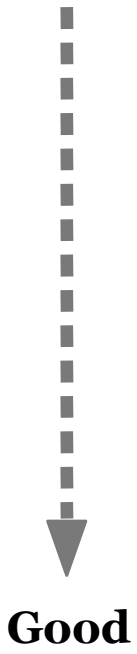



| Rating | Criteria: A failure could… |
|---|---|
| 10 | Damage without warning |
| 9 | Damage with warning |
| 8 | Very high risk |
| 7 | High risk |
| 6 | Moderate risk |
| 5 | Low risk |
| 4 | Very low risk |
| 3 | Minor risk |
| 2 | Very minor risk |
| 1 | No risk at all |

Source: www.fmeainfocenter.com

# Occurrence Rating Scale Example

Occurrence = likelihood that a specific cause will occur




| Rating | Time Period | Probability |
|---|---|---|
| 10 | Very high | 1 in 2 |
| 9 | Very high | 1 in 3 |
| 8 | Very high | 1 in 8 |
| 7 | High | 1 in 20 |
| 6 | High | 1 in 80 |
| 5 | Moderate | 1 in 400 |
| 4 | Moderate | 1 in 2,000 |
| 3 | Low | 1 in 15,000 |
| 2 | Low | 1 in 150,000 |
| 1 | Remote | 1 in 1,500,000 |

Source: www.fmeainfocenter.com

# Sample Occurrence Rating Scale

Occurrence = likelihood that a specific cause will occur

| | Rating | Time Period | Probability |
|---|---|---|---|
| Bad | 10 | More than once per day | > 30% |
| | 9 | Once every 3–4 days | ≤ 30% |
| | 8 | Once per week | ≤ 5% |
| | 7 | Once per month | ≤ 1% |
| | 6 | Once every 3 months | ≤ .03% |
| | 5 | Once every 6 months | ≤ 1 per 10,000 |
| | 4 | Once per year | ≤ 6 per 100,000 |
| | 3 | Once every 1 – 3 years | ≤ 6 per million |
| | 2 | Once every 3 –6 years | ≤ 3 per 10 million |
| Good | 1 | Once every 6 –100 years | ≤ 2 per billion |

# Sample Detection Rating Scale

Detection = vulnerability of the current controls to allow the failure mode to impact the customer

| | Rating | Definition |
|---|---|---|
| | 10 | Absolute uncertainty |
| Bad | 9 | Very remote |
| | 8 | Remote |
| | 7 | Very low |
| | 6 | Low |
| | 5 | Moderately |
| | 4 | Moderately high |
| | 3 | High |
| | 2 | Very high |
| Good | 1 | Almost certain |

Source: www.fmeainfocenter.com

# Sample Detection Rating Scale

Detection = vulnerability of the current controls to allow the failure mode to impact the customer

| | Rating | Definition |
|---|---|---|
| | 10 | Defect caused by failure is not detectable |
| Bad | 9 | Occasional units are checked for defects |
| | 8 | Units are systematically sampled and inspected |
| | 7 | All units are manually inspected |
| | 6 | Manual inspection with mistake-proofing modifications |
| | 5 | Process is monitored (SPC) and manually inspected |
| | 4 | SPC used with an immediate reaction to out of control conditions |
| | 3 | SPC as above with 100% inspection surrounding out of control conditions |
| Good | 2 | All units are automatically inspected |
| | 1 | Defect is obvious and can be kept from affecting customer |

SPC = Statistical Process Control

# Example of FMEA

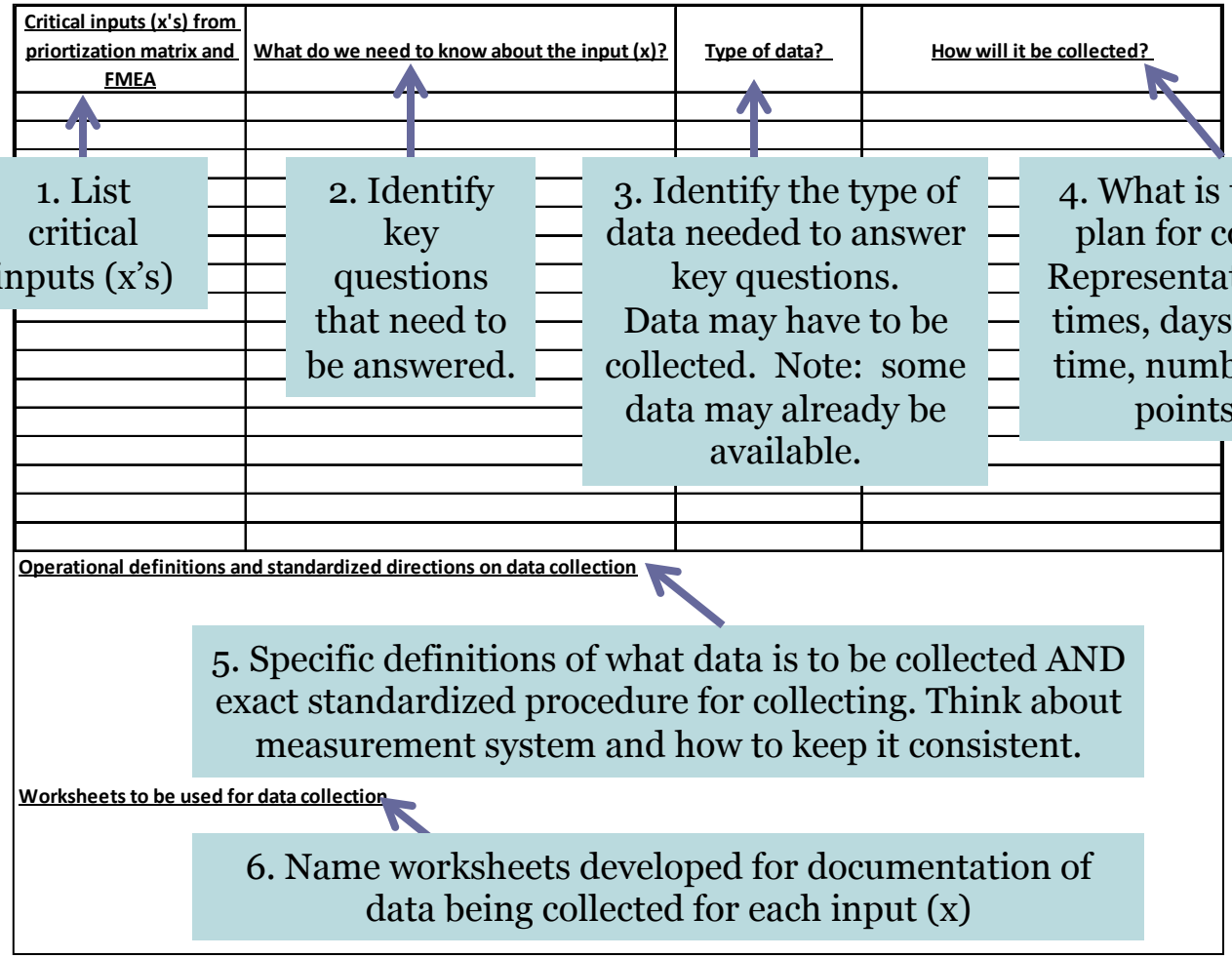


| Process Name: | Lab Order - Lab Results | | Prepared by: |
|---|---|---|---|
| Responsible: | Process Owner | | FMEA Date (Original) _____09/08/07_____ |

| Process Function | Potential Failure Mode | Potential Effects of Failure | SEV | Potential Cause(s)/ Mechanism(s) of Failure | OCC | Current Process Controls | DET | RPN |
|---|---|---|---|---|---|---|---|---|
| The highest value process steps from the C&E matrix. | In what ways might the process potentially fail to meet the process requirements and/or design intent? | What is the effect of each failure mode on the outputs and/or customer requirements? The customer could be the next operation, subsequent operations, another division or the end user. | How Severe is the effect to the customer? | How can the failure occur? Describe in terms of something that can be corrected or controlled. Be specific. Try identify the causes that directly impacts the failure mode, i.e., root causes. | How often does the cause or failure mode occur? | What are the existing controls and procedures (inspection and test) that either prevent failure mode from occurring or detect the failure should it occur? **Should include an SOP number.** | How well can you detect cause or FM? | SEV x OCC x DET |
| Physician writes order for lab in the morning | Incorrect lab test ordered; ordered on wrong patient | Necessary lab result is unavailable | 2 | Lack of sleep, Med student ordered wrong lab test | 2 | No formal controls | 2 | 8 |
| Nurse signs off order; floor clerk enters lab order | First day on unit for pool/float nurse | Pool nurse does not make correlation between patient condition and appropriate or inappropriate lab work order | 2 | Pool/float nurse is unfamiliar with patient history and is overwhelmed with patient load | 5 | No formal controls | 3 | 30 |
| Night charge nurse makes rounds on patients | Night Clinical Nutrition makes rounds at 20:00 but fails to educate patient on fasting morning lab | Patient eats breakfast in the morning unaware of need to fast or inform nurse that breakfast was placed in her room | 1 | Night Clinical Nutrition is also assigned to 3 patients; the rounds at 20:00 are brief | 3 | No formal controls | 5 | 15 |
| Dietary personnel prepare to serve breakfast | Dietary personnel fail to review "hold" breakfast patient list | All patients, regardless of "hold" breakfast status receive a meal | 3 | Staffing shortage in dietary department | 8 | No formal controls | 9 | 216 |
| Lab personnel draws morning lab | Quality controls are conducted on lab equipment at 06:30 | Breakfast is served at 07:00 before lab draws; blood work is no longer based on fasting levels | 3 | Morning lab draws are delayed until 07:30 | 8 | No formal controls | 6 | 144 |
| Physician makes round at 09:30 and reviews lab results posted on patient chat | Physician reviews lab results and does not realize the lab order was incorrect and the patient was not fasting | Physician orders new medications and treatment for patient | 4 | Physician has many patients to see; physician assumes the order was correct | 2 | No formal controls | 4 | 32 |
| Source: OCD ValuMetrix, 2007 | | | | | | **Total Risk Priority Number =** | | **445** |

# Key Inputs are Identified Now for the Data

# Data Collection Plan



# Case Study: Turnaround Time

A 5-site laboratory system is investigating TAT issues

- TAT goal: 95% compliance to 60 minutes
- Current state:
  - 90 minute average
  - Variation of 30-180 minutes

| Laboratory | % meeting 60 minute goal |
|---|---|
| A | 78% |
| B | 42% |
| C | 86% |
| D | 77% |
| E | 68% |

**What should be done with Laboratory B?**

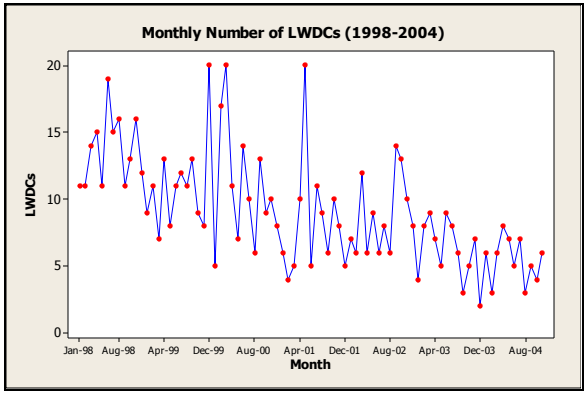
# Case Study (cont'd)

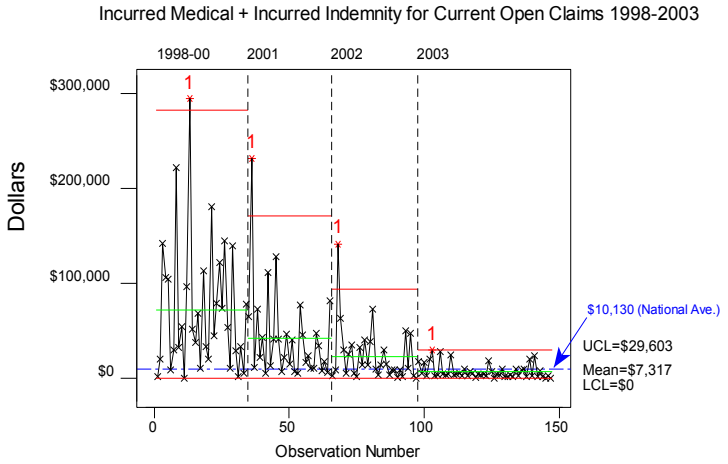
- Operational definitions are extremely important.
- How is TAT measured?
- Laboratory B definition:  Collection to result
- Other sites:  Receipt to result

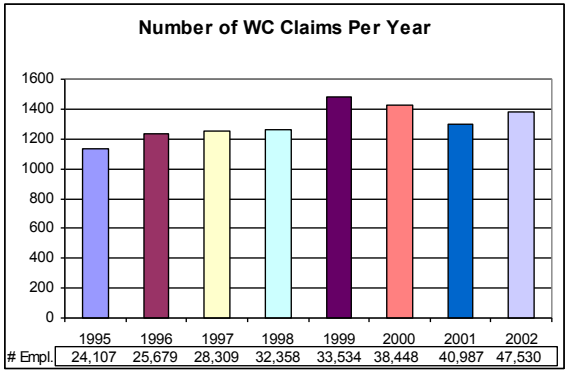
| Laboratory | % meeting 60 minute goal |
|---|---|
| A | 78% |
| B | 42% |
| C | 86% |
| D | 77% |
| E | 68% |

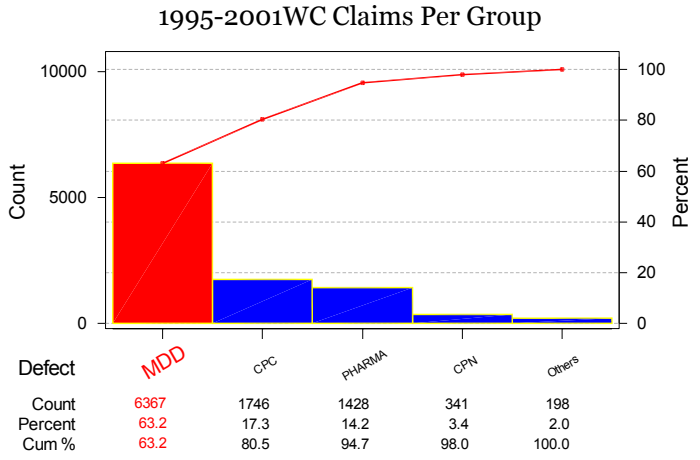
Do your definitions match those of the customer and/or comparative locations?

# Data Displays



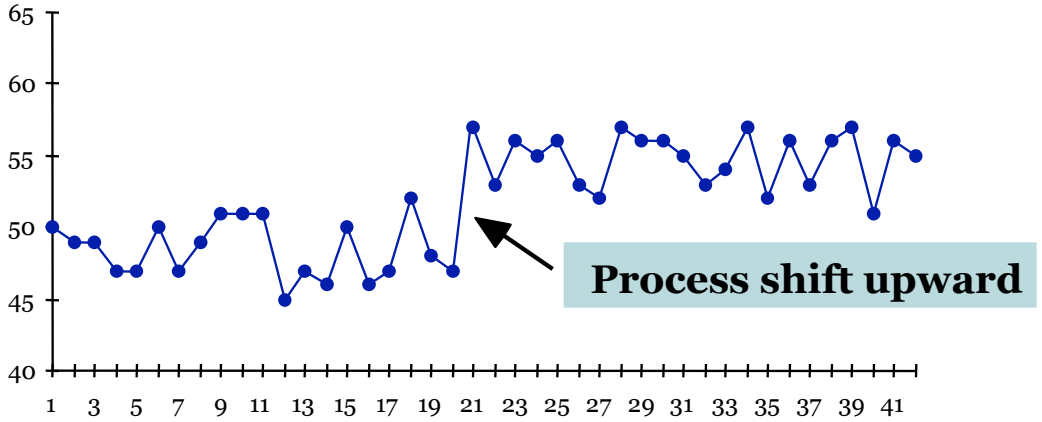



# Common Types of Data Displays

| Data Display | Purpose | Type of Data Used |
|---|---|---|
| Time Series Plot | Track a measurement over time to identify patterns, problems & opportunities | Numeric data in time order – can be Continuous ($, cycle time) or Discrete (proportion, count) |
| Control Chart | Same as Time Series Plot, plus helps to detect Special Cause variation | Numeric data in time order – can be Continuous ($, cycle time) or Discrete (proportion, count) |
| Frequency Plot | Reveal the shape or 'distribution' of data, by showing how often different values occur. | Numeric, Continuous data |
| Pareto Chart | Break a big problem down into its parts and identify which parts are most important | Discrete (attribute) data where categories can be counted or quantified |
| Scatter Plot | Detect a potential relationship between two variables | Numeric, Continuous data |

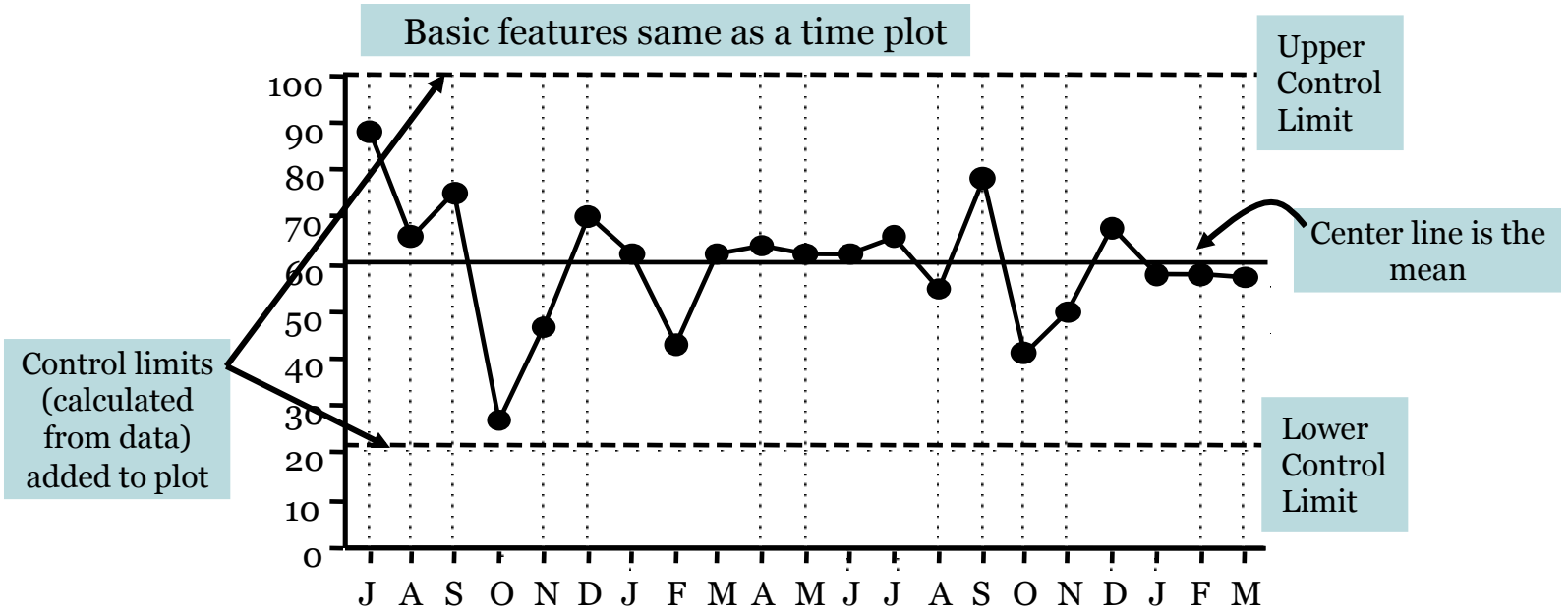
# Time Ordered Data

- Visual representation
- Immediate identification of data changing over time.
- When process conditions change the data points will often shift to some degree.



# Control Charts

- Time ordered plot
- Statistically determined control limits are added

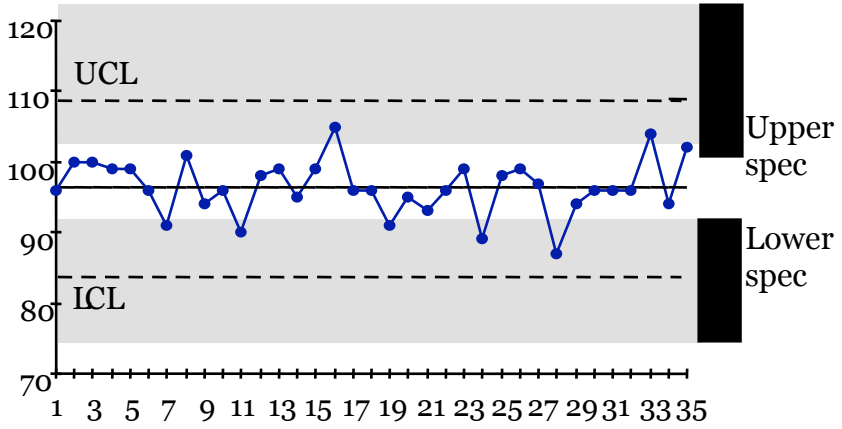


# When and Why Use Control Charts

- To track process performance and variation over time
- To evaluate progress after process changes/ improvements
- To distinguish common-cause variation from special-cause variation
  - A point outside control limits signals a special cause
  - Several other non-random patterns also signal special causes (as on a Run Chart)
- Can be used for almost any type of data collected over time.
- Provides a common language for discussing process performance.

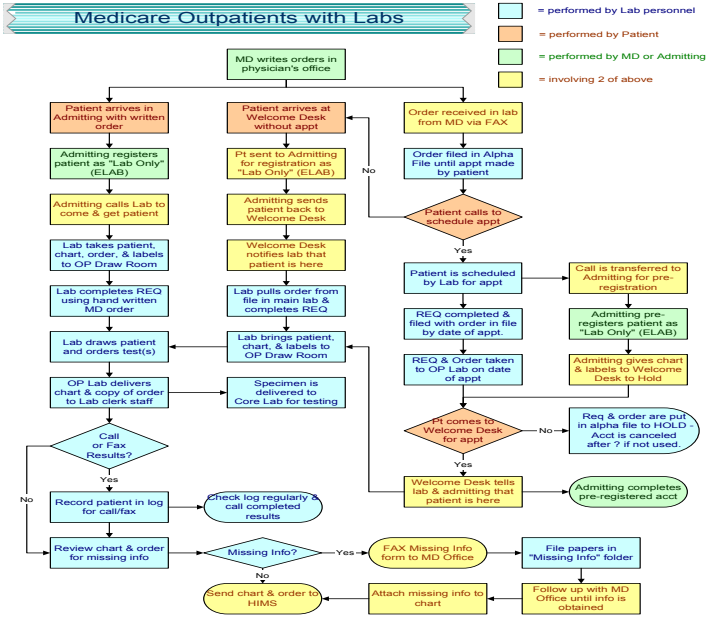
# Control Limits vs. Specification Limits

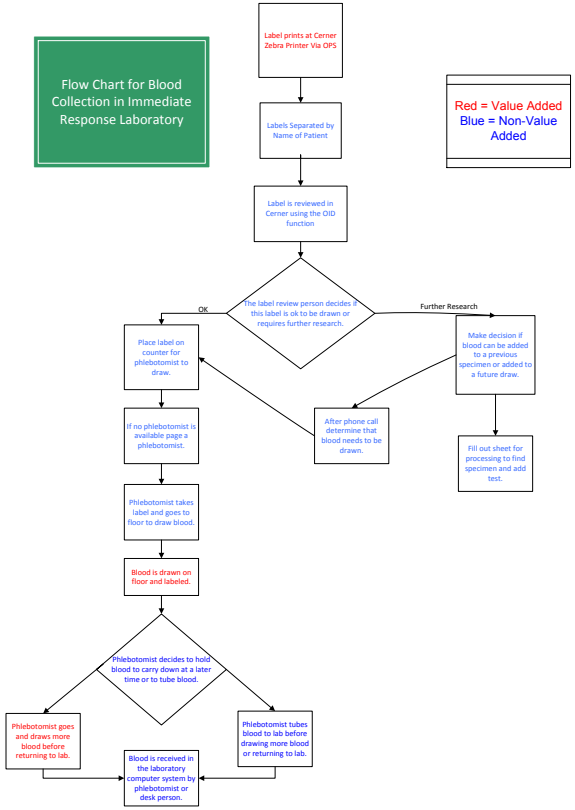
- Control limits are calculated from the set of data
  - Voice of the process
  - Tell us if the process is stable / predictable
- Specification limits come from the customer
  - Voice of the customer
  - Do not provide information on process stability

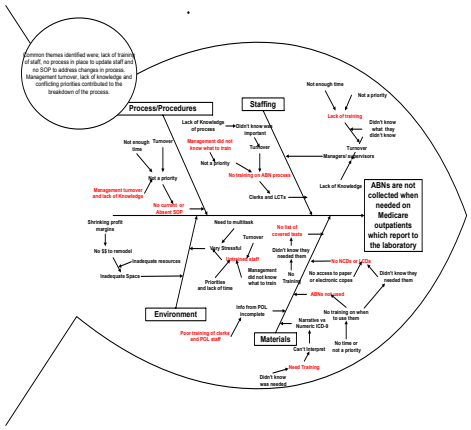


# Key Tools for Process Analysis

- Cause and Effect Diagram (fishbone)
- Flowcharts
- Value analysis

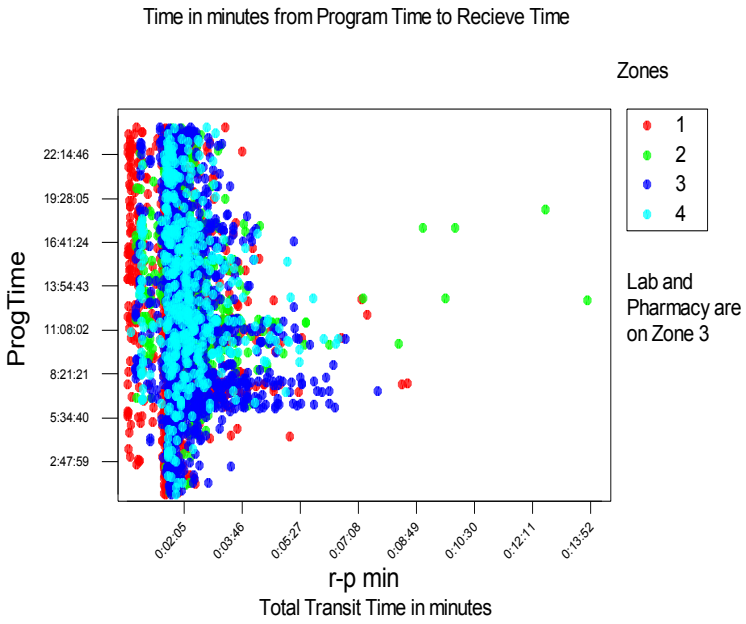


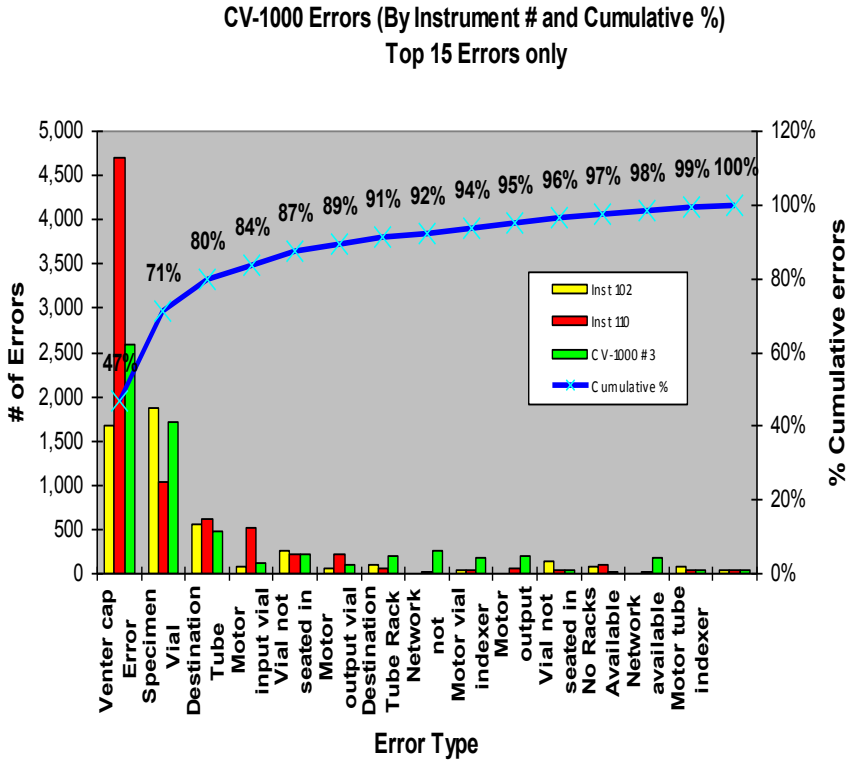



# Key Tools for Data Analysis

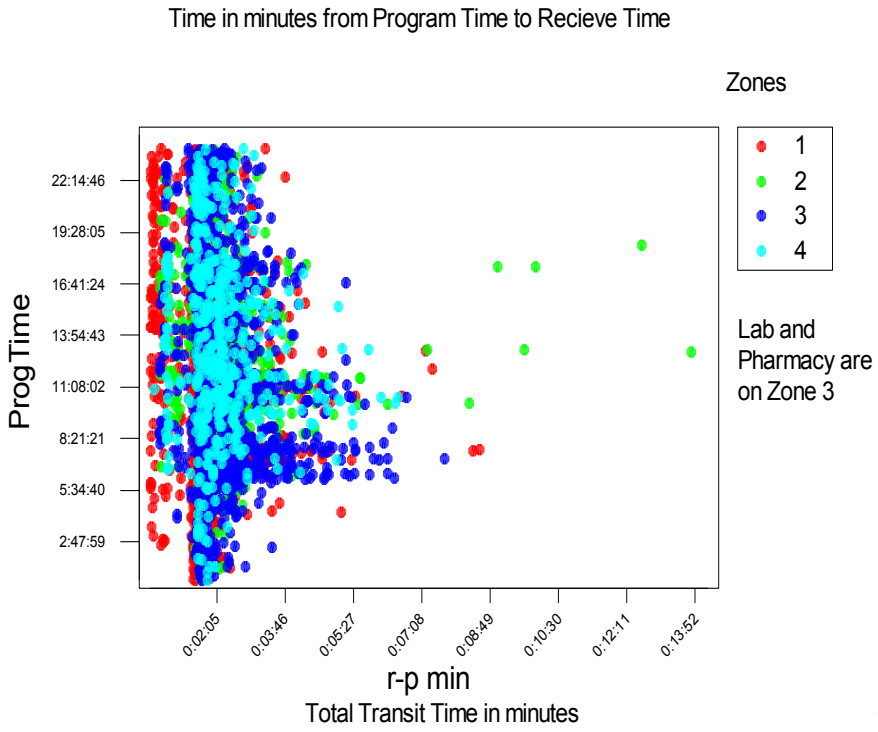
- Data stratification
- Scatter plots
- Pareto analysis



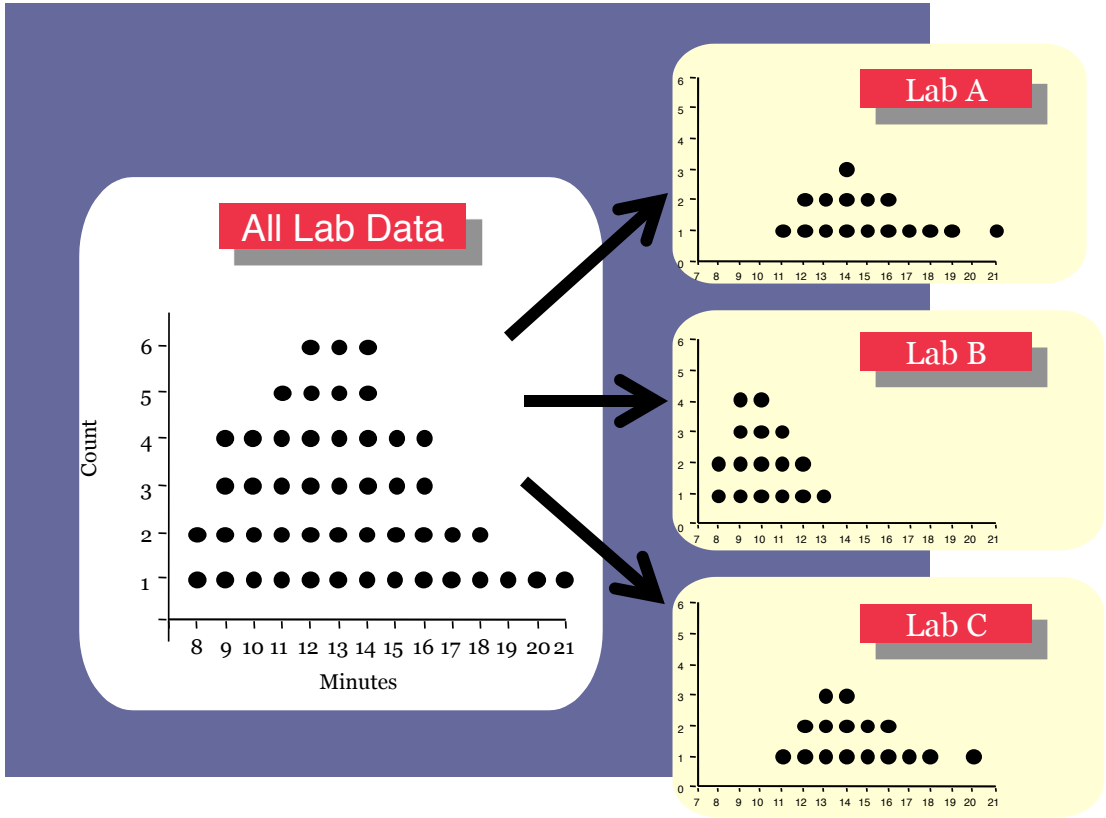
# Stratifying Data

- Break the data into logical groups
- One group within a set of data may be driving cause and remains hidden until stratified.



## Stratified Frequency Plot

# Example 1: Time to Complete Test



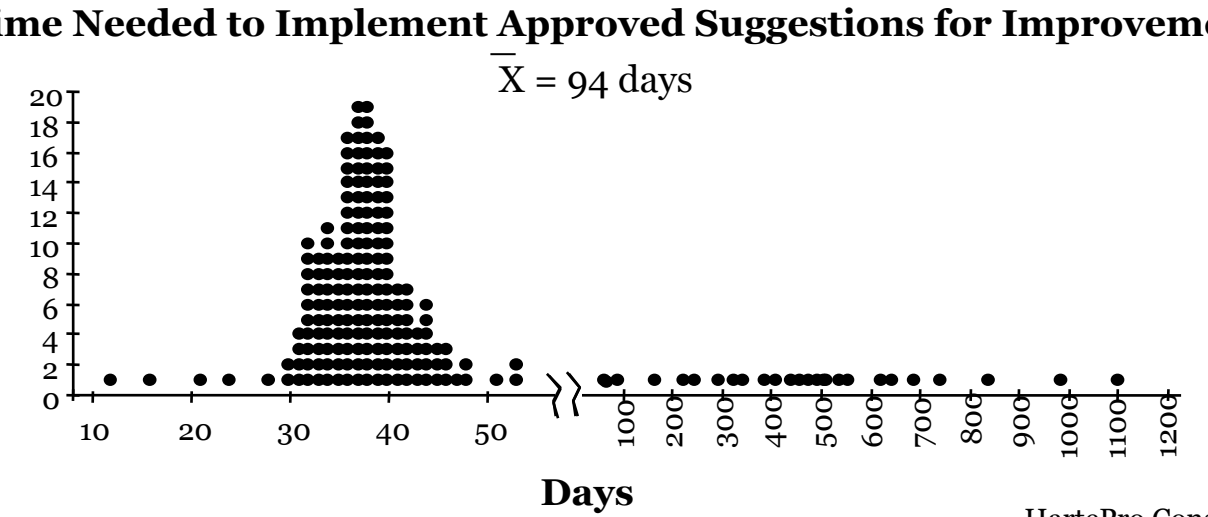

It appears that tests done at Lab B have a lower average TAT than those at Lab A or Lab C.

Next step:

Find out if this is true. If so why? Root cause of something good.

# When and Why to Use Frequency Plots

- To reveal the centering, spread, and variation of the data
  - Visual representation makes tabular data easy to understand or interpret
- To investigate the underlying statistical distribution of the data (hard to detect patterns with < 50 data points)

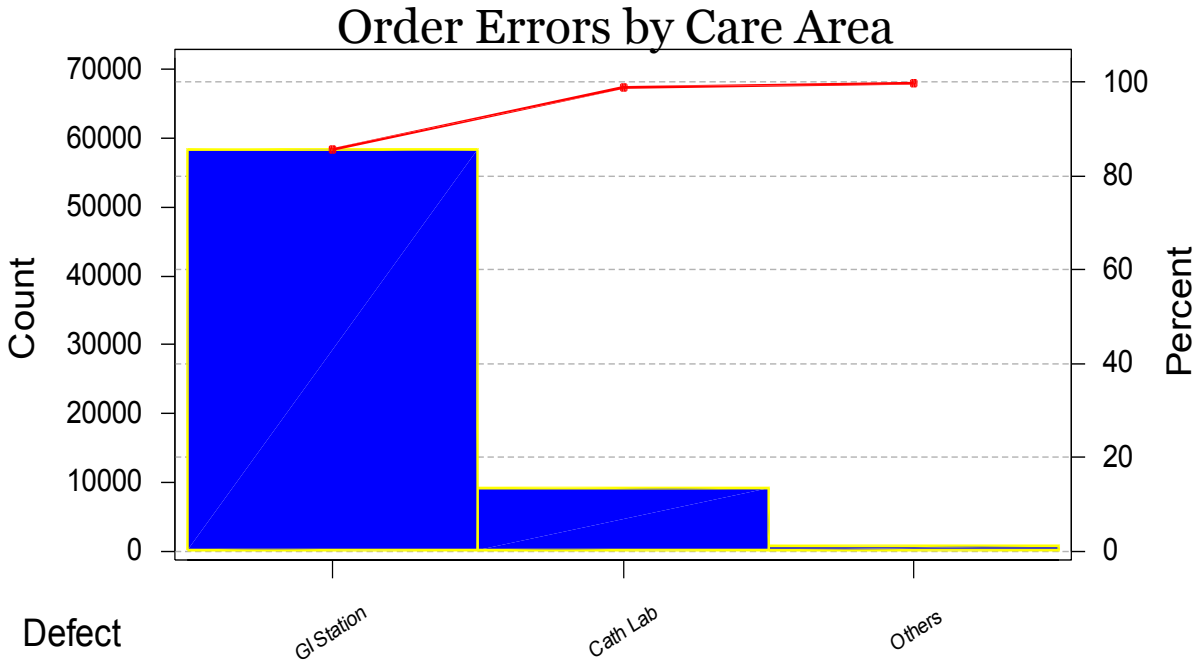


# Pareto Analysis – the 20/80 Rule

- Pareto rule:  20% of the inputs (products, customers, etc.) are causing 80% of the problems
- Pareto chart is a chart separating the data into frequency bars based on output data.
- The bars with highest frequency of the output (cost, time, errors, etc.) are on the left side of the graph
- 100% of the data is contained in all bars

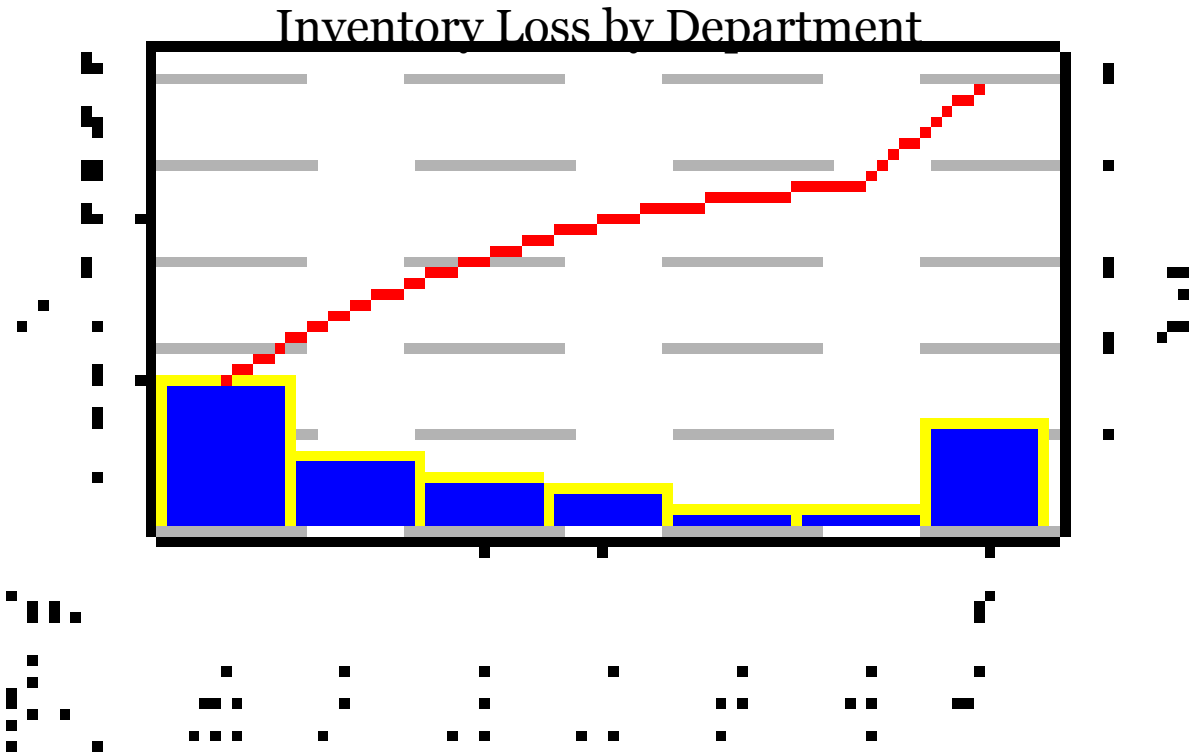
# Pareto Chart Example

- What does this tell us?



# Pareto Chart Example

- What does this tell us?



# Generating Solutions

- Review critical x's with team.
- Use knowledge from process tools.
- Multiple ideas may be combined to form a solution.

# Evaluating Potential Solutions

- Evaluate with one or more of the following:
  - Solution prioritization matrix
    - Score potential solutions against defined criteria
  - Cost-Benefit Analysis
    - Quantify and compare the return on investment
  - Effort vs. Impact plot
  - Design of experiments (advanced statistical tool)
    - An efficient way of testing many solution variations to compare their impact

# Solution Prioritization Matrix

| | Criteria | Criteria 1 | Criteria 2 | Criteria 3 | Criteria 4 | Criteria 5 | |
|---|---|---|---|---|---|---|---|
| | Weight | | | | | | Sum |
| **Potential Solution or New Process Feature** | Potential Solution 1 | | | | | | 0 |
| | Potential Solution 2 | | | | | | 0 |
| | Potential Solution 3 | | | | | | 0 |
| | Potential Solution 4 | | | | | | 0 |
| | Potential Solution 5 | | | | | | 0 |
| | Potential Solution 6 | | | | | | 0 |

# Solution Prioritization Matrix

| | | Criteria 1 | Criteria 2 | Criteria 3 | Criteria 4 | Criteria 5 | |
|---|---|---|---|---|---|---|---|
| | Criteria | | | | | | |
| | Weight | | | | | | Sum |
| Potential Solution or New Process Feature | Potential Solution 1 | | | | | | 0 |
| | Potential Solution 2 | | | | | | 0 |
| | Potential Solution 3 | | | | | | 0 |
| | Potential Solution 4 | | | | | | 0 |
| | Potential Solution 5 | | | | | | 0 |
| | Potential Solution 6 | | | | | | 0 |

1. Identify and list criteria

2. Weight criteria

3. List potential solutions

4. Rank/score solutions based on how well they satisfy criteria. Suggested scale 1, 5, 9 (high score "best")

5. Highest sum = best **potential** solution

# Best Potential Solution

- Check against common sense
- Check against CTQs and critical x's identified
- Complete failure modes and effects analysis
- Pilot!!

# Failure Modes and Effects Analysis FMEA

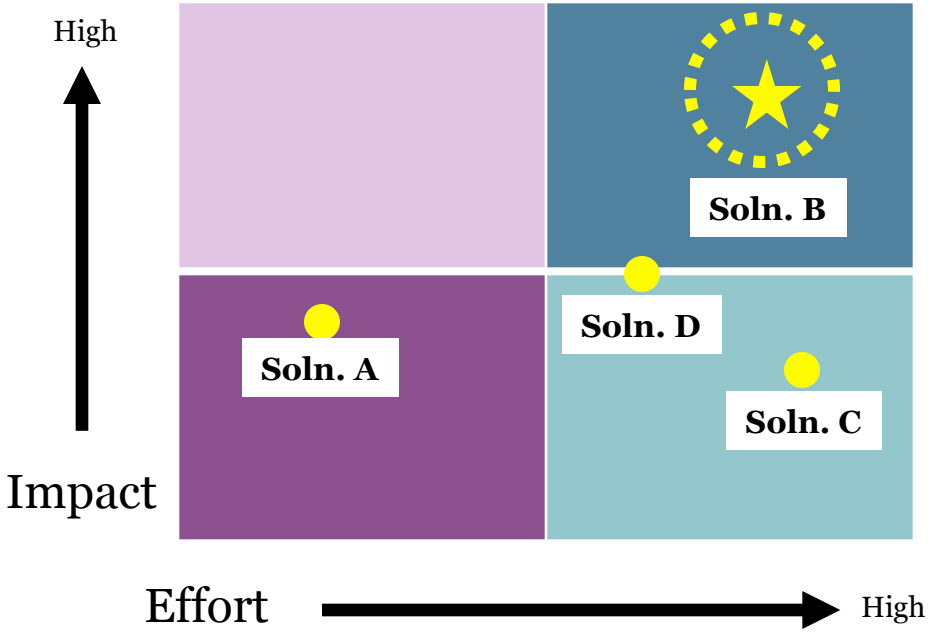
- Assessing risks
- Identify, limit or completely mitigate risks associated with potential solutions
- In some cases the only way to limit or mitigate is to disregard or eliminate the solution from the list.

# Cost Benefit Analysis

- Financial comparison of solutions
- Provides data for Champion and stakeholder acceptance of solution
- Once FMEA is complete gather as much financial information on proposed solution as possible.
- Use financial metrics common for organization

# Effort vs. Impact Plot

- Common sense tells you time or effort to implement may be high but it's worth it.
- Subject matter experts quantify impact versus the effort as much as possible to justify potential solution(s)




**Soln. = Potential Solution**

# When to Pilot

- Medium to large scale, smaller when high risk
- Results need to be confirmed
- Ease of implementation needs to be confirmed
- Reduce risk of implementation failure
- Scope of the change is large and failure would be very costly

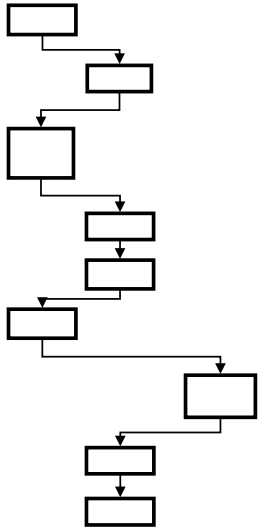
# Implementation Steps

- Identify process owner and document responsibilities.
- Communicate to customers and stakeholders.
  - Scope of change as it relates to each
  - Timeline of implementation
- Complete documentation of new process.
  - Written and visual instruction, i.e. flowcharts
- Provide comprehensive training.
- Revise job descriptions as required.
- Implement on the full scale.
- Monitor and manage issues until process has settled.

# Control Plan/QC Process Chart

- Used to clearly document PDCA (Plan, Do, Check, Act)

- Plan/Do
  - All essential steps
  - Flowchart is common
- Check
  - Items being monitored and specifications
  - Quality measures
- Act
  - How to respond
  - Who is responsible

| PLAN / DO | CHECK | ACT |
|---|---|---|
| Flowchart | Indicators | Corrective Actions & WHO |
|  | *Plot time on each order; should be ≤ 2 hours; check for special causes* | *If time exceeds 2 hours, alert Sam immediately; organize investigation* |
| | *Count errors* | *If more than 1 per order, stop process, contact Sam* |

# Project Closure

- Clearly communicate results
  - Post in area with wide access
  - Open meeting
- Recognize team
- Communicate plan for sustaining results and continuous improvement