Using the DMAIC Process to Direct the Sequencing of Lean/Six Sigma Tools for Successful Project Outcomes

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Ortho Clinical Diagnostics
a Johnson & Johnson company

Intent:

Using the DMAIC Process to Direct the Sequencing of Lean/Six Sigma Tools for Successful Project Outcomes

The purpose of this presentation is to share with the attendees my experience over the past 5 years using the DMAIC Process how to determine what Lean and/or 6 Sigma tools is the best to use when for assuring successful outcomes of your projects.

Learning Objectives:
1.) Clear understanding of DAMIC Process
2.) Clear understanding of which common Lean and 6 Sigma Tools are best used in what stage of DMAIC
3.) Clear understanding of how to assess success for a project and know if you have achieved it.

After Attending the attendees will:
1.) Know what the DMAIC process is and how it is applied in project planning
2.) Understand which Lean and 6 Sigma tools are used in what sequence to assure successful project outcomes

The Driving Forces of Change

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Today's Healthcare Delivery Challenges…

Declining Resources

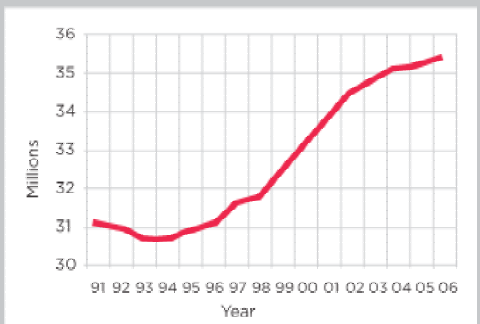
$29.9 billion
Medicare/Medicaid Shortfall

Space
Capital Funds
Skilled Labor
Reimbursement

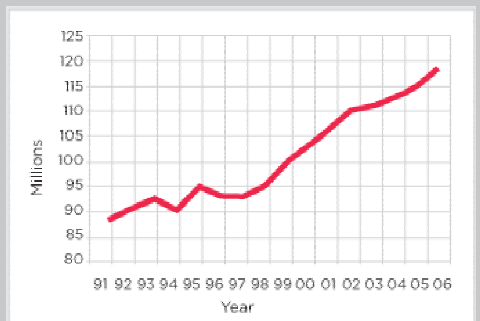
Vacancy Rates

Laboratory Techs	5.9%
Imaging Techs	5.9%
Pharmacists	8.1%
RNs	8.1%

Inpatient Admissions[2]



ED Visits[2]



Volume
New Technology
Market Pressures

Increasing Pressures

Why are labs changing?

“I need to transform my lab!”

Why?

- **2X Volume**
- **½ the Labor**
- **½ the Skill**
- **½ the Reimbursement**
- **New Medical Content**

“Help Me!”

Where do I start?

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Why Should I Even Do This?

- Testing thru-put (TAT) reduced by 50%
- Productivity improvement >40% (Billables per FTE)
- Labor hrs per 24 hrs reduced by >40%
- Cost reduction at 28%
- Space savings of >30%
- Standardized work practices
- Reduction in Errors and Error Potential
- Improved Customer Satisfaction
- Elimination of excess unused inventory
- Elimination of visual noise
- 100% cross-training of staff
- Improved Employee Job Satisfaction

I am Confused!

- Current State
- DOE
- 5 S
- Value Stream
- DMADVV
- Kano
- Muda
- DMAIC
- DESIGN EXCELLENCE
- Stakeholders
- Null
- FMEA
- Fishbone
- Future State
- CTQ
- LEAN
- DMAIC
- Affinity
- Push/Pull
- Pareto
- Regression
- Flow
- 6 SIGMA
- Mistake Proofing
- Y=f(x)
- Charter
- VOC
- Kaizen
- Gauge R&R
- SIPOC

Bringing Order to Chaos:

Improve an Existing Process

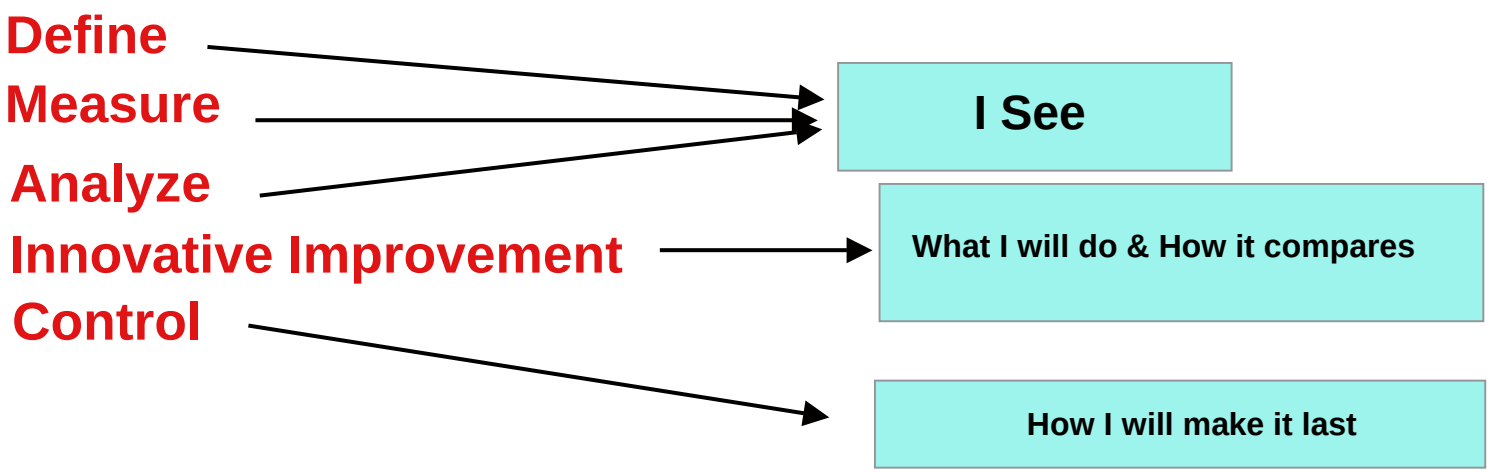
- **DMAIIC**

Create a New Process

- **DMADVV**

Create a New Product

- **DESIGN EXCELLENCE**



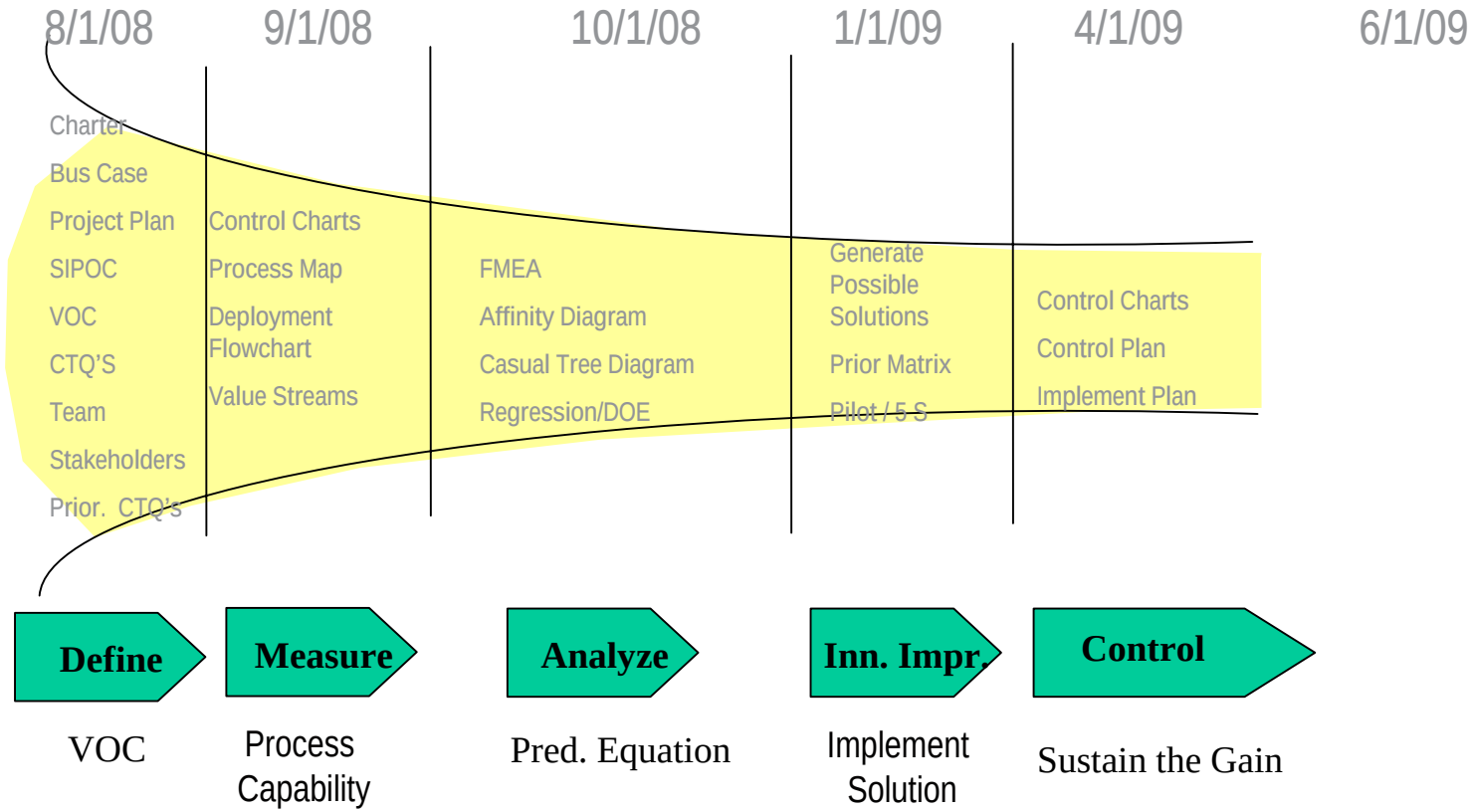
DMAIIC – Define (the hardest to do right!)

- Charter Document
- Business Case
- Gathering the Voice of the Customer (VOC)
- Defining Success – measureable and time bound
- Stakeholder commitment
- High level Current Process map – the SIPOC

Define Phase - Charter

Title:	**Process Improvement Opportunity for XYZ Distribution Center resulting in reduced labor costs, reduced packing costs, reduced customer defects, and reduced square footage.**
Problem Statement:	Today XYZ is spending too much on labor, packaging and storage for its products at its main distribution center. Also, end user customer defects are too high. Improvements must be made within the next 12 months.
Rev:	09/02/08 Stakeholder approval 9/02/08
Scope:	XYZ Products, from order entry to unpacked and receipted into customer's inventory. Includes up stream into Marketing and Product specifications.
Duration:	Immediate through next 12 months
Key Stakeholders:	VP's, CFO's, Line Managers, HR
Steering Team:	To Be Named and type and frequency of communications to be determined following first month of work.
Project Teams:	List all functioning teams
Goals:	1.) Reduce labor hours needed in picking and packing process from Current State for both domestic & international. 2.) Reduce packaging total costs (cartons, corrugate, gel card staging & obsolescence) from Current State. 3.) Reduce end-user customer defects from Current State. 4.) Reduce square footage (footprint).
Resources Needed:	Work this out for all resources needed
Expense Funds:	Detail out and get approval
Methodology:	PE – Lean primarily following a DMAIIC roadmap with use of Value Streams for documenting Current and Future States.
Success Defined:	At the end of the 12 months time, XYZ Corp. is delighted with the transferable, replicable process improvements from the project that have substantially reduced the amount of labor hours needed to perform the process, substantially reduced the cost of the packaging used in the process, substantially reduced the number of end user defects produced by the improved process and substantially reduced the square footage to store products. Magnitude of improvement for each of the 4 Goals is expected to be at least 20% .
Environmental Impact:	Improvements consistent with movement towards "Green"

DMAIIC High Level Project Plan



Define Phase: VOC – CTQ Tree

NEED ---------- DRIVERS ---------- CTQ'S

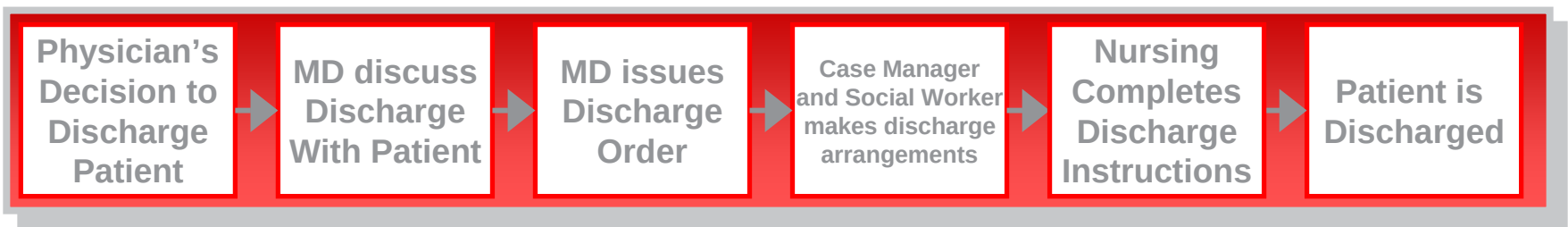
1 of 4 Goals

Reduce Sq. Footage of Products in Warehouse by at least 20%

- Demand
  - Units Shipped per 24 hrs
- Inventory Req.
  - Total Units Required including safety stock/24 hrs
- Footprint of Product
  - Cubic ft/SKU

Define: SIPOC Analysis

S	I	P	O	C
Physicians Offices	Booking Admission Information / Date			Physicians
Physicians	Estimated Discharge Date		Discharged Patient	Patients
Patients	Special Discharge Needs			Insurance Co.
Insurance Co.				Nurses
Nurses				Case Manager
Case Manager				Social Worker
Social Worker				Senior Management



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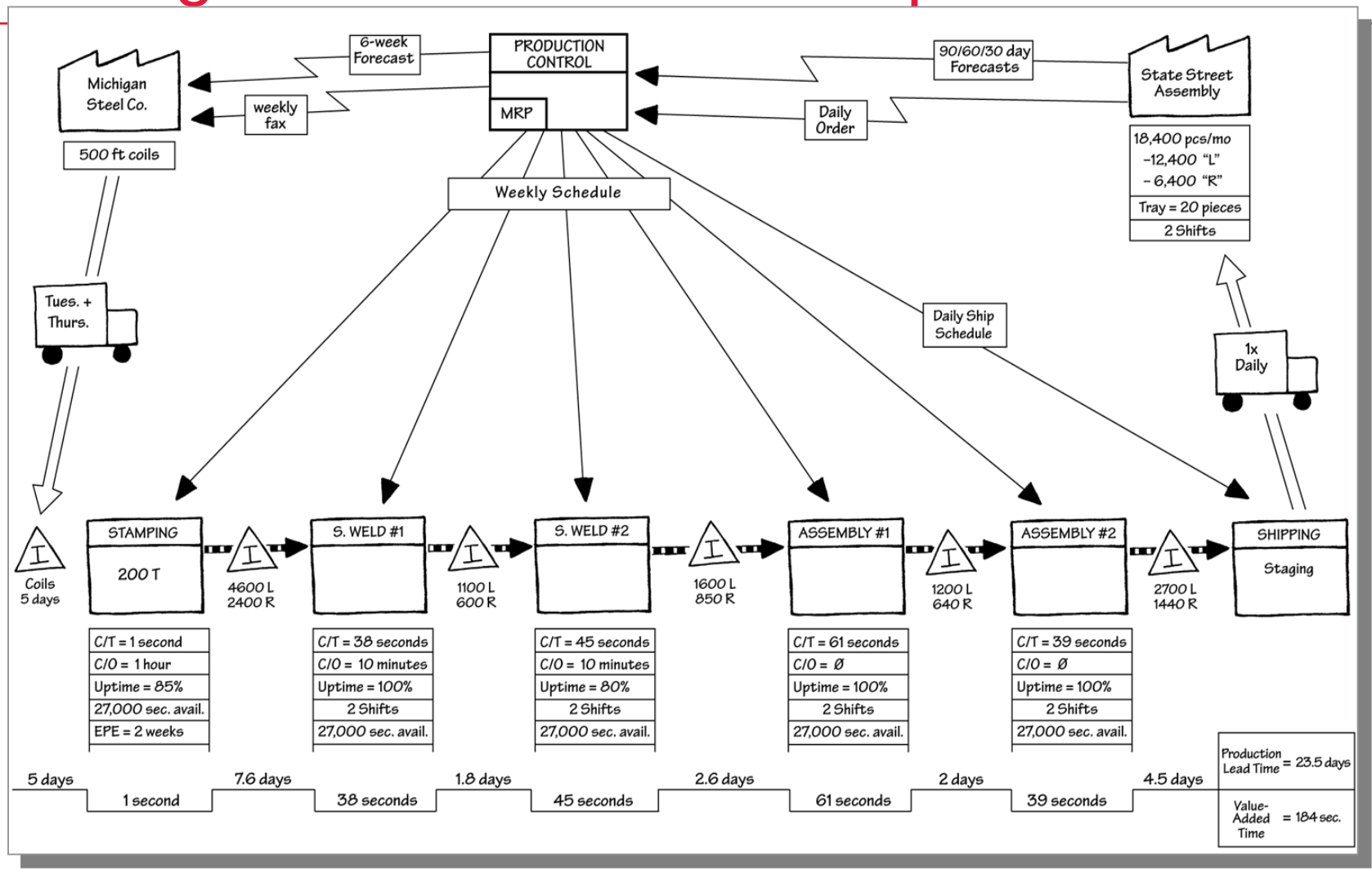
DMAIIC – Measure (its all about the Current State – is it Capable?)

- Value Stream
- Process Map
- Data Collection Plan – how much is enough?
- Is Current State in Control? – Control Charts
- Is Current State Capable? – Specs (VOC) vs. Control Limits
- Funneling – the trivial many X's – FMEA

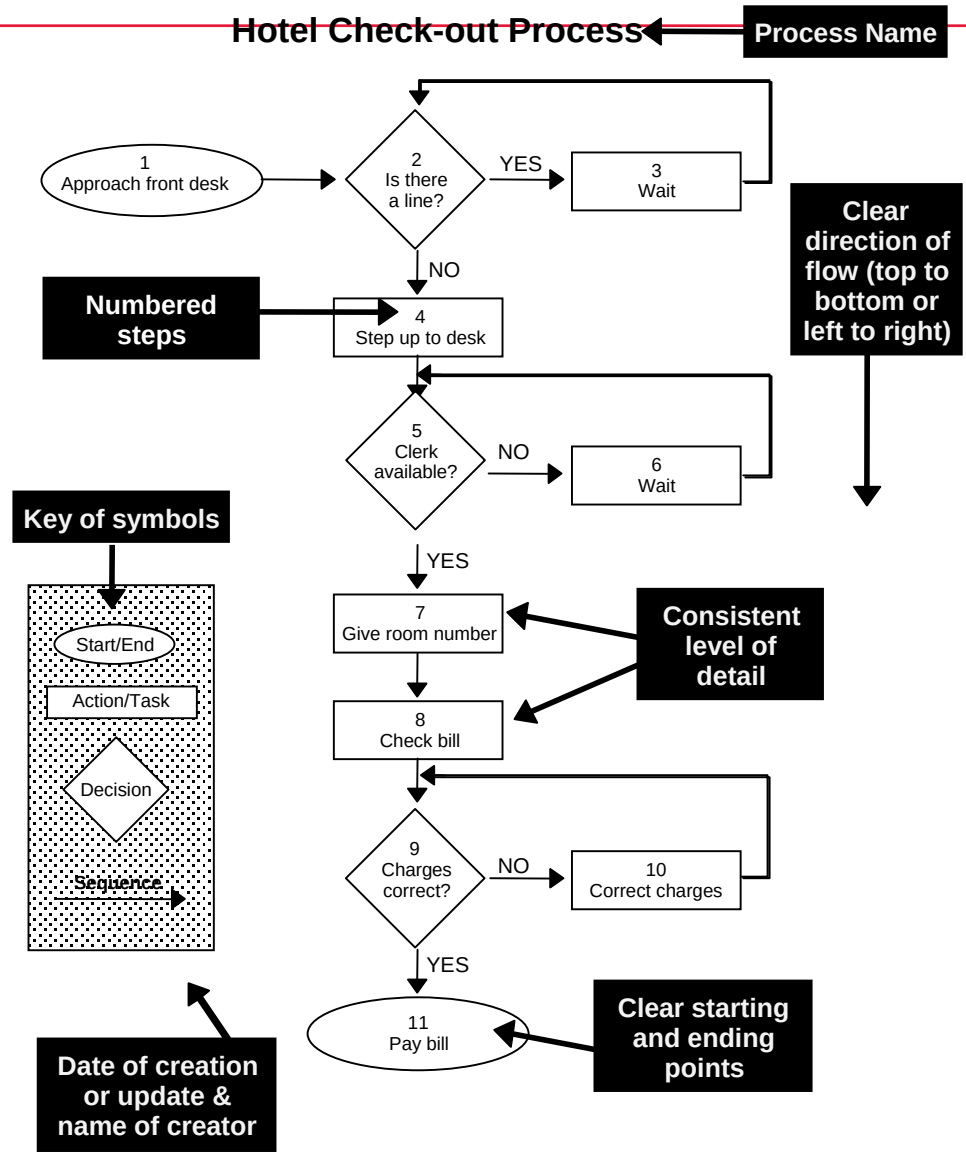
Creating the Current-State Map



Ref "Learning to See" Rother & Shook

Measure: Process Maps - Activity Flowchart Example

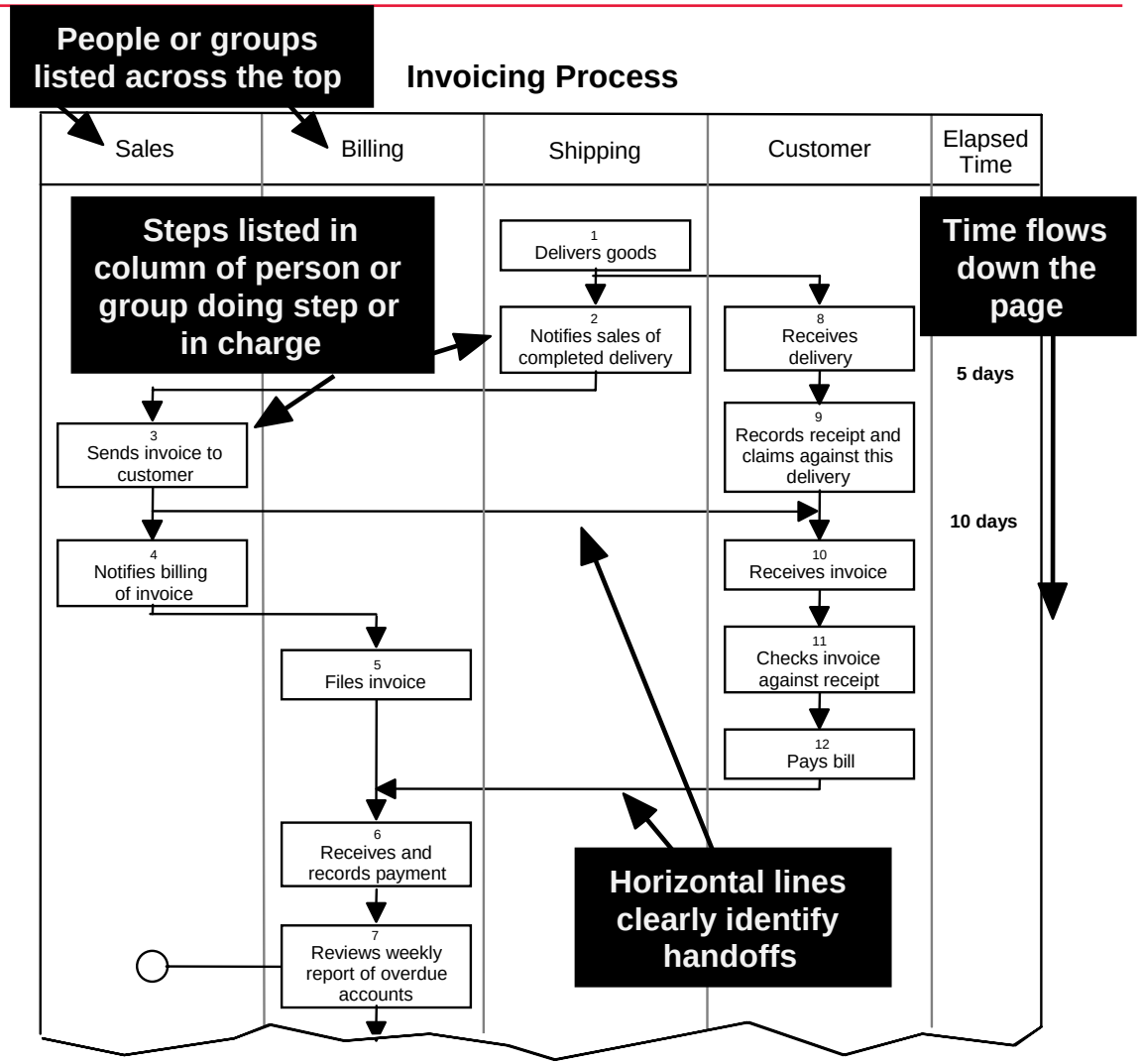
- **Activity flowcharts** are specific about what happens in a process. They often capture decision points, rework loops, complexity, etc.



Measure: Process Maps - Deployment Flowchart Example

- **Deployment flowcharts** show the detailed steps in a process and which people or groups are involved in each step.

- They are particularly useful in processes that involve the flow of information between people or functions, as they help highlight handoff areas.



Measure: Data Collection Plan Features

Data Collection Plan **Project** _____

What questions do you want to answer?

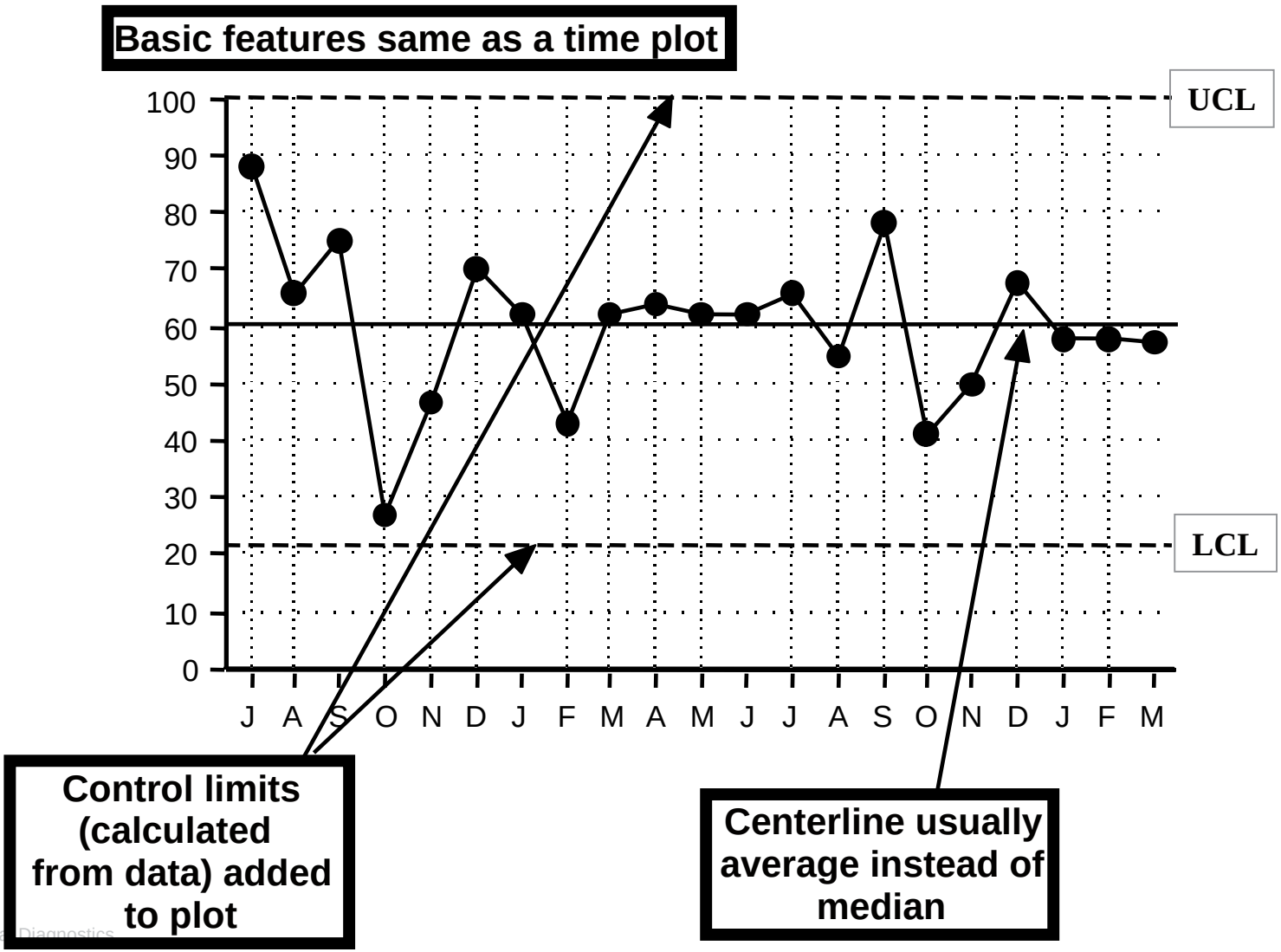
Being clear about your question will help you make sure you collect the right data.

Data		Operational Definition and Procedures			
What	Measure type/ Data type	How measured[1]	Related conditions to record[2]	Sampling notes	How/where recorded (attach form)

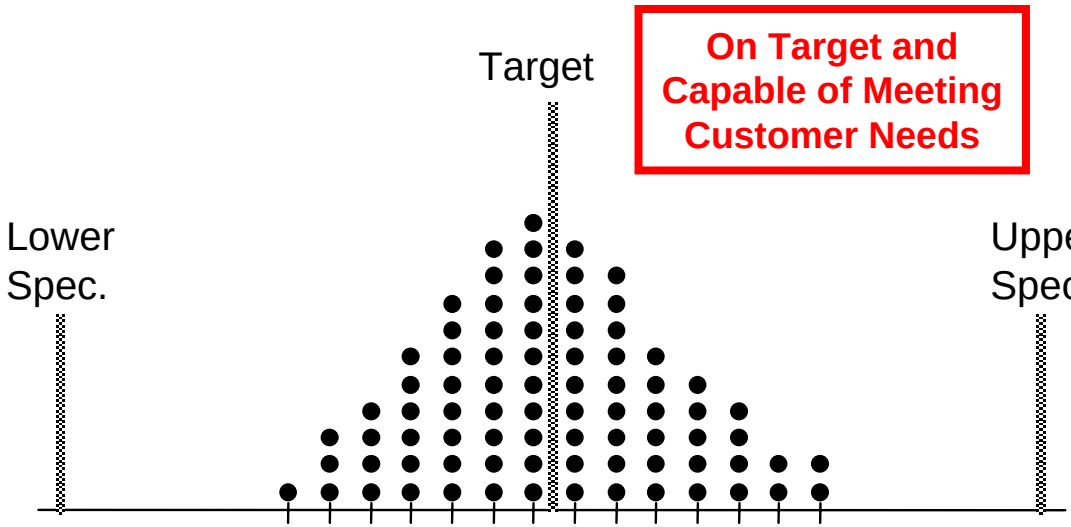
Recording what data you are going to collect reminds you what you want to accomplish. Noting the type of data helps you decide how you should analyze the data.

An operational definition defines exactly how you will go about collecting and recording the data.

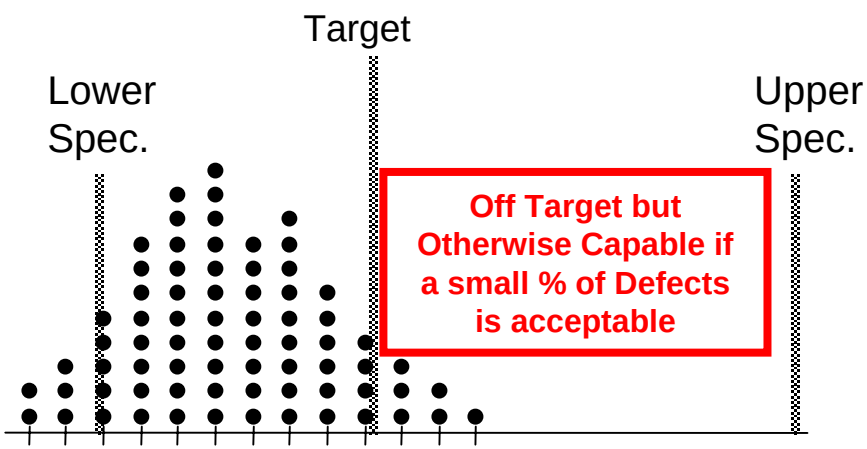
Measure: Control Chart Features (In Control?)



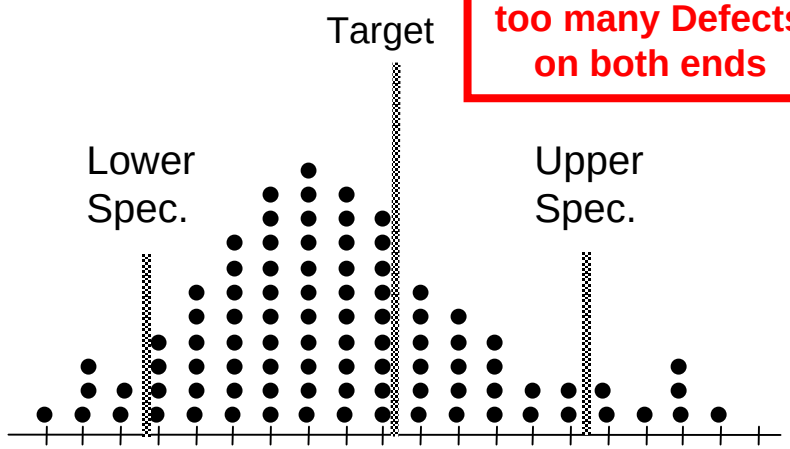
Measure: Process Capability



On Target and Capable of Meeting Customer Needs



Off Target but Otherwise Capable if a small % of Defects is acceptable



Not Capable Even if On Target too many Defects on both ends

Measure: FMEA (funneling the x's)

- FMEA identified 3-5 Input Variables that were causing the majority of the concerns within the process

Input X's from Process Map	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 cusotmer?	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
Not Global	Not look at all parameters of the process that might effect customer satisfaction ratiing	Departments cannots improve process to have an impact to customer satisfaction	9	Process to obtain feedback only focuses on one part of the process from lead to audit, thus data is not global.	9	None	9	729
Subjective Vs. Objective	Inaccurate data	In ability to impact satisfaction	9	Not a universal or objective measurement system	9	None	9	729
BIAS	Inaccurate Data Collected	Cannot improve process	9	Not collected by 3rd party; Results impacted by current system operations, such as uptime	9	None	9	729
Not understood by the customer	Not clear on the process	minimal impact to satisfaction	5	No proper explanation of the process	5	Review with internal customer of data	5	125
Measurement Interval	Not measuremd consistently	Do not know impact	5	Lack of interval established	5	None	5	125
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Alignment to Strategic Imperiaives	Not relevent to organizations goals	Not relevent to organizatoins goals	2	No alignment	2	None	2	8
NPS	Incldued/not included	Not included in satisfaction rating	1	Incorporate into rating	1	None	1	1
						Total		2454

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NPS	Incldued/not included	Not inclu rating

How often does or does not occur	Severity	Ranking
90%	Highest probability does not occur	9
50%	Moderate probability it does not occur	5
10%	Low probability it does not occur	1

Probability of failure	Occurrence	Ranking
90%	High probability of failure most of the time	9
50%	Moderate probability of failure most of the time	5
10%	Low probability of failure most of the time	1

Detection	Detection	Ranking
90%	Highly likely will not detect	9
50%	Moderately likely will not detect	5
10%	Low probability it will not detect	1

DMAIIC – Measure (its all about the Current State – is it Capable?)

- Value Stream
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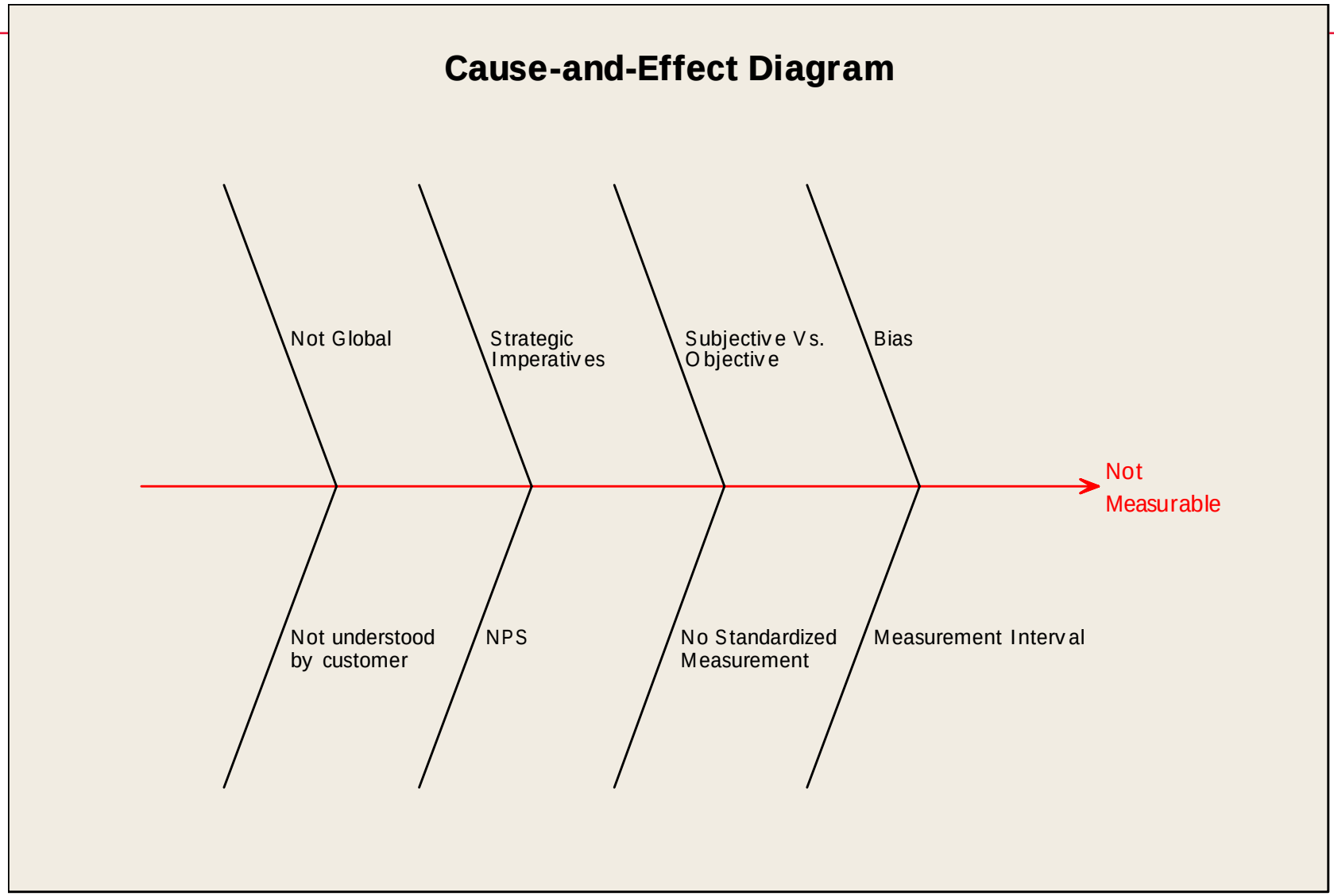
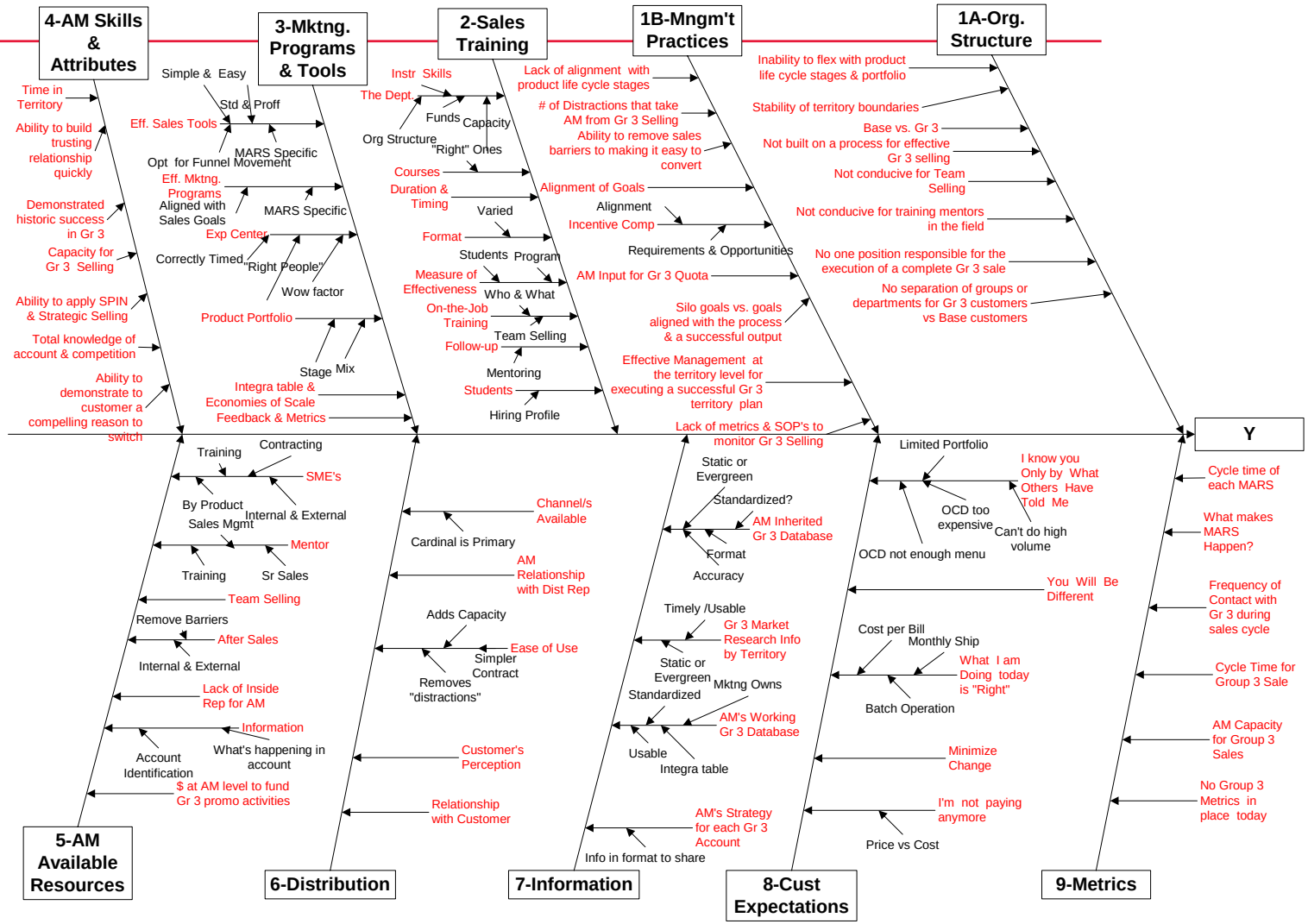
DMAIIC – Analyze (what is the relationship of my “vital few” x’s, input, to my Y, output?)

- The “Holy Grail” – the predictable equation – Y=f(x1, x2,…xn)
- Root Cause Identified
- Fishbone Diagram
- Regression Analysis
- Design of Experiments (DOE)

Analyze: Fishbone Diagram (vital few X's that impact Y)



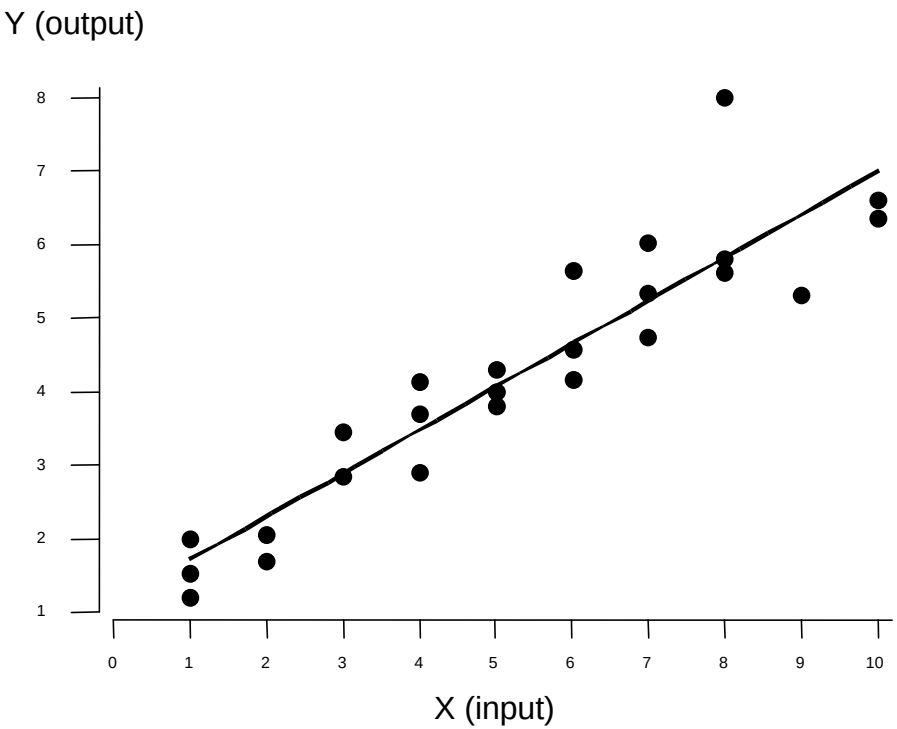
Analyze: Fishbone Diagram (vital few X's that impact Y)



These 10 "branches" were deemed the "Vital Few X's" since they represented all the Affinity Groupings and the Top 15 High RPN's were embedded within the "branches".

Analyze: Regression Analysis Quantifies the Relationship Between X and Y

Regression analysis generates an equation (represented graphically by a line) that quantifies the relationship between X and Y.



The line, or **regression equation**, is represented as

$$Y = b_o + b_1X \qquad y = mx + b$$

b_o = **intercept** (where the line crosses X= 0 or the Y axis)
b_1 = **slope** (rise over run, or change in Y per unit increase in X)

Analyze: Design of Experiments (DOE)

PROBLEM: Gas prices have been skyrocketing. The fuel economy of the company car is 20 MPG. Management would like an increase to 30 MPG

BRAINSTORM LIST OF WAYS TO IMPROVE MPG:

- Change brand of gas
- Change octane rating
- Drive slower
- Tune-up car
- Wash and wax car
- Buy new tires
- Change tire pressure

QUESTIONS: How can you "rule in" or "rule out" these possible causes?

How would you know if these possible causes act alone or if they interact with any of the others?

Analyze: Design of Experiments (DOE)

Std. Order	Factor 1	Factor 2	Factor 3
1	–	–	–
2	+	–	–
3	–	+	–
4	+	+	–
5	–	–	+
6	+	–	+
7	–	+	+
8	+	+	+

- A **full factorial** involves all possible combinations
  - For 3 factors, each at 2 levels, there are 2 x 2 x 2 = 8 combinations of factor settings
  - 2 x 2 x 2 is often written as 2^3
    - The superscript 3 indicates the number of 2's multiplied together
  - For 3 factors there are $2^3 = 8$ possible combinations of factor settings

After I am done with this I should have a Predictable Equation for my Y/Y's. Be sure to test Predictability!

DMAIIC – Analyze (what is the relationship of my “vital few” x’s, input, to my Y, output?)

- The “Holy Grail” – the predictable equation – Y=f(x1, x2,…xn)
- Root Cause Identified
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Bringing Order to Chaos:

Improve an Existing Process

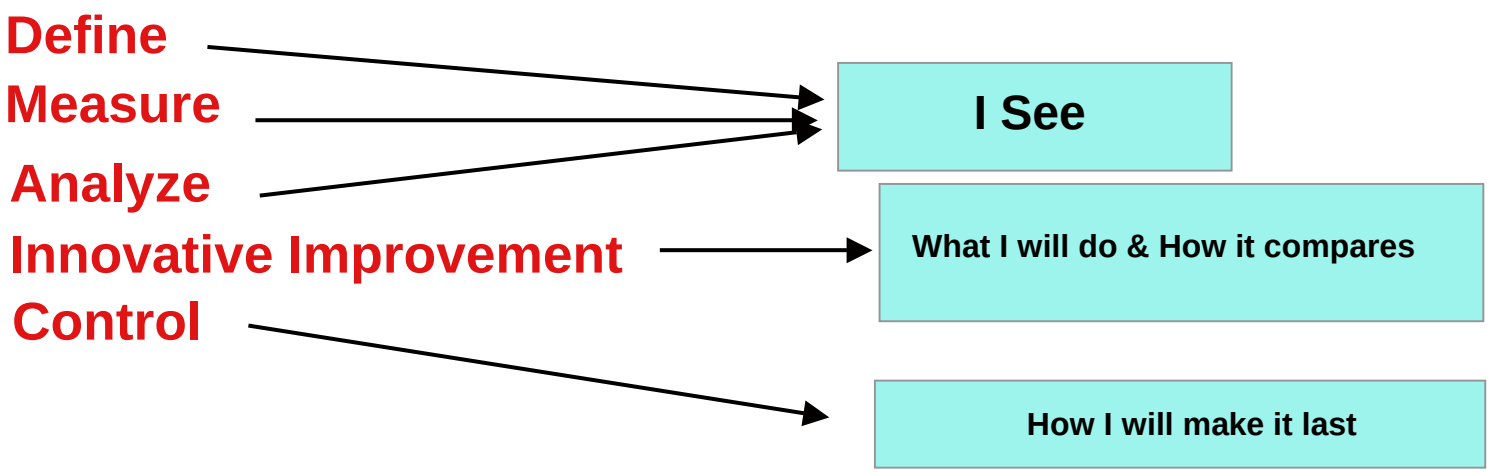
- **DMAIIC**

Create a New Process

- **DMADVV**

Create a New Product

- **DESIGN EXCELLENCE**



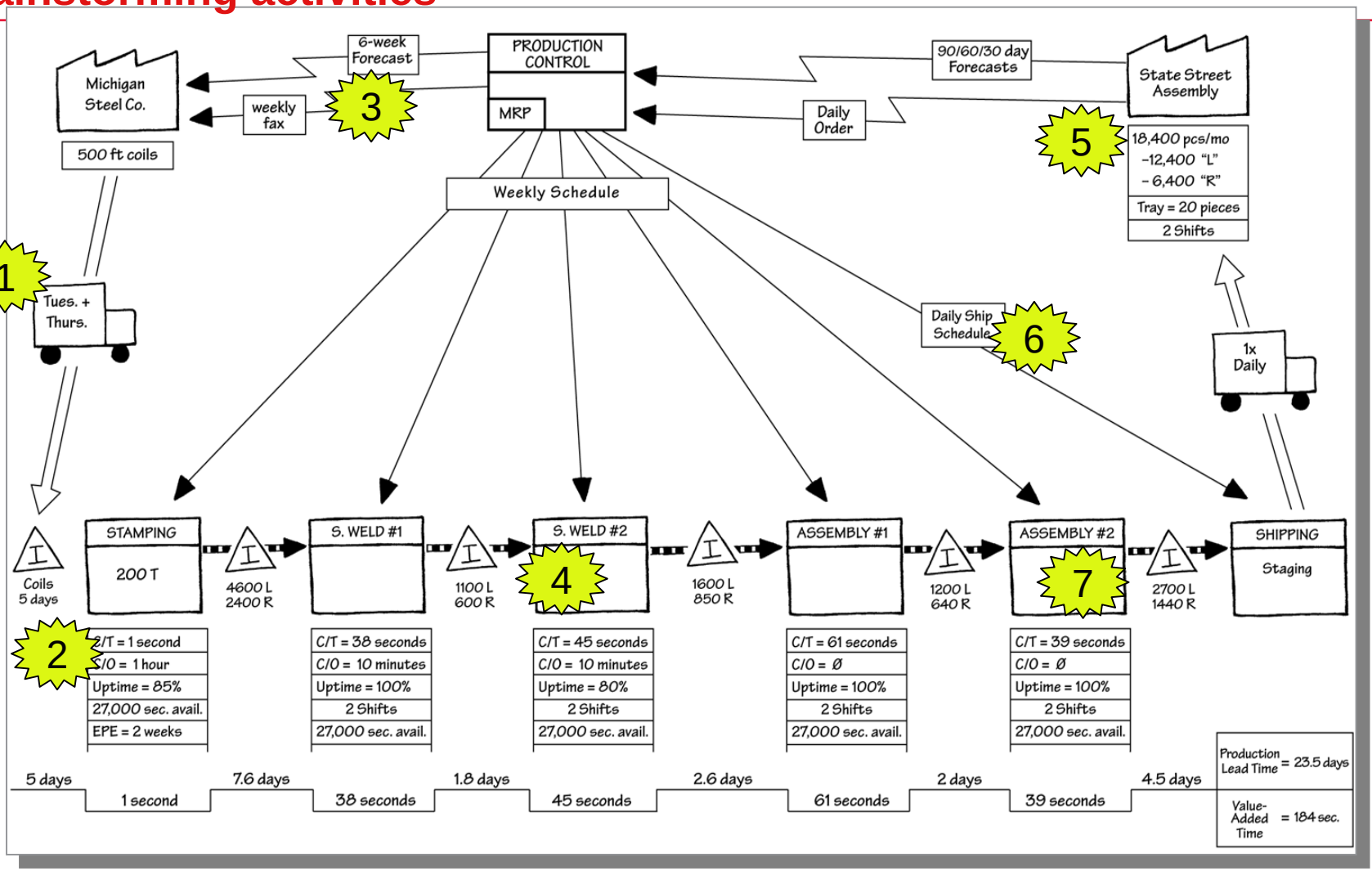
DMAIIC – Innovative Improvement (create solution, pilot, compare & implement)

- Brainstorm
- Solution Prioritization Matrix
- Effort vs. Impact Graph
- Kaizen on Current State Value Stream to Create Future
- 5S (Sort, Set in Order, Shine, Standardize, Sustain)
- Mistake Proofing
- Flow
- Pilot
- Retest Process Capability
- Revisit FMEA (calculate new RPN’s for improved process)
- Implementation Plan

Innovative Improvement: Brainstorming Techniques to create solutions

- **Quick and Dirty Techniques:**
  - Think Like a Kid
  - Challenge the Rules
  - Set a Deadline
  - Get Rid of Excuses
- **Alternatives to**
- **Face to Face:**
  - Chain Letter
  - Billboard
- **More Involved Techniques:**
  - Channeling
  - Anti-Solution ('Evil Twin')
  - Analogy
  - Musical Chairs
  - SCAMPER
  - Slice and Dice
  - Idea Box
  - Brutethink

Innovative Improvement: Current Value Stream Map with Kaizen Bursts indicating opportunity areas for improvement from Brainstorming activities



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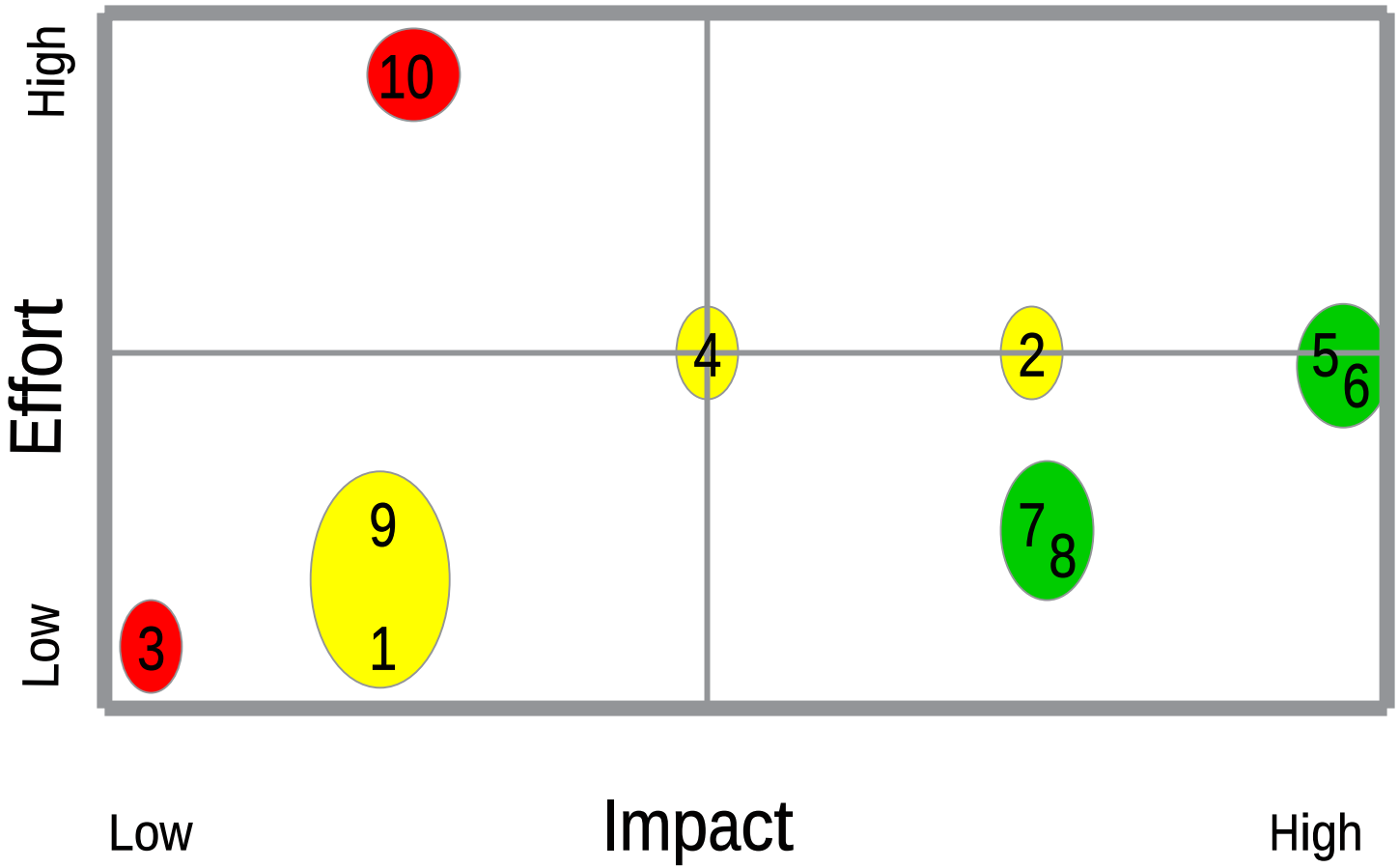
Innovative Improvement: Effort vs Impact Graph for prioritizing all possible solutions



Innovative Improvement: Solution Prioritization Matrix for prioritizing solutions

This is a team exercise! Has to be collective alignment of your project team!

Alternative Solutions	Criteria>	Cheap Implem.	Quick Implem.	Compat. Technol.	Cheap to Operate	Satisfies CTQs	SUM
	Weight>	4	5	2	1	8	
	Alt. A	1	5	1	5	9	108
	Alt. B	5	1	5	1	5	76
	Alt. C	9	1	9	9	1	76
	Alt. D	5	9	5	5	5	120

Innovative Improvement: Lean Improvements

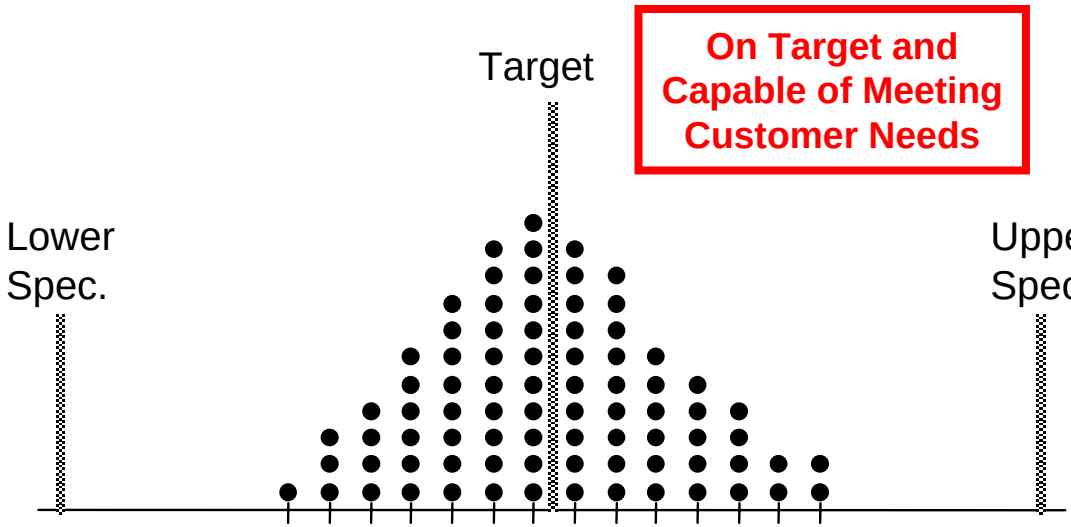
Pictures of Lean examples:

- 5S (Sort, Store, Shine, Standardize, Sustain)
- Mistake Proofing
- Flow

Innovative Improvement: Run the Pilot

Take the best solution/s and run a pilot!

Innovative Improvement: Redo Process Capability with New Process to be sure the New Process is Fully Capable



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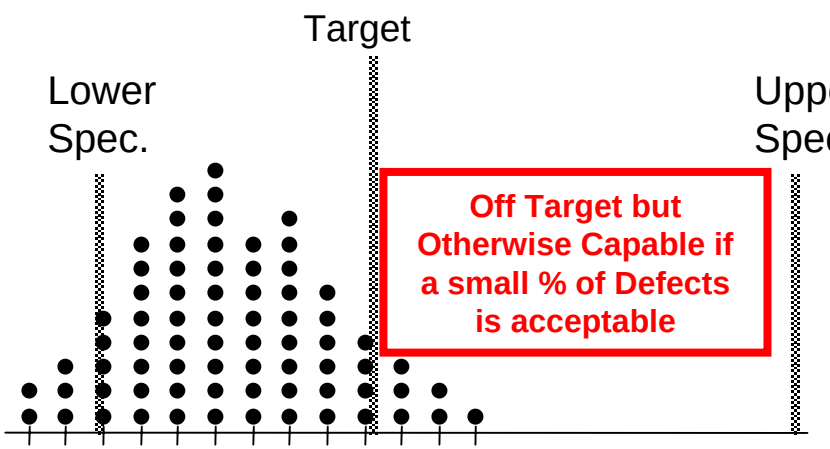

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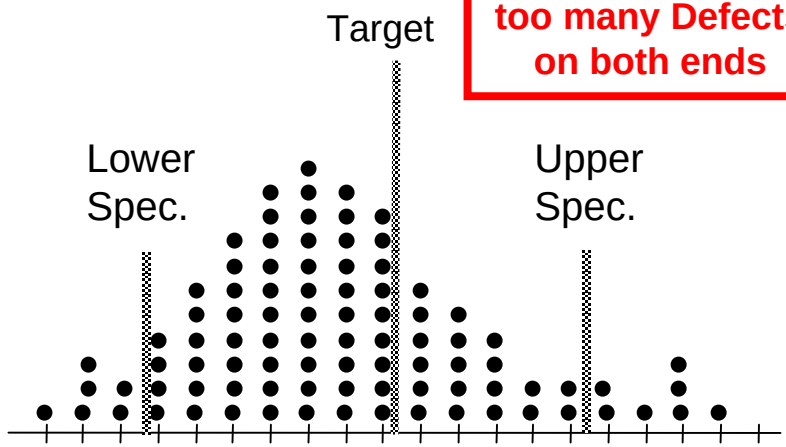

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Innovative Improvement: ReVisit the FMEA & reclassify with improvements

- FMEA identified 3-5 Input Variables that were causing the majority of the concerns within the process

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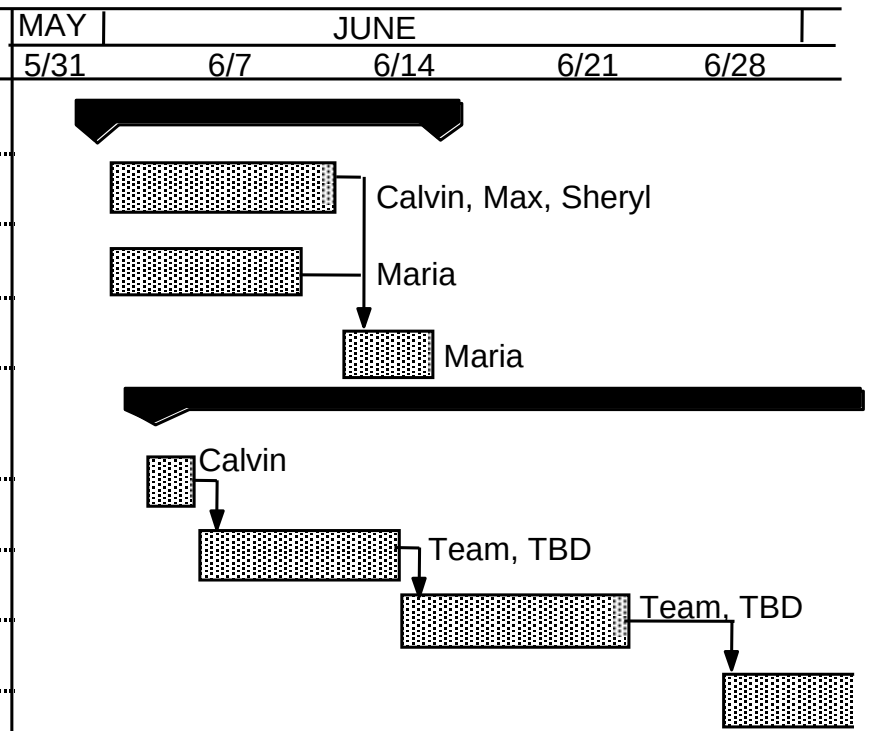
Reclassify the severity, occurrence, and detection ratings with the new improvements to get a new, lower RPN. Proving that the improved process is quantifiably better.

Innovative Improvement: Create an Implementation Plan, e.g. Gantt Chart

- A Gantt chart is a diagram that shows the timing, duration, and interrelationship of steps in a plan**.** See sample below, made in Microsoft Project software:

Rearrange Machine Controls

ID	Task Name
1	**Redesign Control System**
2	Develop new wiring schematic
3	Conduct Changes
4	Revalidate System
5	**Train Operators**
6	Update documentation
7	Develop Training Plan
8	Train operators
9	Test



DMAIIC – Innovative Improvement (create solution, pilot, compare & implement)

- Brainstorm
- Solution Prioritization Matrix
- Effort vs. Impact Graph
- Kaizen on Current State Value Stream to Create Future
- 5S (Sort, Store, Shine, Standardize, Sustain)
- Mistake Proofing
- Flow
- Pilot
- Retest Process Capability
- Revisit FMEA (calculate new RPN’s for improved process)
- Implementation Plan

Bringing Order to Chaos:

Improve an Existing Process

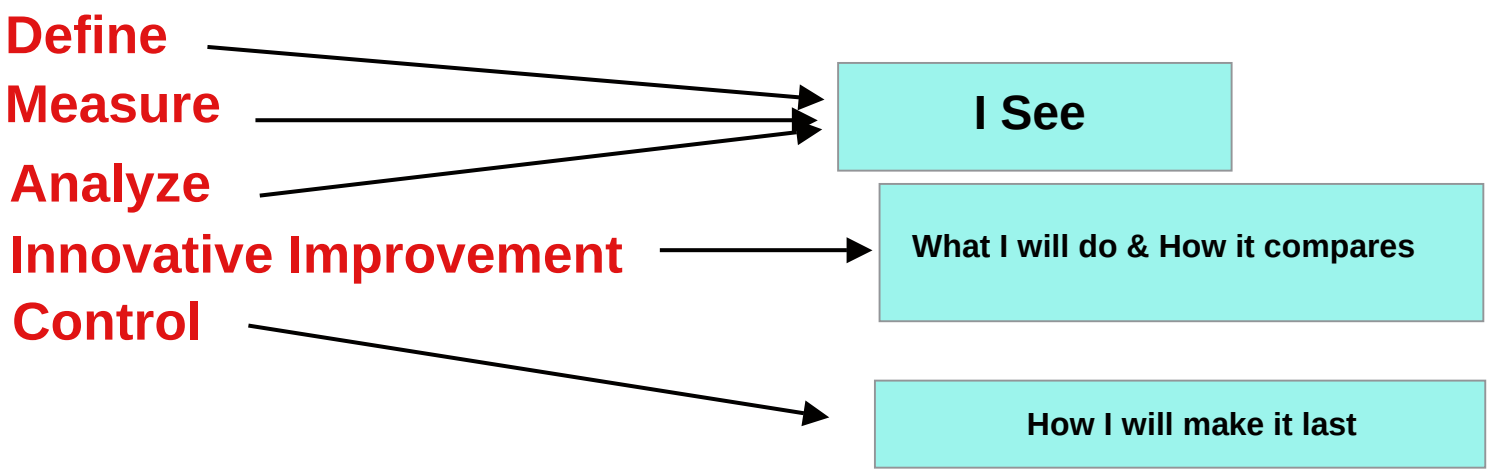
- **DMAIIC**

Create a New Process

- **DMADVV**

Create a New Product

- **DESIGN EXCELLENCE**



DMAIIC – Control (sustain the gain!)

- Visual Controls
- Production Metrics
- Audits
- SOP’s
- HR Performance Measures
- Huddles
- Kaizens

Control: Visual Control in the Workplace

Pictures of Lean examples of Visual Control in the Workplace

Control: The Periodic Audit (great tool for sustaining improvements)

Rating Scale Guide

Score	Description of Score
1	No apparent attempt to institute/enforce &/or adhere to the principle
2	Principle has been instituted, but no apparent attempt to enforce or sustain
3	Principle has been instituted and displays signs of sustainability and enforcement
4	Principle is being sustained and enforced, and there are positive signs of a plan to track performance
5	Principle is sustained and enforced. Kaizen events occur frequently.

Main Menu | 5S | Operations | Metrics | Supply Chain

Control: The Periodic Audit (great tool for sustaining improvements)

Auditor's Checklist

1	☐	WORK SCHEDULE WITHIN HEPATITIS TESTING AREA
2	☐	SCHEMATIC DIAGRAM OF HEPATITIS WORK CELL
3	☐	SCHEMATIC DIAGRAM OF PRODUCT / OPERATOR FLOW
4	☐	SOP OF HEPATITIS WORK CELL OPERATIONS
5	☐	SOP FOR HEPATITIS TESTING AND / OR REPEATS
6	☐	DOCUMENTATION OF PREVENTATIVE MAINTENANCE
7	☐	DOCUMENTATION OF QUALITY CONTROL LOG
8	☐	DOCUMENTATION OF PRODUCTION METRICS
9	☐	Example of LIS Printout
10	☐	DIGITAL CAMERA

Control: The Periodic Audit (great tool for sustaining improvements)

Section 2: Work cell Operations

2.1 FLOW

2.1.1 Tubes received into ID testing area are batched according to assay family?	☑ Yes ☐ No
2.1.2 Defects are being detected and documented throughout the process?	
- Pre-Analytical Area	☑ Yes ☐ No
- Analytical Area	☑ Yes ☐ No
- Post-Analytical Area	☐ Yes ☐ No ☑ Not Applicable
2.1.3 Each person(s) is only working on one process at a time and completing the process prior to moving to next tube	☐ Yes ☑ No
- Flow of Operator adheres to schematic diagram	☐ Yes ☑ No
2.1.4 Flow of Product adheres to schematic diagram	☐ Yes ☑ No
2.1.6 VISUAL MANAGEMENT CONTROL	
2.1.6.1 Are tubes presented visually for processing?	☑ Yes ☐ No
Is there a specific area designated for the activity above?	☑ Yes ☐ No
2.1.6.2 Are repeats / defects presented visually for corrective action?	☐ Yes ☑ No
Is there a specific area designated for the activity above?	☑ Yes ☐ No
2.1.6.3 Are tubes presented visually for cold storage racking?	☑ Yes ☐ No
Is there a specific area designated for the activity above?	☑ Yes ☐ No

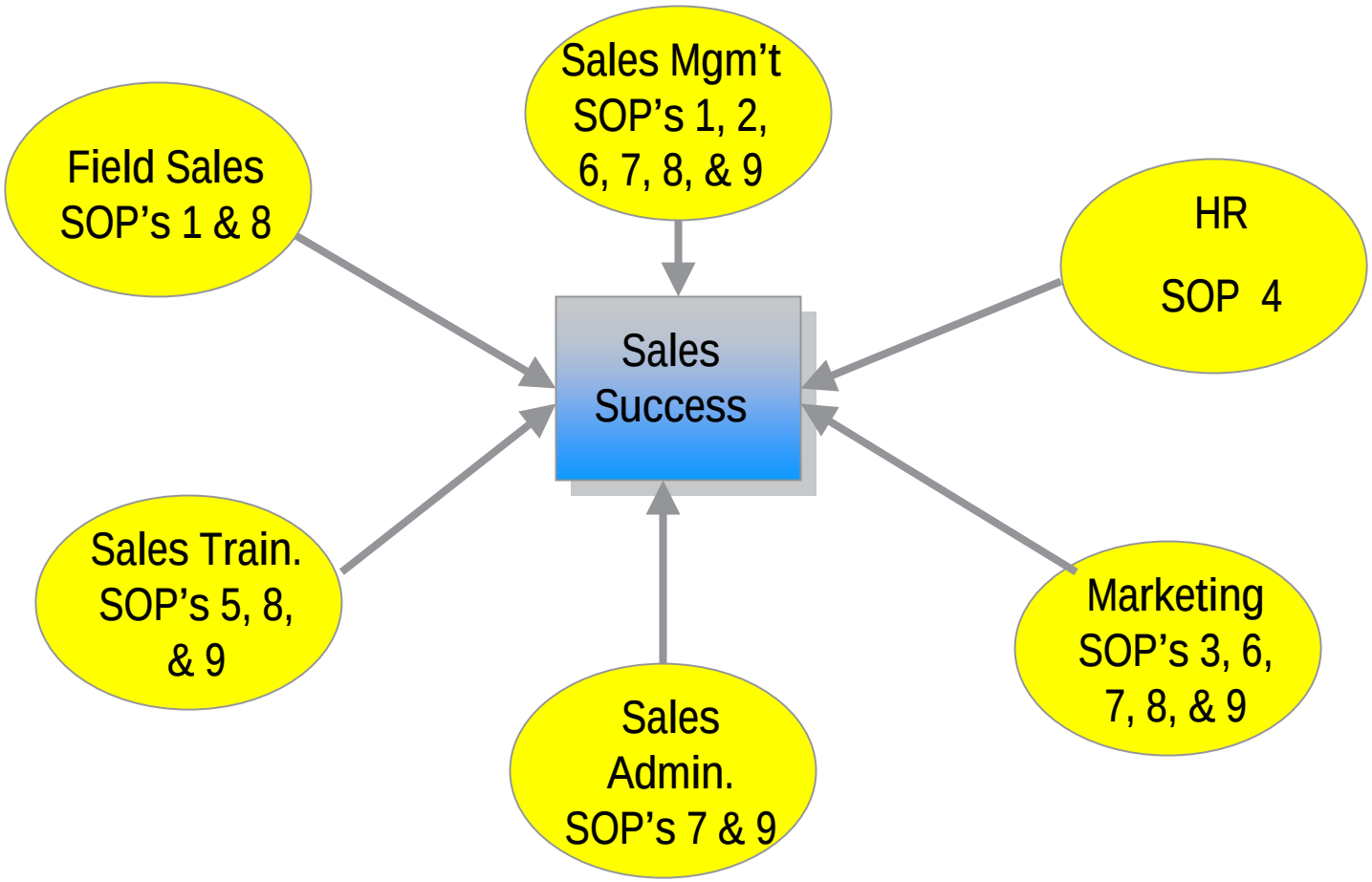
Control: The Periodic Audit (great tool for sustaining improvements)

Section 5: Integrated Supply Chain

5.1 VISUAL MANAGEMENT CONTROL - 5S

		RATING
5.1.1 Are supplies and reagents neatly organized and labeled properly?	☐ Yes ☑ No	2
5.1.2 Is there method standardization for storing and stocking of supplies and reagents?	☐ Yes ☑ No	2
5.1.3 Evidence of Re-Order points and/or Kanban cards?	☐ Yes ☑ No	1
5.1.4 Evidence of Product Stock rotation - FIFO Methodology?	☐ Yes ☑ No	1
5.1.5 Evidence of Poka-Yoke system for new lots received?	☐ Yes ☑ No	1
5.1.6 Evidence of Poka-Yoke system for product replenishment at Hepatitis work cell?	☐ Yes ☑ No ☐ Not applicable	1

Control: SOP Integration for Success



Sales Success was the "Y" of the project

DMAIIC – Control (sustain the gain!)

- Visual Controls
- Production Metrics
- Audits
- SOP’s
- HR Performance Measures
- Huddles
- Kaizens

Bringing Order to Chaos:

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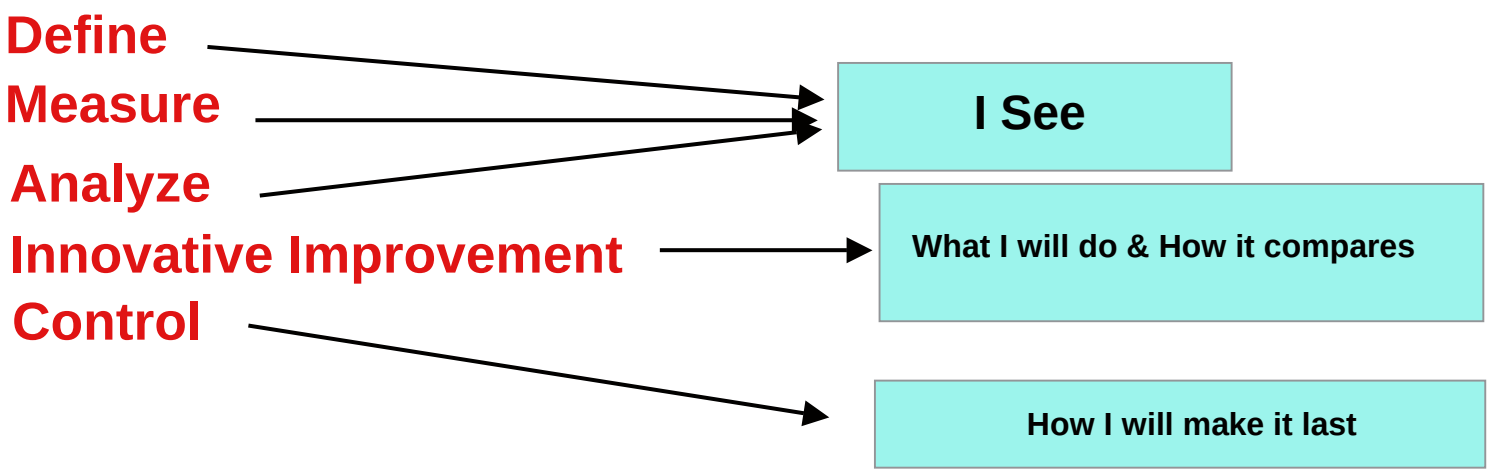

Intent:

Using the DMAIC Process to Direct the Sequencing of Lean/Six Sigma Tools for Successful Project Outcomes

The purpose of this presentation is to share with the attendees my experience over the past 5 years using the DMAIC Process how to determine what Lean and/or 6 Sigma tools is the best to use when for assuring successful outcomes of your projects.

Learning Objectives:
1.) Clear understanding of DAMIC Process
2.) Clear understanding of which common Lean and 6 Sigma Tools are best used in what stage of DMAIC
3.) Clear understanding of how to assess success for a project and know if you have achieved it.

After Attending the attendees will:
1.) Know what the DMAIC process is and how it is applied in project planning
2.) Understand which Lean and 6 Sigma tools are used in what sequence to assure successful project outcomes

Using the DMAIC Process to Direct the Sequencing of Lean/Six Sigma Tools for Successful Project Outcomes

GOOD LUCK!!

Ortho Clinical Diagnostics
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