

#### leder proces kent niet wenselijke variatie,

kan ik er iets aan doen?

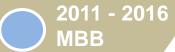


### Introduction









Log & Business Lean Six Sigma (DMAIC & DIDOV)



2006 - 2011

MBB; Program Mgr; DfX

Mfg & Dev

Six Sigma (DMAIC & DIDOV)



2001 - 2006 Quality + BB Mfg & Dev

Six Sigma (DMAIC) 1994 - 2001









Electrical cabinets

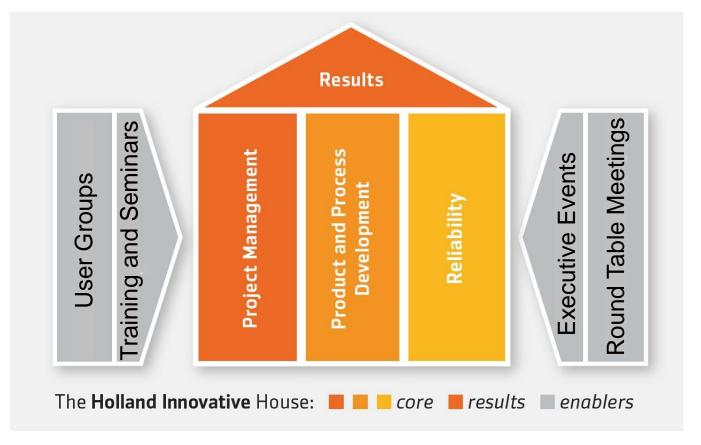


Marcel Logger

www.Holland-innovative.nl



### **Holland Innovative**













# Why improve processes?





### **Typical issues - Cost**

(Netherlands: total medical costs are 14% of GNP)

#### Examples:

- Low utilization of high CAPEX resources (MRI, CAT scanners)
- Inefficient deployment of staff.
- Long length-of-stay of patients.
- Waste of food, linen, pharmaceuticals
  - → Inefficient inventory management policies ("Just buy a lot ...")
  - → Poor process control (<43% of food is actually consumed by patients ...)
- Naïve purchasing policies.
  - → Purchase price vs. Total Cost of Ownership



### Typical issues- speed

#### Examples:

- Long admission times. Should be < 1 month for a specialist, but is often > 4 months.
- Long waiting times before a consult.

#### Perception:

- Long waiting and admission times due to insufficient capacity ("We need more doctors and staff")
- But ... waiting lists and queues are stable (do not grow) ⇒ demand and capacity are balanced.



# Typical issues: Safety (& reliability)

#### Examples:

- Netherlands: 8 deaths / day due to medical errors (Compare: 2 deaths / day due to traffic accidents).
- Besides safety hazards: excessive occurrence of small errors resulting in poor service and waste of time and resources.



### **Overview quality costs**

#### Internal failure:

- (Yield) losses
- Rework
- Losses due to poor supplies
- Unplanned stops
- Resolving cause of stops
- Retesting

#### External failure:

- Customer treatment
- Rejects from market
- Keeping a customer service
- Loss of goodwill
- Fines

#### **Prevention costs:**

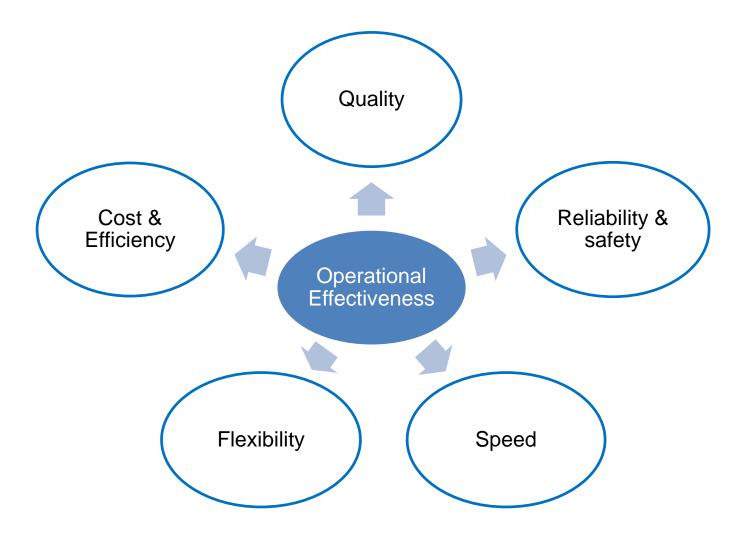
- Training and education
- Planning of quality
- Process control
- Pilot series production
- Qualifying supplies
- Customer service

#### **Testing & Examination:**

- Inspection of supplies
- Maintenance of equipment
- Calibration
- Quality department
- Testing
- Quality audits



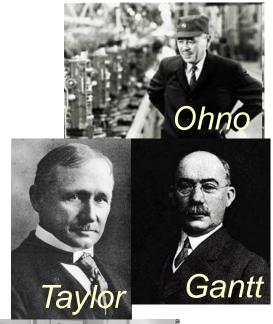
# The answer: Operational Effectiveness

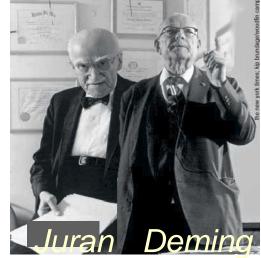




### **Operational Effectiveness**

- Lean Six Sigma
- 1990s:
  - Six Sigma
  - Lean Thinking & Just-In-Time
  - Theory of Constraints (TOC)
  - Business Process Management (BPM)
- 1980s:
  - Total Quality Management (TQM)
  - Business Process Reengineering (BPR)
- 1920–1950s:
  - Quality Control
- 1880–1920s:
  - Scientific management







### **Operational Effectiveness**

#### **Industry**



#### **Health Care**



- A lot of variation ('one-of-a-kind' jobs) vs less variation (standard jobs)
- High vs Low involvement of customer
- High vs Low predictable demand

But hospitals are within the normal spectrum of process varieties seen in operations management

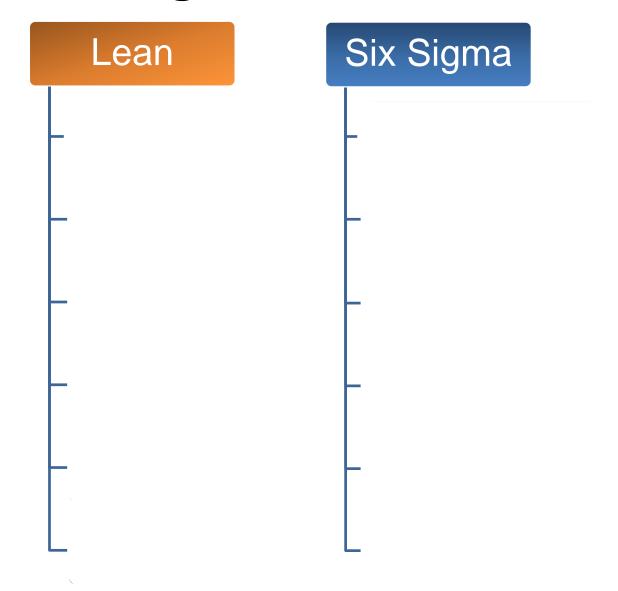






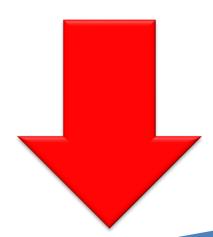
- Lean Six Sigma is a combination of two powerful methodologies: Lean and Six Sigma
- The Lean toolkit provides ways to streamline processes by reducing Waste.
- The Six Sigma toolkit provides tools to reduce defects by conducting root cause analysis.
- Together, they provide the fastest, most effective way to improve processes.







### **Benefits**



#### **Reductions in:**

Defects
Quality issues
Variation
Lead time
Inventory
Waste

Employee Engagement
Quality improvement
Customer satisfaction
Bottom line savings
Customer focused
Data based decisions
Profit
Safety
Responsiveness
Productivity

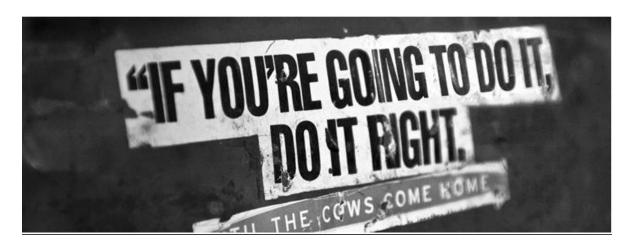






### An approach, a philosophy

- An Attitude, a structured way to execute activities (a philosophy) to be engraved in your DNA.
- A Method, to achieve the first time right development and sustainable improvement.
- A Metric, related to variation related to a specification.





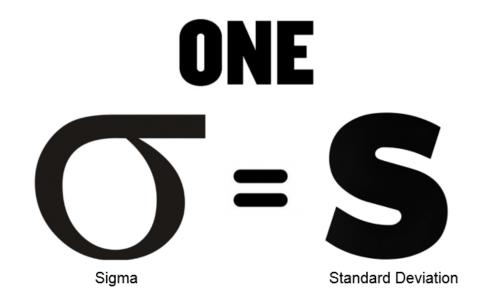
# Sigma - a Metric

#### Sigma:

- Greek character "σ"
- Measure for spread or variation from an mean value

#### In statistics:

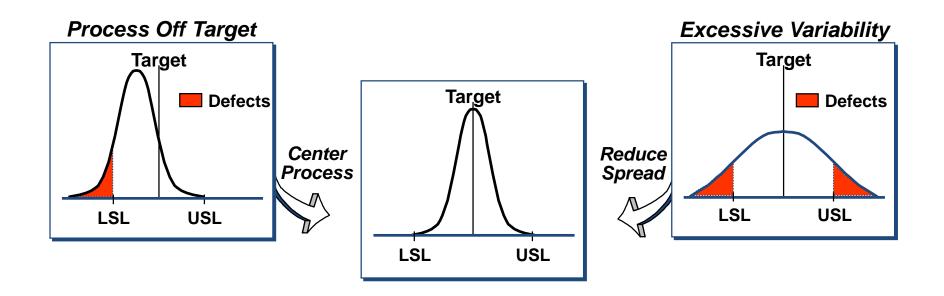
Standard Deviation of a population





# Six Sigma - a Metric

Understanding variation in relation to functional and design specifications is the essence of Six Sigma



High defects and variability: expensive



### Based on....

- Understanding customers needs,
- Understanding Performance Specifications at all levels.
- Meeting these needs every time, over a specified lifetime, under all use conditions.





### **Exercise**



- Purpose: Demonstrates Variation
- Instructions:
  - Read the next page carefully.
  - How many times does the 6<sup>th</sup> letter of the Alphabet appear in the text?
  - You will have 2 minutes.



### **Exercise**



The necessity of training farm hands for first class farms in the fatherly handling of farm livestock is foremost in the eyes of farm owners. Since the forefathers of the farm owners trained the farm hands for first class farms in the fatherly handling of farm livestock, the farm owners feel they should carry on with the family tradition of training farm hands of first class farmers in the fatherly handling of farm livestock because they believe it is the basis of good fundamental farm management.



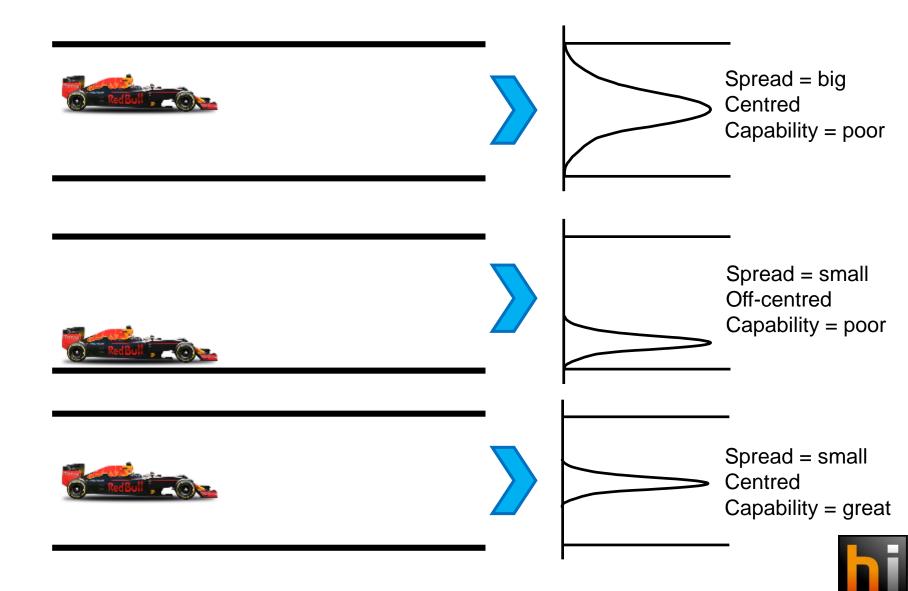
YB LSS Training

### What is variation?

- Variation is deviation from expectation.
- It's part of everydays life and part of every organisation.
- Inevitable change in the output or result of a process.
- All processes vary over time.
- The goal is to understand variation, control it, and minimize its impact.



### Interest in variation

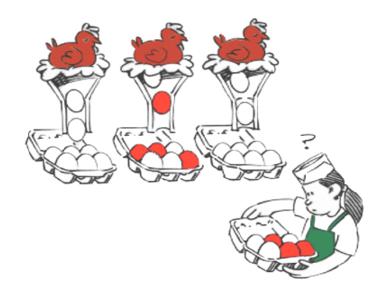


### **Variation**

#### **Common cause variation**

- Always present in a process
- Stable and predictable

#### **Special cause variation**

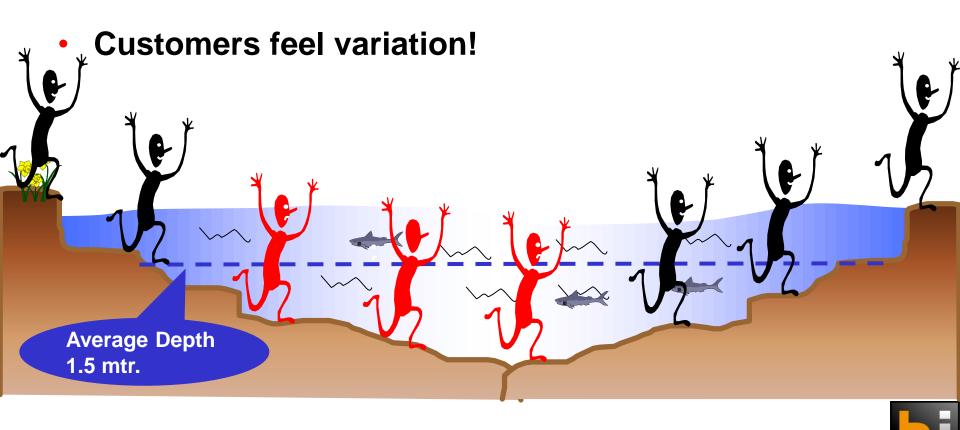


- Different from normal
- Unstable and unpredictable



### Why is it important?

 To see how the process is behaving compared to customers Critical To Quality parameters.



#### YB LSS Training



Who is your customer?



What are your customers' requirements?







© Holland Innovative CTQ Flow Down



### Critical to Quality (CTQ) Definition

 A CTQ is important for the Customer, in other words it is a characteristic that determines whether the overall process or product performance is perceived to meet the Customers Expectation

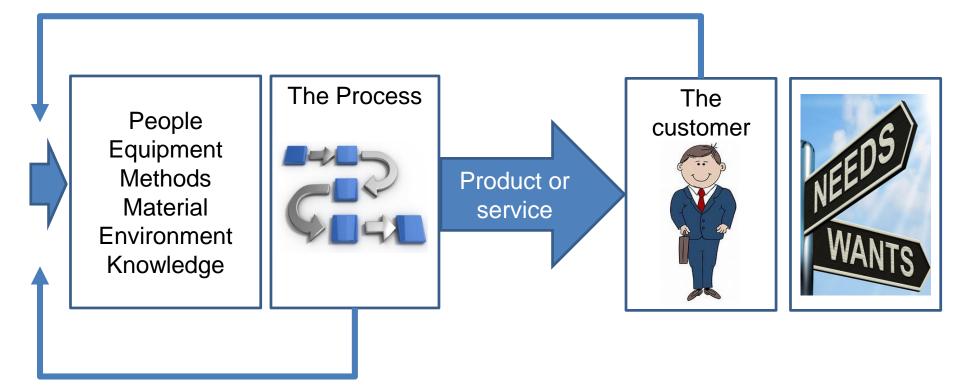




© Holland Innovative CTQ Flow Down



#### Voice of customer



#### **Voice of Process**



### CTQ Flow Down (1/2)

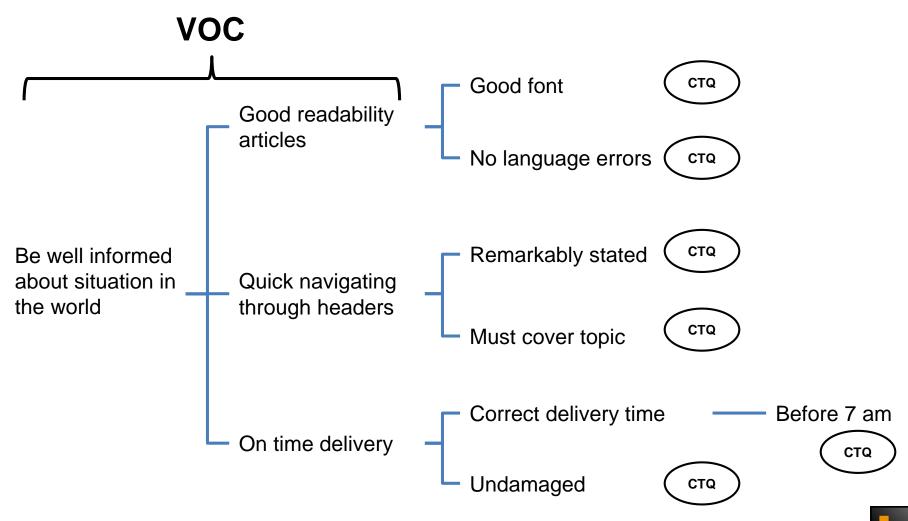
 CTQ flow down is a method of converting the Voice of the Customer into specific features for a service or product which have a significant impact on the Customer Experience

Need Aspects (CTQs) Measurable characteristic Voice of Characteristic Quality CTQ 1 Discrete Measurement Customer Targets (VOC) Time Spec limits **CTQ 2 Continuous** Capability goals Cost Voice of Design **CTQ 3 Critical factor** specification **Business**  Verification ....... (VOB) methods Verification criteria's Pass or fail

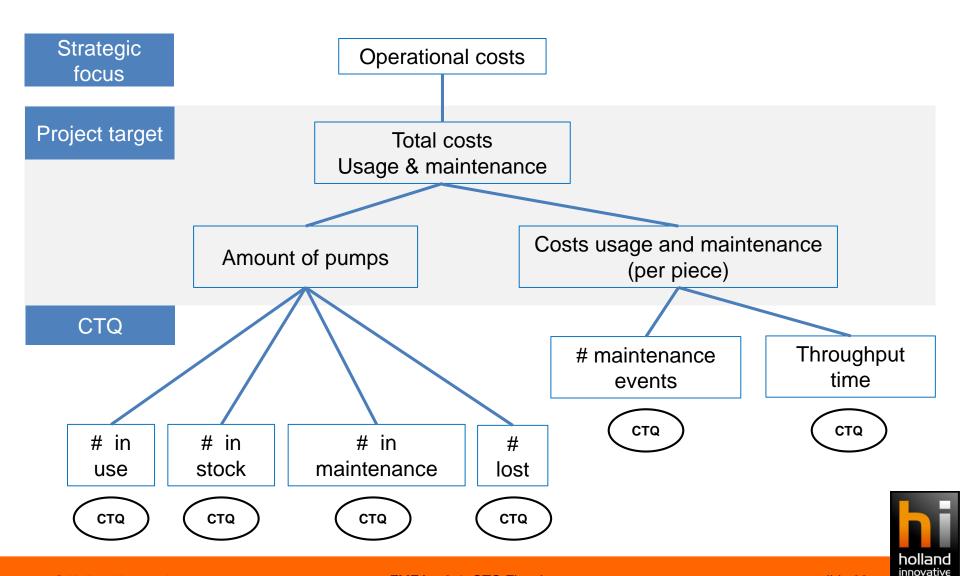
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© Holland Innovative CTQ Flow Down

### CTQ example – newspaper subscriber



### CTQ example – infusion pumps



# Measurement System Analysis

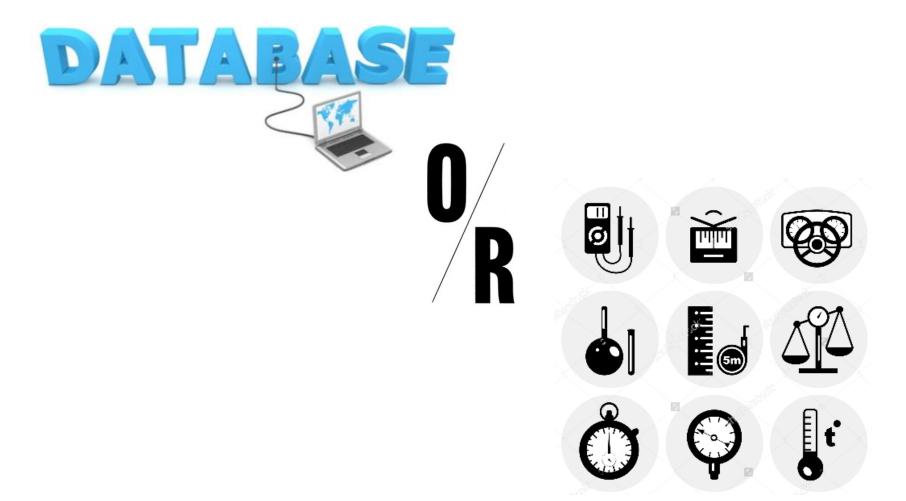


# If you cannot measure, you cannot improve!

"Taguchi"



# Where is Data coming from?





## Validity of Measurement System

- Do the measurements reflect the property that we think to measure?
- Do disturbing factors make the measurement results invalid?







#### **Measurement Devices**



## **Terminology - Gage**

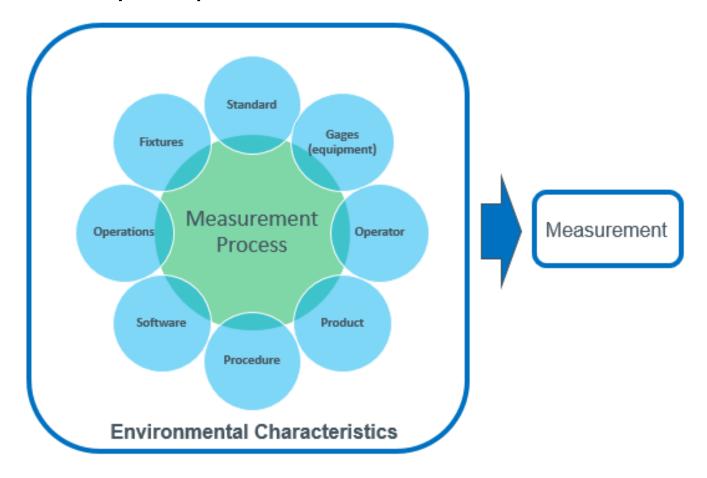
"Gage is any device used to obtain measurements\*"





# Terminology – Measurement System

"The complete process used to obtain measurements\*"



<sup>\*</sup> Measurement System Analysis, Reference Manual, 4th edition



#### **Process of Measurement**

- Too many business problems are analyzed with data that is known to be suspect.
- Just as a process has inherent variation, the process of measurement has variation too.
- Process variation observed comprises of the true process variation and the measurement variation.
- When unaware, we face the risk of making a poor decision.



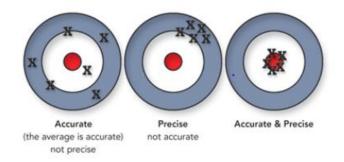


#### What is a MSA?

 Measurement System Analysis (MSA), is a designed experiment to determine the amount of variation contributed by the measurement system.

#### Objective:

- Confirm that the measurement system used to collect the data is valid (fit for use)
- Minimize the measurement system variation,
- And its impact on the total variation so the amount of process variation can be understood as precisely as possible





#### **Sources of Variation**

- Observed variation is the sum of all variation-sources:
  - Part-to-Part variation
  - Measurement system variation
- If measurement system variation is large compared to the total observed variation

#### then

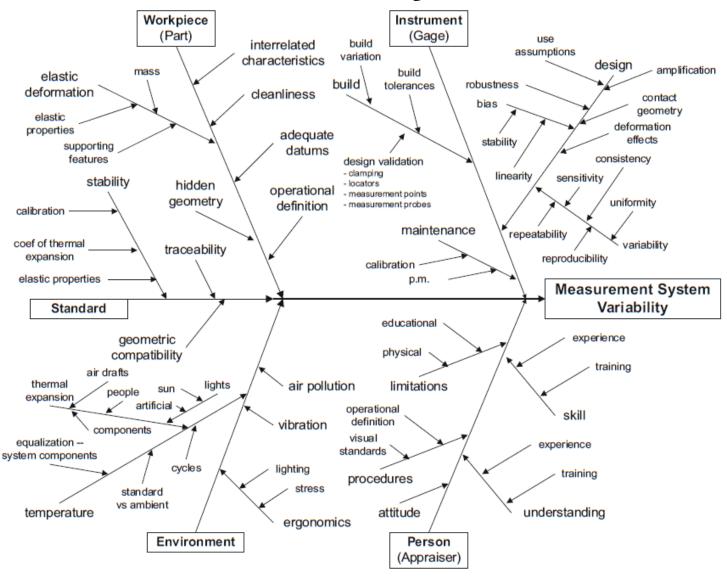
- your measurements will not tell much about process quality
- It is not possible to distinguish between part-to-part variation and measurement system variation
- you cannot predict if your customer will get satisfactory products.



# "Measurement variation is often the biggest source of variation"



# **Sources of Variability**





#### All MSAs involve:

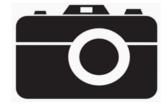
Measuring equipment (gage):











Items / parts being measured:











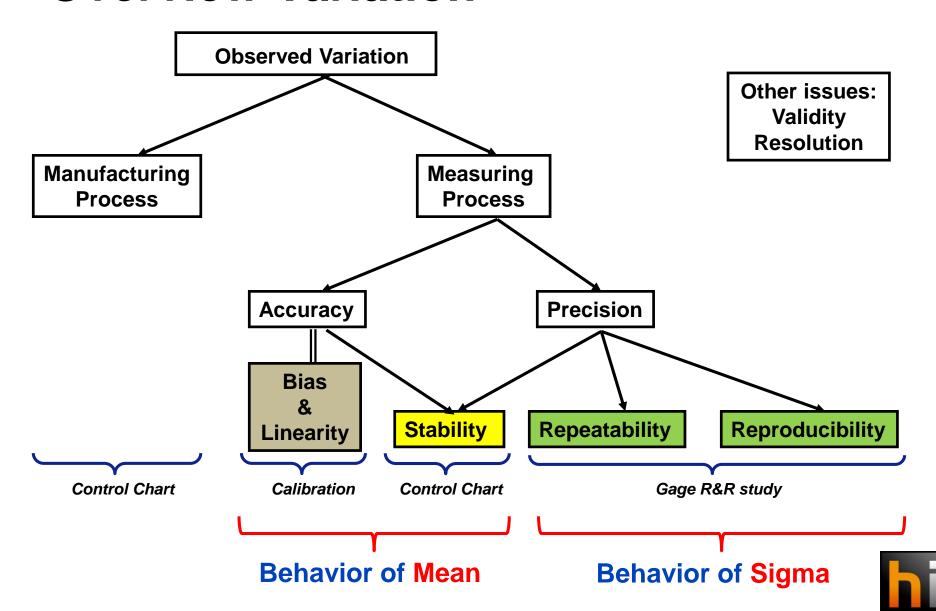
Appraisers (testers):





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#### **Overview Variation**



#### Measurement System Evaluation - GR&R

#### **Purpose**

 To check whether your measurement system and measurement process is accurate, repeatable and reproducible enough in relation to the specifications of the CTQ to be measured.

#### **Activities**

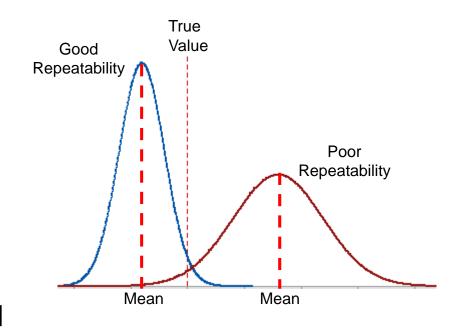
 Repeatability and Reproducibility evaluation, also called a GR&R, Gage Repeatability & Reproducibility, is to be executed by repeatedly measuring CTQs by different operators. Several other WoWs are possible for destructive measurements, or discrete measurements.

#### Results

- A quantitative analysis, which percentage of variation measured can be attributed to the measurement system and its operators.
- A statement whether the measured data can be trusted.
- A statement whether the measurement system needs improvement.

## Repeatability

- Repeatability is measurement error obtained when one operator (one appraiser) repeats measurement with same gage on same part. (All variation sources are identical)
- This variation can be caused by operator and/or gage under assumption that <u>part</u> <u>does not change</u>!!! (nondestructive measurement)
- "Gage R&R study" investigates this variation



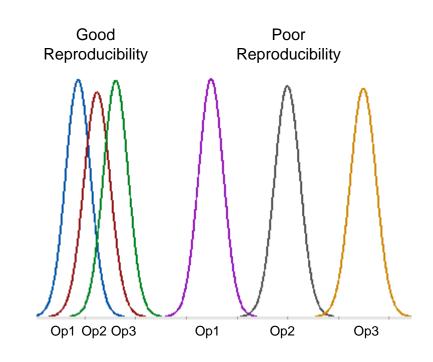
Repeatability: Differences in the values determined if one person measures the same characteristic on one and the same part on a number of occasions using the same measuring device.

Repeatability generally depends on the design of the measuring device.



## Reproducibility

- Reproducibility is measurement error obtained when different operators (appraisers) reproduce measurement with same gage on same part. (One variation source is changed!!)
- This variation can be caused by operator and/or gage under assumption that <u>part does not</u> <u>change</u>!!! (non-destructive measurement)
- "Gage R&R study" is used to investigate this variation



Reproducibility: Difference between the average measured values determined with the same measuring device by different persons or at different locations if the same characteristic is measured on the same part.

# Risk Analysis





# Why Risk analyses?



#### **Need for FMEA**

# Failure Mode and Effects Analysis is the key tool that supports high Reliability, ensures Safety and achieves Customer Satisfaction

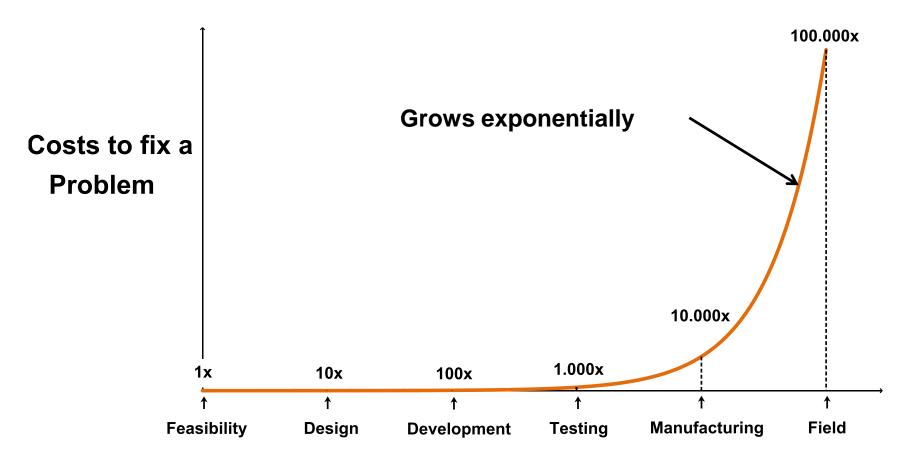
- It is required by standards...
- It is required by customers...
- It is required by your company ...

But most of all ...

Benefit for you and your company!



#### The factor of 10 rule



**Product Development Process** 



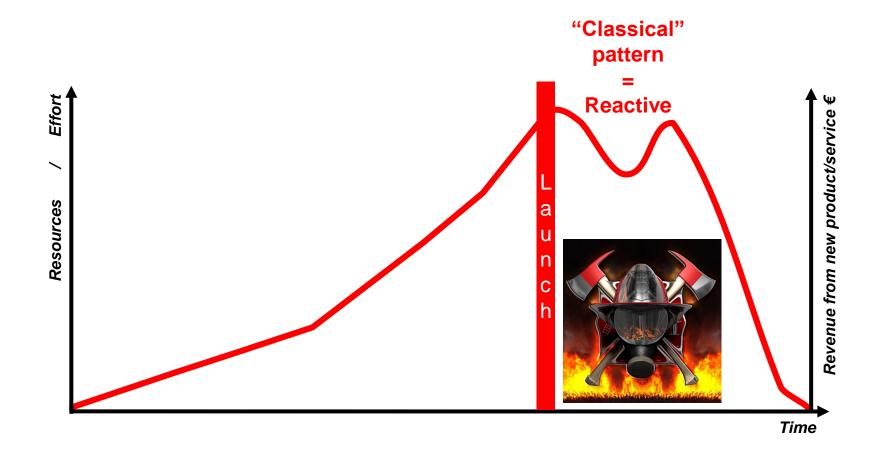
© Holland Innovative FMEA - 1-1: Introduction slide 54

#### Other benefits

- Effective FMEA studies are powerful tools that benefit the organization, customers, and end users by:
  - Improving Yield and profit margins
  - Reducing time to market
  - Increasing machine and human resource availability
  - Ensuring employee and customer safety
  - Identifying necessary controls and developing test procedures
  - Supporting due diligence claims in legal disputes



#### Reactive = after the fact



Firefighting close to launch and after-launch



# Some after-the-fact 'firefighting'



Space Shuttle Challenger Explosion (Jan. 28<sup>th</sup> 1986)

O-ring seals used in a joint were not designed to handle the unusually cold conditions



Deep Water Horizon Explosion (April 20<sup>th</sup> 2010)

Fail-safe on seabed wellhead (blowout preventer) was unable to close due to presence of off-centre drill pipe



Samsung – Galaxy Note 7 Battery fire (2016)

Weakened separator between electrodes causing short circuit (2.5 million phones affected)



## Typical FMEA frustrations....











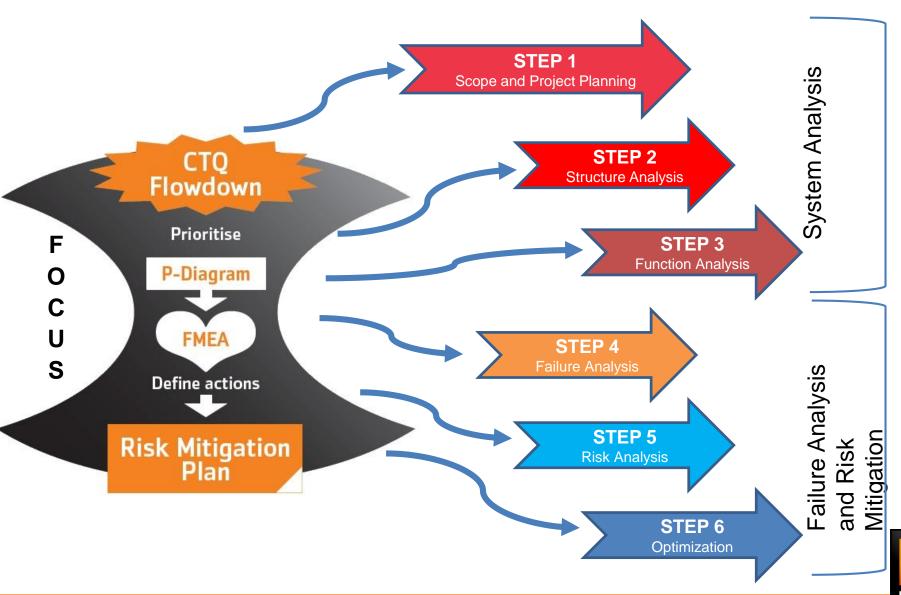


**Too many participants** 





## Proactive approach





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# 1<sup>st</sup> Step: Scope Definition

Important points in the scope steps are:



#### 5T's

#### **FMEA Team**

- Who needs to be on the team?

#### **FMEA Timing**

- When is this due?

#### FMEA InTent

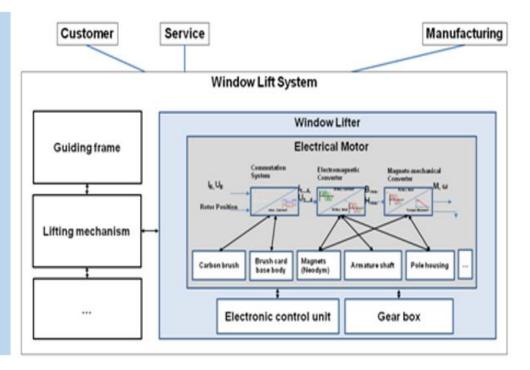
- Why are we here?

#### FMEA Tool

- How do we conduct the analysis?

#### **FMEA Task**

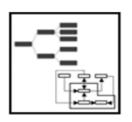
- What work needs to be done?



Five T's

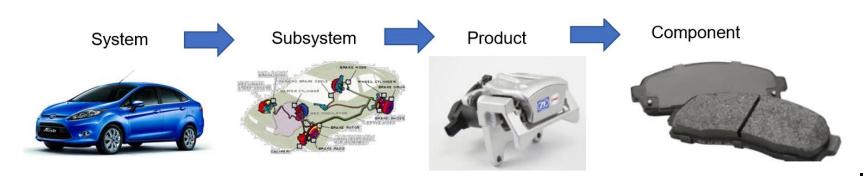
Block Diagram





# 2<sup>nd</sup> Step: Structure Analysis

- The Structure Analysis transfers the information gathered in the scoping step to visualize the relationships and interactions between the design or process elements
- The structure analysis is the basis for the next step (function analysis)







# 3<sup>rd</sup> Step: Function Analysis

 In this step the functionality of the product or processes are ensured by allocating a description of the activities, purposes or tasks intended for the product performance.



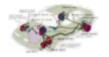
Vehicle:

Safe Stop

passengers







Subsystem





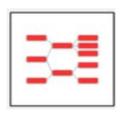






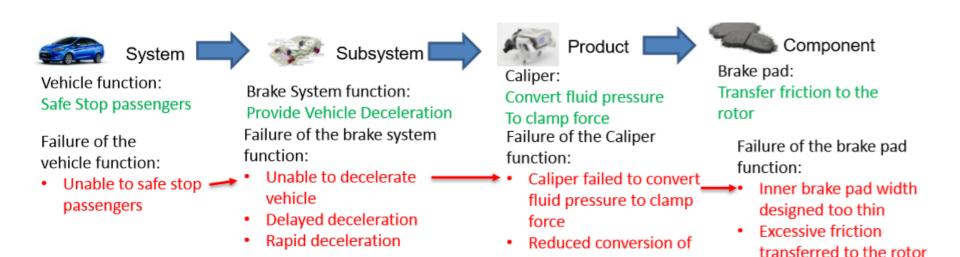
Caliper: Convert fluid pressure to clamp force Brake pad: Transfer friction to the rotor





# 4<sup>th</sup> Step: Failure Analysis

- The failures of the functions are deducted from the functions already identified in step # 3.
- Step # 4 is to identify failure causes, modes, and effects, and show their relationships to enable risk assessment.



pressure to clamp force



# 5<sup>th</sup> Step: Risk Analysis

- In this step prevention and detection controls are assigned, as well as the rankings for severity, occurrence and detection
- Risk Priority Number is calculated and decided when to take action

   action prioritization.



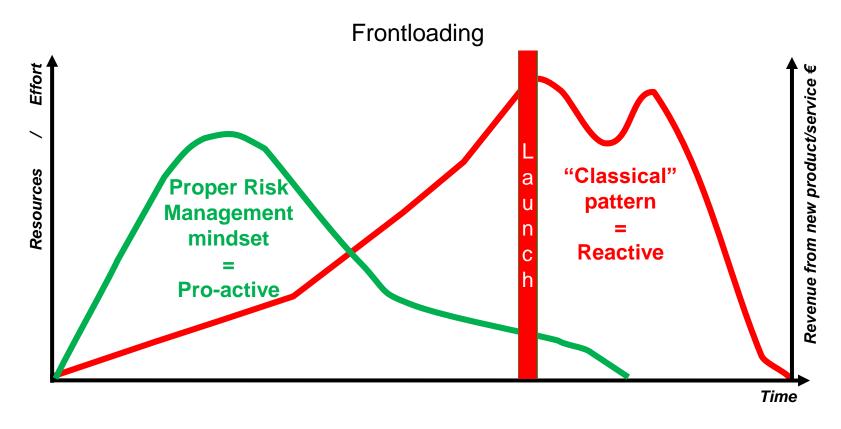


# 6<sup>th</sup> Step: Optimization

- The primary objective of optimization is to develop actions that reduce risk and increase customer satisfaction by improving the design or process.
- The FMEA can be used as the basis for continuous improvement for design or process.



## **Frontloading**



Stay ahead of the game!



- On time!
- Less time pressure!
- Better involvement!



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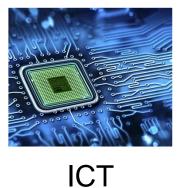
# **Applications**



Aerospace



Energy





**Transport** 



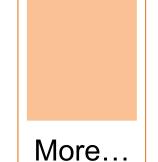
Medical



**Automotive** 



**Production** 





# Why utilize Lean Six Sigma?



## Why Lean Six Sigma?

- Unlike industry, where a defective product can be rejected without any problem, in healthcare defects and rework directly affect the patient and therefore, the patient's perception of quality.
- Decisions are often based on assumptions and feelings and on inaccurate and incomplete information.
- Utilising Lean Six Sigma personnel can take responsibility and provide management with solutions based on facts and data.



#### Why Lean Six Sigma

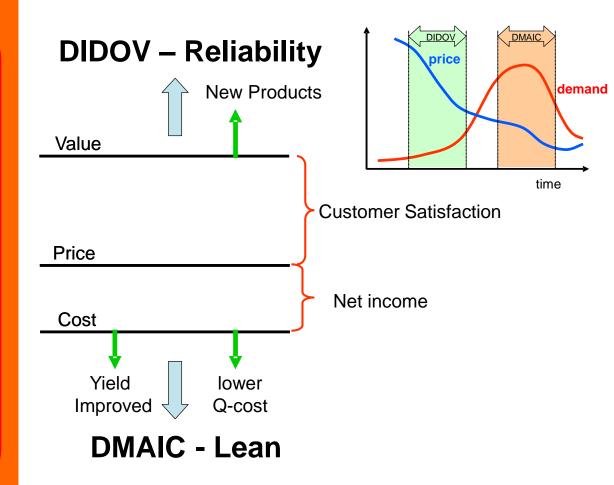
- Progress of LSS projects is very easy to manage due to the uniformity of the project approach in 12 steps and well defined outcomes.
  - This transparency has proven to be a very powerful management tool.
  - It limits developing each and every time a project approach, project documentation, planning, etc.



## (Design for) Six Sigma Benefits

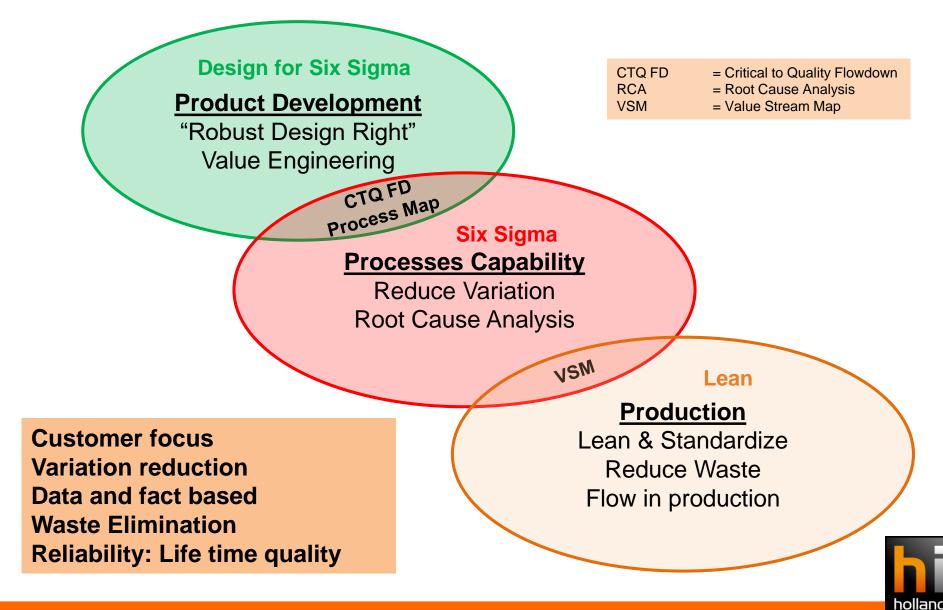
#### **Benefits**

- Value creation by Customer focus
- Capable processes
- Quality products meeting Customer Expectation
- Knowledge building by fact based and structured way of working
- Awareness of design rules & risk management
- Focus: Robustness, error proneness and tolerance
- Shorter time to market





## **Overview of Six Sigma Methods**



#### Potential area's to improve\*

- Shortening the length of stay of patients
  - Reducing admission time
  - Analysing full content of a clinical pathway
  - Potential result:
    - Positive net effect on budget
    - More patients can be admitted using the same capacity
    - Optimal usage of available bed capacity
- Minimising the use of materials and devices
  - Intravenous medication change to oral medication at the earliest possible moment
  - Reducing the number of intravenous pumps by pooling



<sup>\*</sup> Van den Heuvel, J., Does, R.J.M.M and Verver, J.P.S (2005) 'Six Sigma in healthcare: Lessons learned from a hospital'

#### Potential area's to improve\*

- Optimising the use of available capacities
  - Optimising capacity of the operating theatre
  - Optimising the use of costly diagnostic scanners such are MRI and CT
- Improving cash flow
  - Reducing accounts receivable
  - Revision of terms of payment
- Additional benefits apart from financial benefits linked to the quality of healthcare and directly affect the patient:
  - Shorter waiting lists
  - Elimination of unnecessary examinations
  - Reducing number of complications

holland

<sup>\*</sup> Van den Heuvel, J., Does, R.J.M.M and Verver, J.P.S (2005) 'Six Sigma in healthcare: Lessons learned from a hospital'

## **Example projects**



# Shortening the length of stay of gynaecology patients



## Background\*

- In The Netherlands, hospitals receive, as part of their budgets, a fixed amount of money for every admission.
   Therefore, reducing the length of stay of patients has a direct impact on the financial results of the hospital because more patients can be admitted.
- The objective of this project was to shorten the stay of gynaecologypatients who had to undergoan abdominal uterus extirpation (AUE) or a vaginal uterus extirpation (VUE).



#### **Define** 1. Define the CTQs (Critical To Quality charact.s) Measure 2. Validate measurement procedures 3. Diagnose the current process **Analyze** 4. Identify potential influence factors 5. Establish the effect of influence factors **Improve** 6. Design improvement actions 7. Improve / design process control Control 8. Close the project



Define 1. Define # ical To Ouality charact.s) Measure Objective: Shorten stay of gynaecology patients **Analyze** Financial benefit estimation: € 57 800 Additional benefit: Reduction in waiting lists **Improve Project duration estimated: 6 month** Carried out by two Green Belts in training Control 8. Close the project

#### **Define**

Measure

- 1. Define the CTQs (Critical To Quality charact.s)
- 2. Validate measurement procedures

Project objectives are translated into measurable and quantitative metrics

"You cannot improve what you cannot measure"

Control

- 7. Improve / design process control
- 8. Close the project



- CTQ characteristic is the length of stay of patients with AUE or VUE. This CTQ was defined as the length of the stay measured in days.
- Only patients who had to undergo an AUE or VUE were included.
- The measurement of the length of stay by means of the computer system had to be validated. This was done by comparing the length of stay measuring 30 patient dossiers.
- There were no differences found in this sample. Based on these observations we concluded that the measurement system was valid.

#### **Define**

Measure

- 1. Define the CTQs (Critical To Quality charact.s)
- 2. Validate measurement procedures

- 3. Diagnose the current process
- Analyze 4. Identify potential influence factors

Attempts at improvement should be preceded by a data-based diagnosis "What is the nature of the main bottleneck?"

<del>o. ciose the project</del>



- Data for one year was used.
- There appeared to be a few outliers, which were analyses and excluded from the data by performing capability analysis.
- The average stay of patients with VUE or AUE was 7 days, and the standard deviation was 2 days.
- Factors influencing the length of stay were listed by using a cause and effect diagram and a failure mode and effect analysis (FMEA)



#### **Define** The effectiveness of proposed interventions must be demonstrated: **Evidence-based intervention** "In God we trust, all others must bring data" 5. Establish the effect of influence factors **Improve** 6. Design improvement actions 7. Improve / design process control Control 8. Close the project



- The most relevant factors influencing the length of the stay were found to be:
  - Treatment protocols of patients; and
  - Situation at home, i.e. whether there are relatives who can take care of the patients after discharge.
- The most fruitful improvements were:
  - An out-patient clinic to prepare the patient for the operation (this action reduces the length of stay of patients by one day);
  - Improved protocols;
  - Check on the situation at home and offer home care if needed; and
  - Information about the length of the stay given to the patient in advance



Structures for continued control and improvement of the process

"It takes all the running you can do to stay in the same place"

Previous suggested improvements were implemented and resulted in:

- The average length of stay reduced to 5.2 days
- The standard deviation reduced to 0.9 days

ovement actions

Control

- 7. Improve / design process control
- 8. Close the project



# Improving a CAT scan process



### **Background**

- CAT scan process in a hospital
- Objectives:
  - Capacity should be increased (current: 19 patients / day)
  - Lower costs.





#### **Define** 1. Define the CTQs (Critical To Quality charact.s) Measure 2. Validate measurement procedures 3. Diagnose the current process **Analyze** 4. Identify potential influence factors 5. Establish the effect of influence factors **Improve** 6. Design improvement actions 7. Improve / design process control **Control** 8. Close the project

#### **Define**

Measure

- 1. Define the CTQs (Critical To Quality charact.s)
- 2. Validate measurement procedures

**Analyze** 

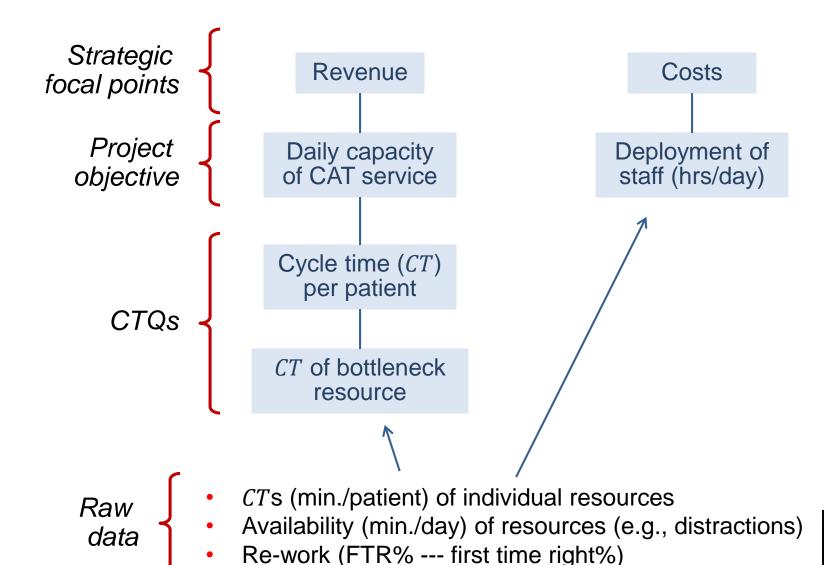
the current process

Project objectives are translated into measurable and quantitative metrics "You cannot improve what you cannot measure"

**Control** 

- 7. Improve / design process control
- 8. Close the project

## **CAT-scan example:** *DMAIC*



#### **Define**

#### Measure

- 1. Define the CTQs (Critical To Quality charact.s)
- 2. Validate measurement procedures

#### Analyze

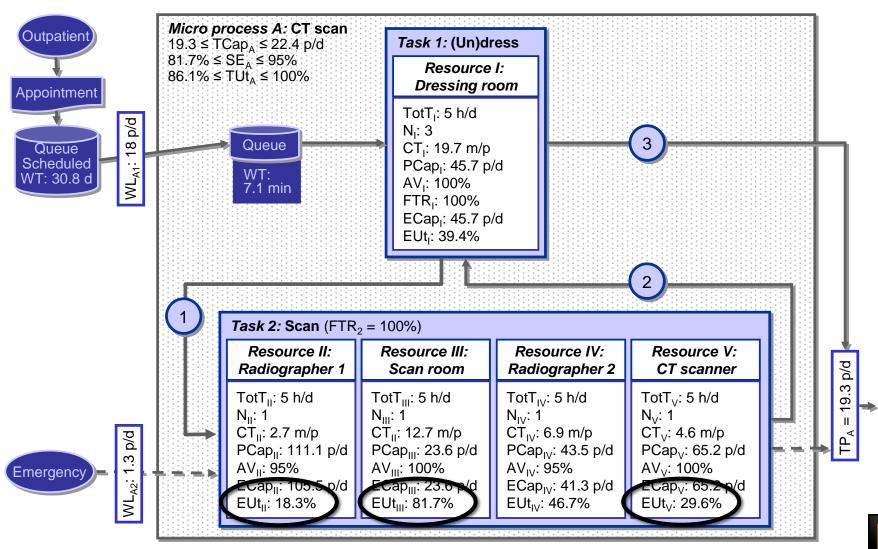
- 3. Diagnose the current process
- 4. Identify potential influence factors

the offeet of influence factors

Attempts at improvement should be preceded by a data-based diagnosis

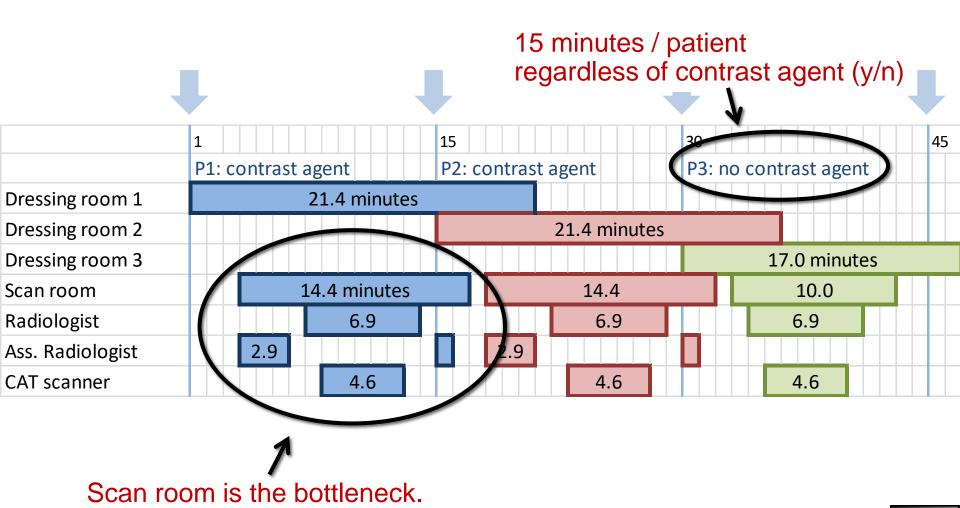
"What is the nature of the main bottleneck?"

## CAT-scan example: DMAIC



h/d = hours per day; m/p = minutes per patient; p/d = patients per day

#### CAT-scan example: DMAIC





Scan room cycle time: 14.4 min / patient.

Includes injection with contrast agent.

#### **Define**

The effectiveness of proposed interventions must be demonstrated:

ract.s)

**Evidence-based intervention** 

"In God we trust, all others must bring data"

**Improve** 

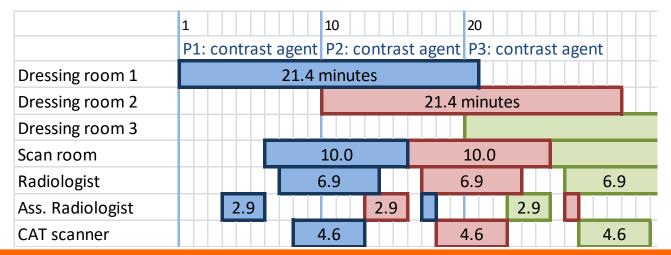
- 5. Establish the effect of influence factors
- 6. Design improvement actions

**Control** 

- 7. Improve / design process control
- 8. Close the project

## CAT-scan example: DMAIC

- The scan room is the bottleneck, so should be the focus:
  - Move tasks (injection) from the scan room elsewhere:
- Schedule patients without contrast agent in shorter time slot.
- Assist. Radiologist is not needed for patients without contrast agent
  - Schedule patients without contrast agent in one block; the assist. radiologist is not needed in this time slot.
- ⇒ Capacity from 19 to 30 patients / day.





#### **Define**

Measure

- 1. Define the CTQs (Critical To Quality charact.s)
- 2. Validate measurement procedures

Structures for continued control and improvement of the process

"It takes all the running you can do to stay in the same place"

Control

- 7. Improve / design process control
- 8. Close the project

### Summary

- Focus on: Variation & Waste
- How?
  - Measure data with adequate measurement method -> Performance
  - Aquire customer requirements
- Performance + Requirements = potential performane gap
- Which could be the start of an improvement event
- Choose any method.....
  - Lean
  - Six Sigma
  - Design for Six Sigma
  - 8D
  - \_\_\_\_\_



# **Appendix**



## Exercise – letter "f" counting

The necessity of training farm hands for first class farms in the fatherly handling of farm livestock is foremost in the eyes of farm owners. Since the forefathers of the farm owners trained the farm hands for first class farms in the fatherly handling of farm livestock, the farm owners feel they should carry on with the family tradition of training farm hands of first class farmers in the fatherly handling of farm livestock because they believe it is the basis of good fundamental farm management.



