SVCE

Sri Venkateswara College of Engineering

Autonomous - Affiliated to Anna University

ME 18015 – Lean six sigma

OBJECTIVES & OUTCOMES

OBJECTIVES:

- To impart knowledge on the Lean manufacturing concepts.
- To expertise in the implementation of lean metrics, VSM and all lean assessments.
- To gain knowledge on the six sigma principles, tools and its techniques.
- To inculcate the knowledge on the application of Six Sigma principles of three phases to improve the quality of process outputs.
- To induce a knowledge on the analyze and control the processes using six sigma concept.

OUTCOMES :

1. The students will understand the Lean Manufacturing concepts and related tools.
2. The students will implement the lean metrics, value stream mapping and all lean assessments.
3. The Students will be competent to apply the six sigma principles, tools and its techniques.
4. The Students will experiment the implementation of define, measure and analyze phases of six sigma methods.
5. The Students will determine the improve and control phases of six sigma

UNIT I LEAN MANUFACTURING **9**

Evolution of lean; traditional versus lean manufacturing; ford production system concept of lean; Toyota's foray in lean, Customer Need; lean tools- Process mapping value stream management- 3 M; 7 types of Muda; 7 major losses reduction. cell layout; line balancing; concept of kaizen; steps involved in kaizen deployment; kanban concepts; types of Kanban; and practical application; push vs pull; changeover time reduction - single minute exchange of die; concept of TPM; poka-yoke; 5S; maintenance - preventive, time based and condition based; autonomous maintenance, JIT, Autonomation, DFMA

UNIT II LEAN METRICS **9**

Identify lean metrics; kaizen cloud identification in VSM; lean assessment. improving targets and benchmarks.

UNIT III SIX SIGMA , TOOLS AND TECHNIQUES **9**

SIPCO,QFD; voice of the customer, kano models, , cost of poor quality (COPQ), statistical process control, DMAIC

UNIT IV SIX SIGMA DEFINE, MEASURE AND ANALYSE PHASE **9**

DMAIC phases, overview, project charter – voice of the customer – high level process map – project team – case study, types of measures – introduction to statistical methods – sampling plan – data collection – choosing statistical software – measure tools – process maps, pareto charts, cause and effect diagrams, histograms, six sigma measurements – measurement system analysis – process capability calculations. Analyze – process analysis – hypothesis testing – statistical tests and tables – tools for analyzing relationships among variables – survival analysis.

UNIT V IMPROVE AND CONTROL PHASE **9**

Process redesign – generating improvement alternatives – design of experiments – pilot experiments – cost/benefit analysis – implementation plan. Control phase control plan – process scorecard – failure mode and effects analysis – final project report and documentation. DMADV, DFSS–six sigma in manufacturing and services case studies & Sustainability of Lean Six Sigma.

TOTAL : 45 PERIODS

Lean


1. Identify Customer Value
2. Map the Value Stream
3. Create Flow
4.Establish Pull
5. Seek Perfection
What is lean

Lean Philosophy

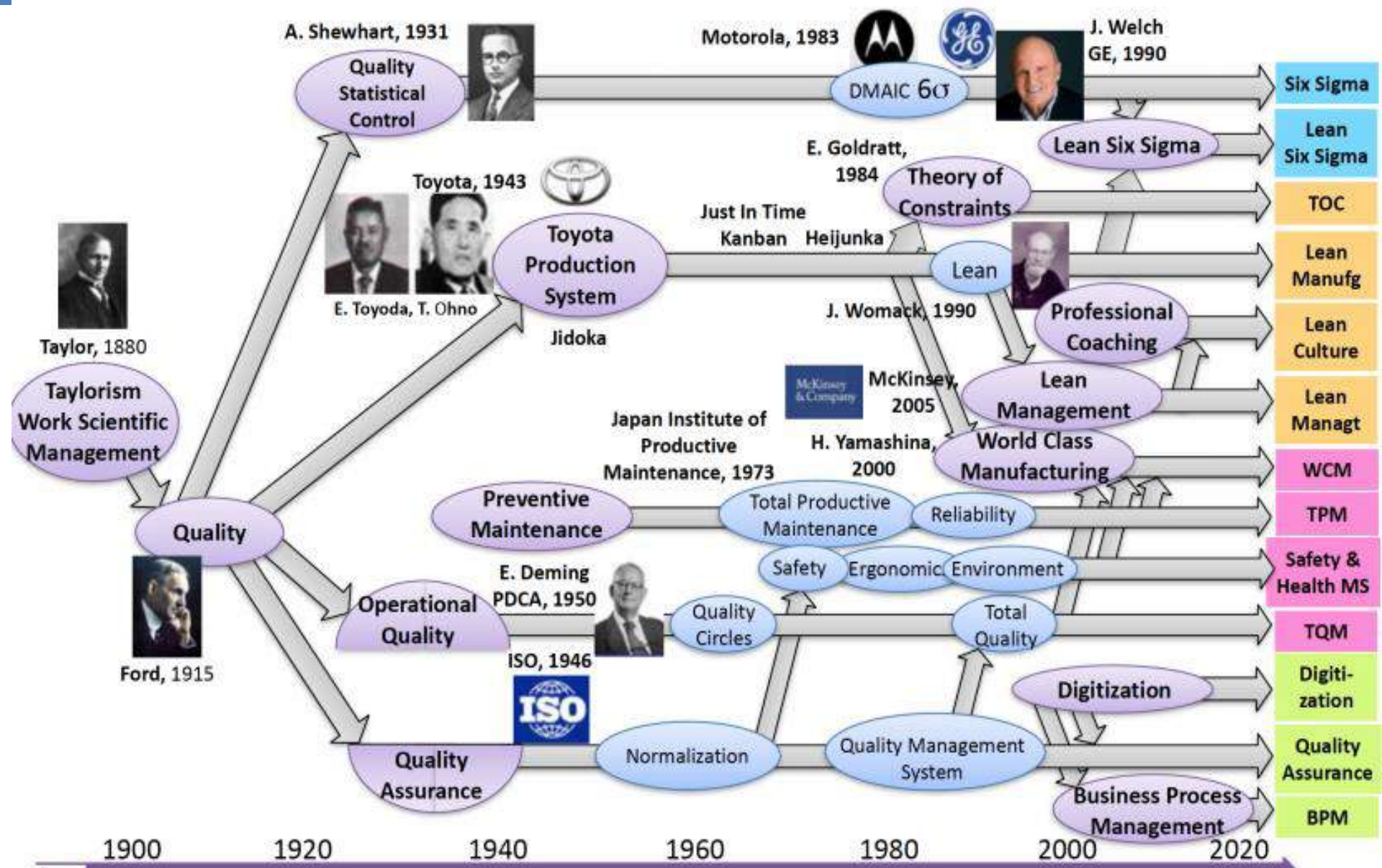
- Lean is a way of thinking. It it is all about continuous improvement with a focus on eliminating all forms of waste in a process.

"No Process can never be declared perfect, therefore there is always room for improvement"

Toyota Sakichi

A BRIEF -HOWEVER COMPLEX- HISTORY OF LEAN

Several branches & trends influence its evolution



Evolution of lean

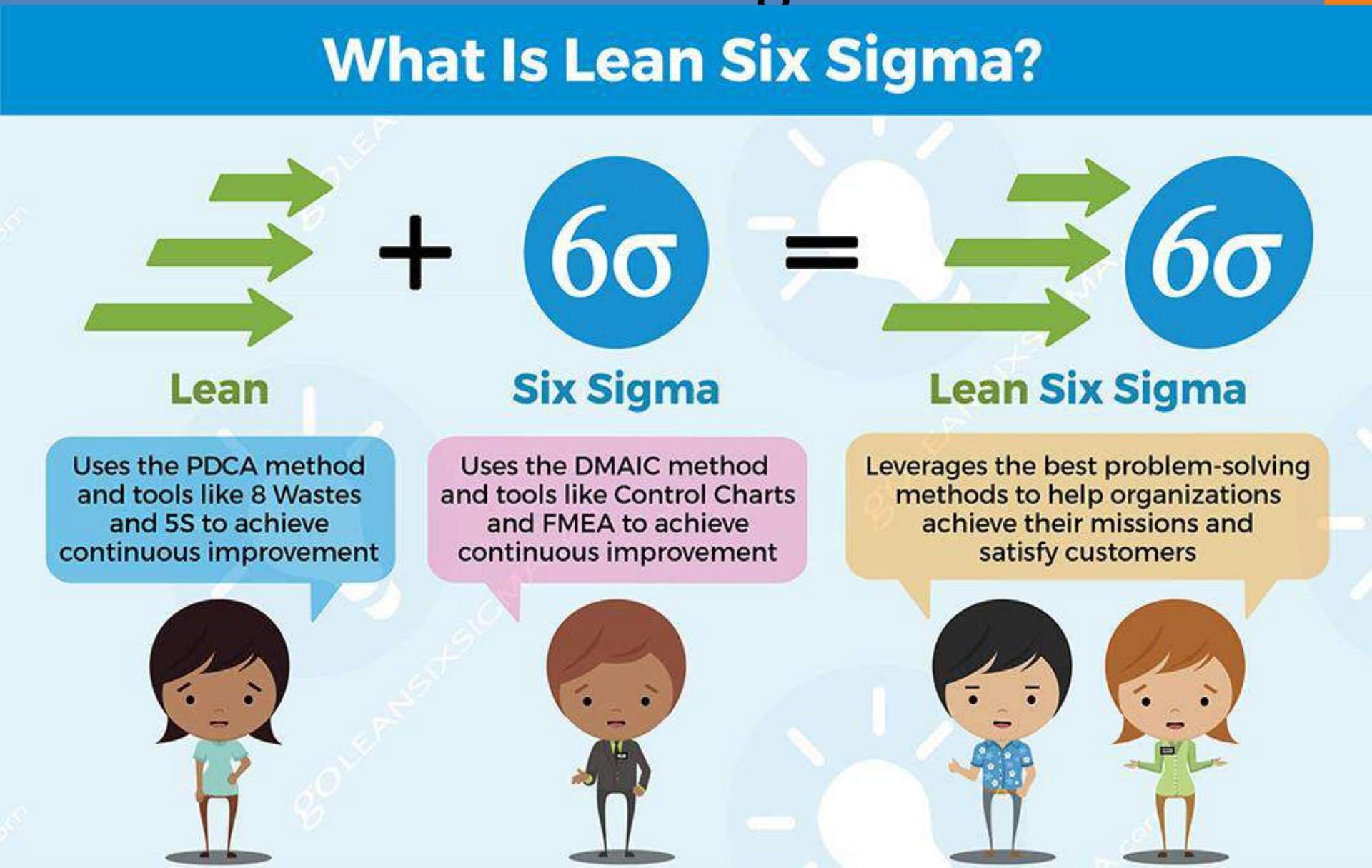
- Started out with Henry Ford's assembly line in the early 1900's. First person who continuously worked to make sure his process was as efficient as possible.
- Then shortly after WWII Taichi Ohno and Kiichiro Toyoda took aspects of Ford's work with new ideas for continuous improvement and created the Toyota Production System.

- It started in Japan at the Toyota Motor Company In 1902 Sakichi Toyoda, founder of the Toyota group, invented an automated loom that stopped anytime a thread broke.
- quality defects significantly decreased and one operator was able to monitor several machines at one time.
- Several decades later Taiichi Ohno, a production engineer at the Toyota Motor Company applied the same concept as he sought to eliminate waste, or non-value added activities, within the Toyota organization.
- In addition to stopping production at every defect (Jidoka), he employed another key concept, JIT (just in time). Together, Jidoka and JIT are the pillars of the Toyota Production System, supported by a foundation of Heijunka (level loading)

Lean Manufacturing

- Lean Manufacturing is all about making a product in the most efficient and effective manner, while looking for ways to continuously improve.
- Continuous Improvements:
  - Decrease Cycle Time
  - Eliminate sources of waste in a process
  - Increase Throughout

Difference between Lean, Six Sigma & Lean Six Sigma



TRADITIONAL VS LEAN

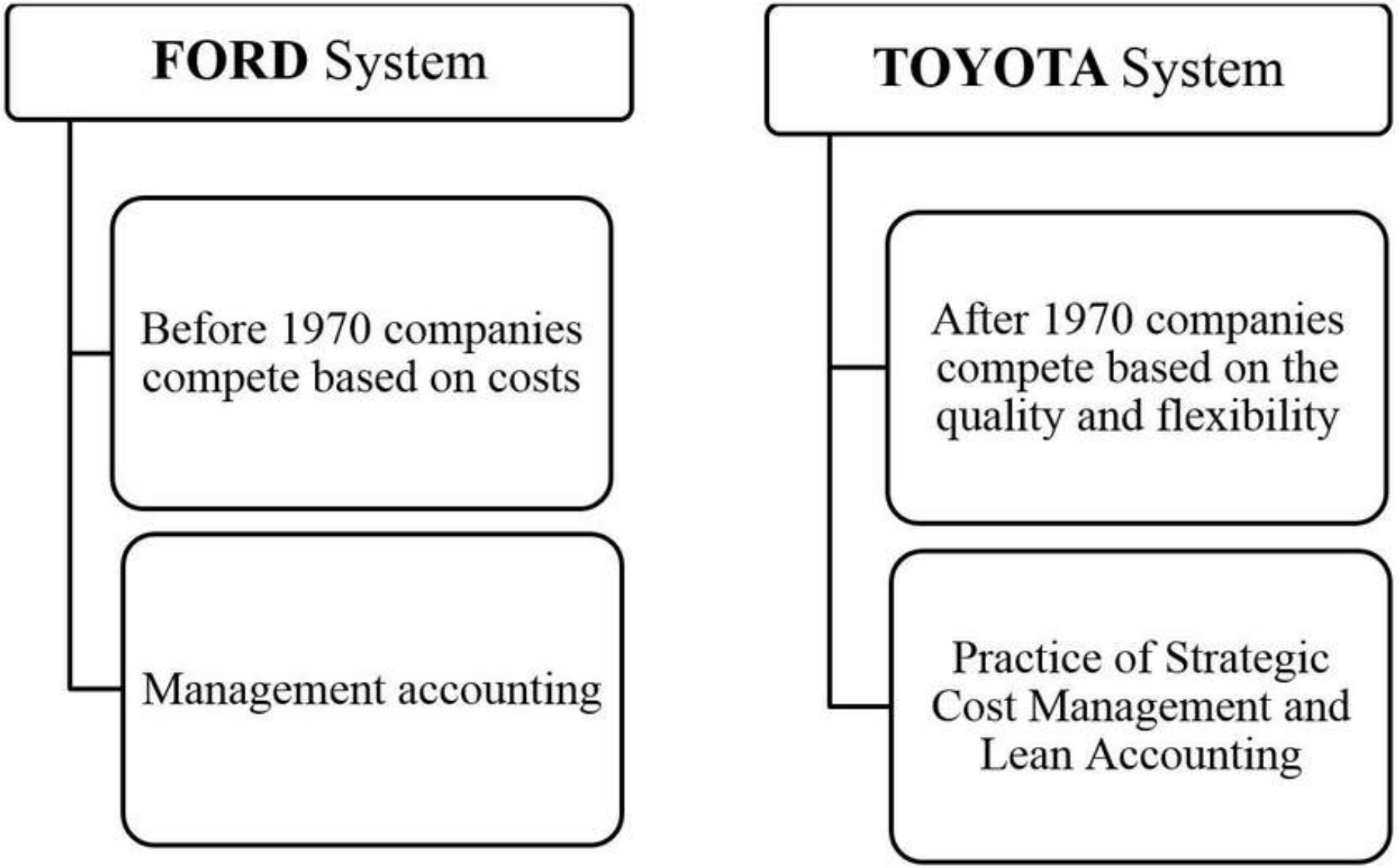
Comparing Lean and Traditional Manufacturing (Table 2)	
Lean	**Traditional Manufacturing**
People: • Clusters of employees working in teams • Extensive, continuing training	**People:** • Employees contribute minimally to total product • Training for limited skills • Management makes decisions
Products: • Focused on internal/external customer	**Products:** • Standardized, focused on volume not quality
Work Environment: • Some discretion, group effectiveness, empowerment, team accountability, and work cells	**Work Environment:** • Limited skills and knowledge • Repetitive, mind-numbing work • Little discretion, simplified tasks

Source: Adapted from National Institute of Standards and Technology Manufacturing Extension Partnership "History of Manufacturing" Table.

MANUFACTURING COMPARISON

	Craft	Mass	Lean
Workforce	Highly skilled	Unskilled; interchangeable	Multi-skilled teams
Operations	Single item	Batch and queue	Synchronized flow and pull
Tools	Flexible tools	Single purpose machines	Flexible machines
Outcome	Low productivity, high quality, high cost	High productivity, low quality, medium cost	High productivity, high quality, low cost

FORD & TPS


FORD System
Before 1970 companies compete based on costs
Management accounting
TOYOTA System
After 1970 companies compete based on the quality and flexibility
Practice of Strategic Cost Management and Lean Accounting

FORD PRODUCTION SYSTEM

Areas where Ford established the baseline for the Lean and Six Sigma techniques to come.

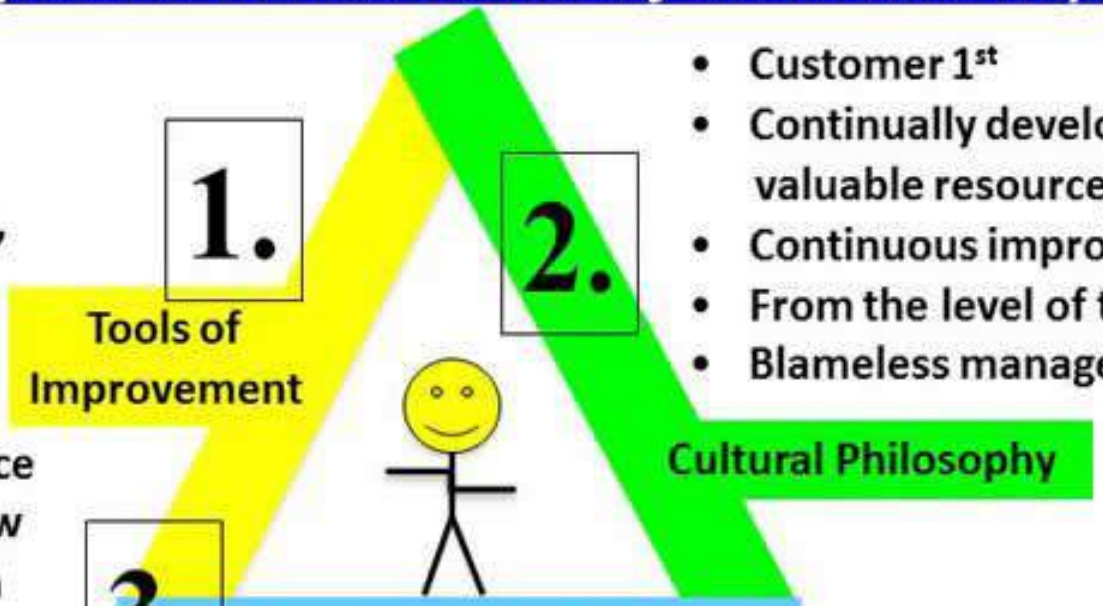
- **Standardization**
- **High Wages**
- **Wasted Movement**
- **Wasted Materials**
- **Just-in-Time Manufacturing**

MODEL T

Limitation: His processes, while revolutionary, did not allow for the types of variations that modern businesses require.

Henry Ford Production System

Integrated Systems Achieve Culture of Continuous Improvement



- Standard Work, Connections, Pathways
- 5S
- Visual workplace
- Continuous flow
- Pull production
- Kanban
- Just in Time
- Load leveling
- Batch size
- Mistake proof

- Customer 1st
- Continually develop your most valuable resource, your PEOPLE
- Continuous improvement
- From the level of the work
- Blameless management

3. Management SubSystems

- Hoshin Planning/Policy deployment
- Team leader system
- Improvement management- PDCA (kata)
- Coaching and human development (kata)
- Deviation management
- Daily management
- Document management
- Audit system
- Management review system

TOYOTA'S LEAN

- TPS is based on two concepts: jidoka and just-in-time.
- Jidoka, a Japanese term that can be translated as "automation with a human touch"
- Just-in-time is about refining and co-ordinating each production process so that it only produces what is required by the next process in the sequence.

TPS

To identify and reduce three primary obstacles or deviations from optimal allocation of resources within the system

- Overburden (muri)
- Inconsistency (mura)
- Waste (muda)

TPS is grounded on two main conceptual pillars:

- Just-in-time

meaning “Making only what is needed, only when it is needed, and only in the amount that is needed”

- Jidoka (Autonomation)

meaning “Automation with a human touch

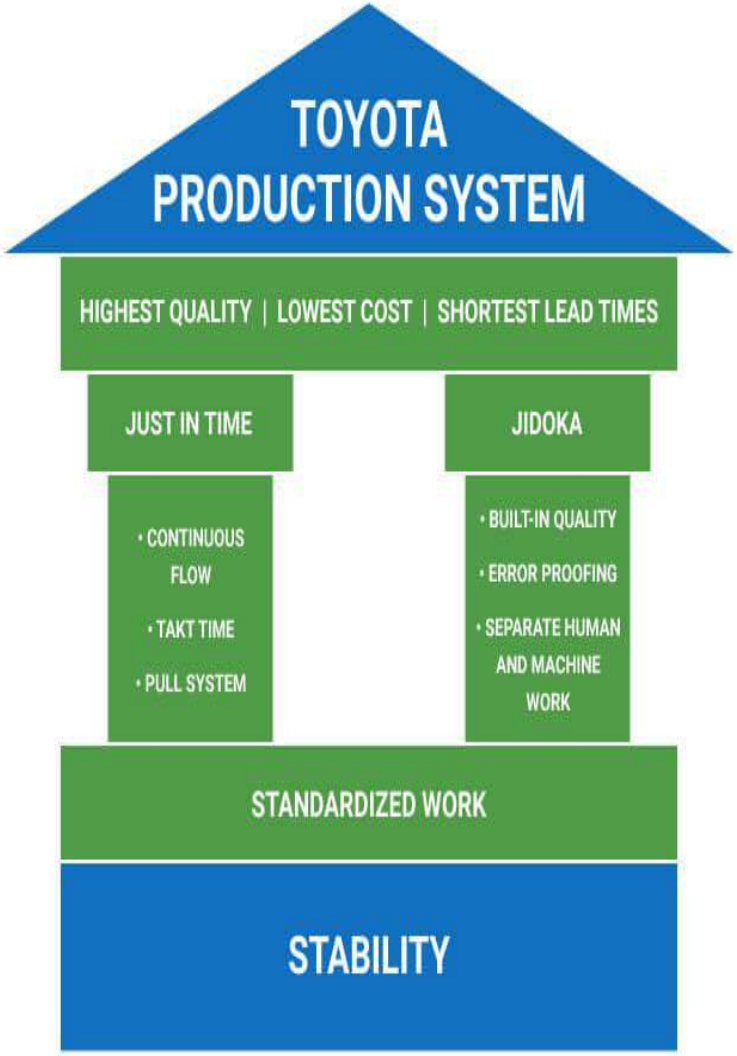
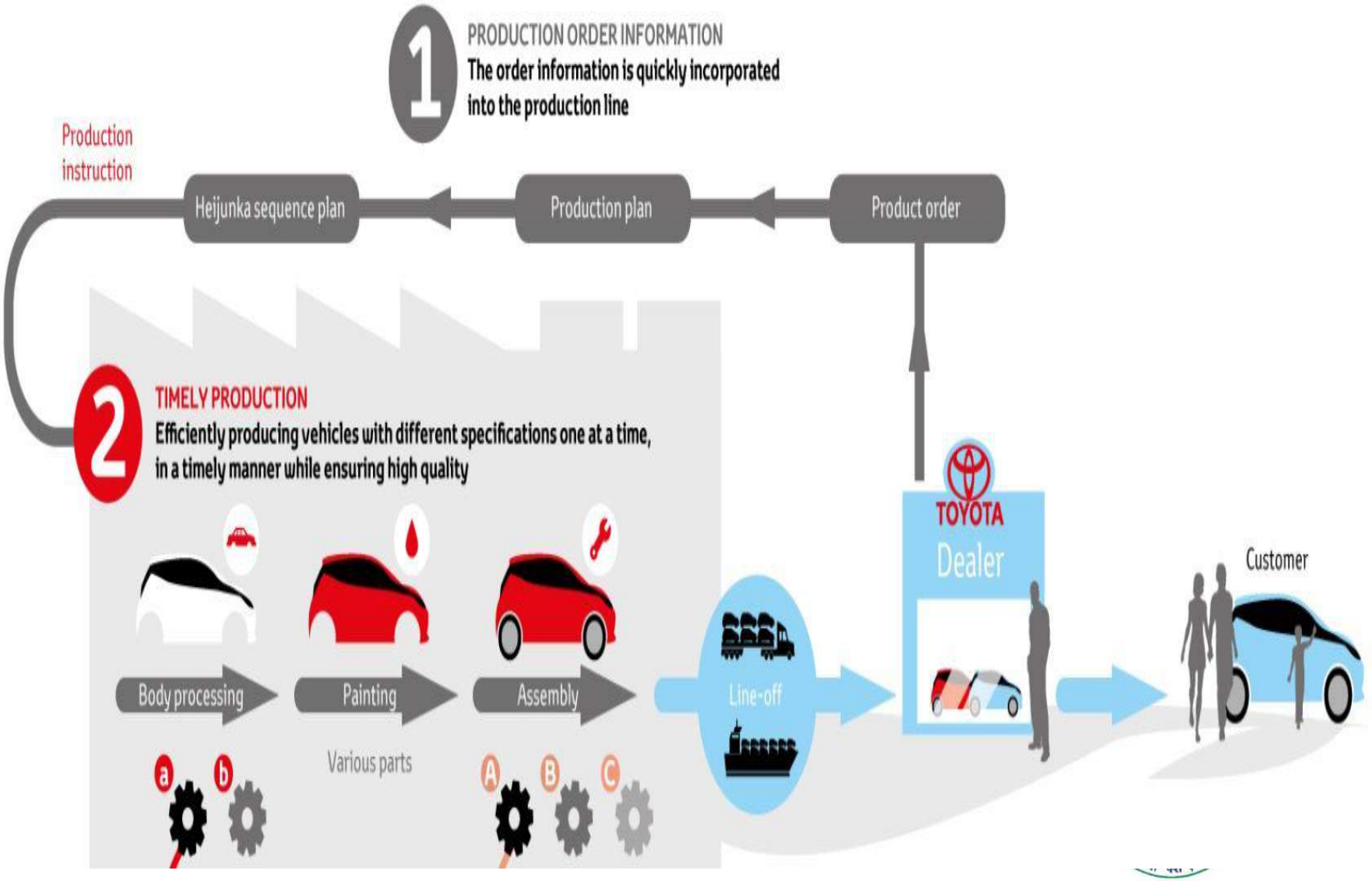


ILLUSTRATION OF THE TOYOTA PRODUCTION SYSTEM



4P model of Toyota

- **4P model - Philosophy, Process, People & Partners and Problem Solving.**

3 M's of Lean

- Muda, Mura, and Muri are terms often used together in the Toyota Production System (and called the Three Ms) that collectively describe wasteful practices to be eliminated.

MUDA

- Muda means wastefulness, uselessness and futility, which is contradicting value-addition
  - work that is necessary but not recognized by the customer as adding value
  - work that simply is not necessary.

The second type of Muda should be identified and eliminated

Muda's 7 wastes

DEFECTS

Waste from a product or service failure to meet customer expectations

OVERPRODUCTION

Waste from making more product than customers demand

WAITING

Waste from time spent waiting for the next process step to occur

UNUSED TALENT

Wastes due to underutilization of people's talents, skills, and knowledge

TRANSPORTATION

Wasted time, resources, and costs when unnecessarily moving products and materials

INVENTORY

Wastes resulting from excess products and materials that aren't processed

MOTION

Wasted time and effort related to unnecessary movements by people

EXTRA-PROCESSING

Wastes related to more work or higher quality than is required

MURA & MURI

- Mura means unevenness, non-uniformity, and irregularity.

  Ex: companies ramp up production to meet targets, even when there is no customer demand.

- Muri means overburden, beyond one's power, excessiveness, impossible or unreasonableness.
- Muri can result from Mura and in some cases be caused by excessive removal of Muda (waste) from the process

CASE STUDY

- A firm needs to transport six tons (with 2 different set of weights) of material to its customer and is considering its options. Capacity of one truck is of 3 tons.

Option 1

- One is to pile all six tons on one truck and make a single trip.
- But this would be muri because it would overburden the truck.
- Leads to breakdowns, which also would lead to muda and mura.

Muri = overburdened

Option 2

- A second option is to make two trips, one with four tons and the other with two.
- But this would be mura because the unevenness of materials arriving at the customer would create jam-ups on the receiving dock followed by

Mura = unevenness, fluctuation, variation

Option 3

- A third option is to load two tons on the truck and make three trips.
- But this would be muda, even if not mura and muri, because the truck would be only partially loaded on each trip.

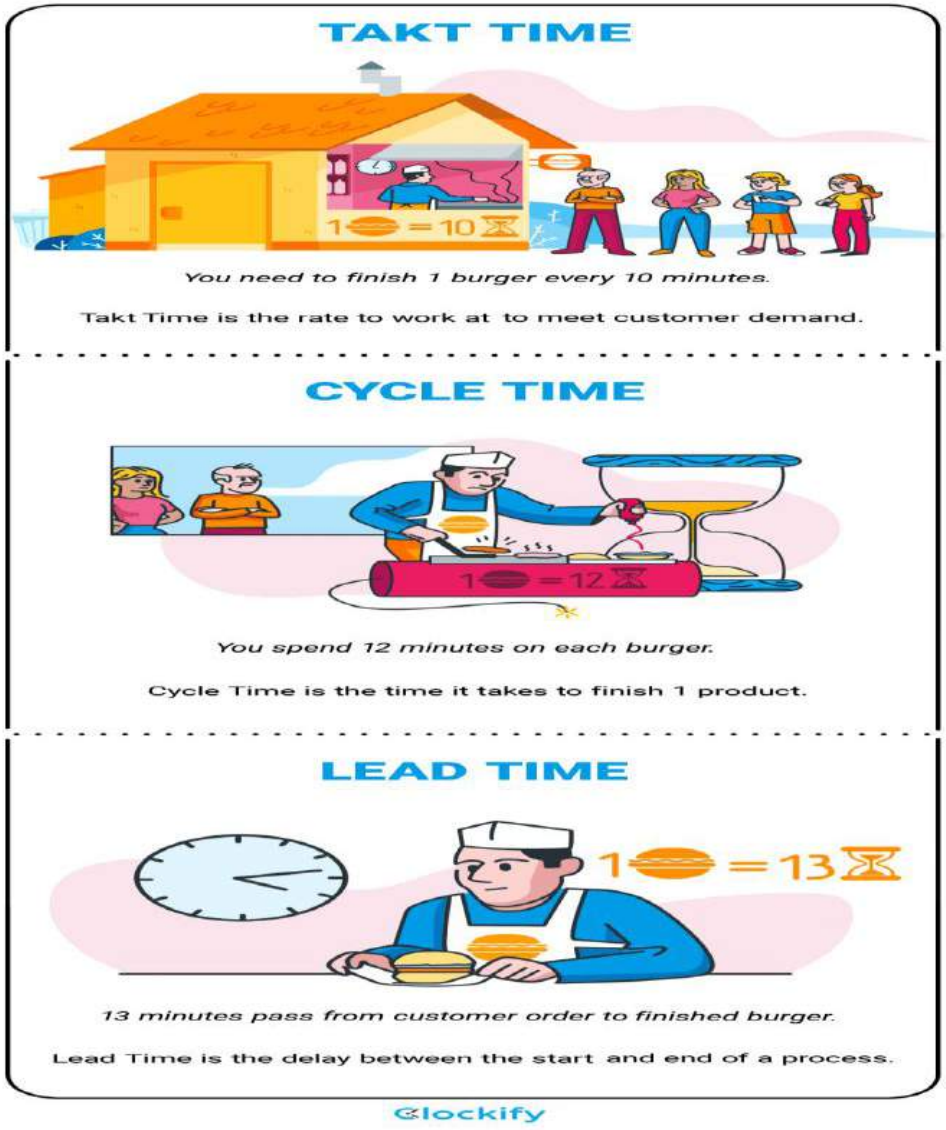
Muda = waste

OPTIMAL SOLUTION

- Muda does not exist because the trucks are carrying the loads at their maximum capacity.
- Mura does not exist because the workload between the two deliveries are uniform
- Muri is absent from this option because both the truck and the operators are not working beyond their capac

No Muri, Mura, or Muda

Cycle time vs Lead time vs Takt time

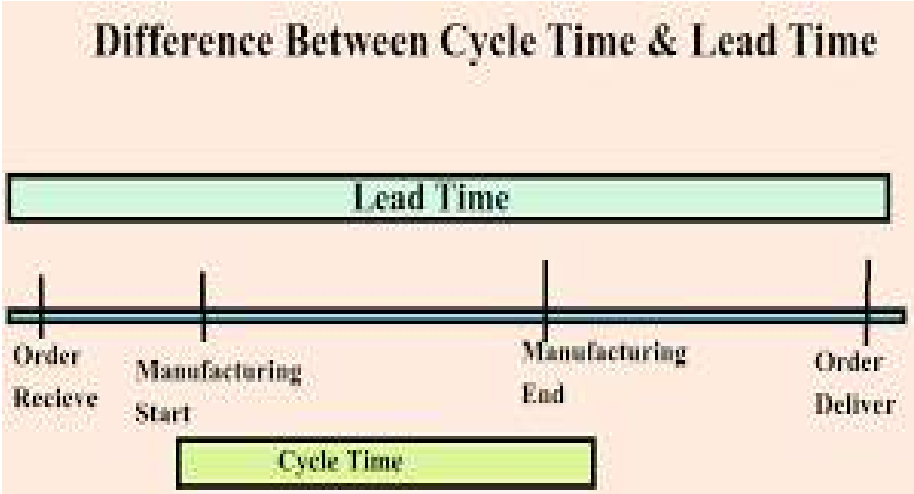


$$\text{Takt Time} = \frac{\text{Workable Production Hours}}{\text{Units Required (Customer Demand)}}$$

$$\text{Cycle Time} = \frac{\text{Net Production Time}}{\text{Number of Units Produced}}$$

$$\text{Lead Time} = \text{Order Delivered} - \text{Order Received}$$

machinemetrics



KANBAN

- The word kanban is Japanese and roughly translated means "**card you can see**."
- Toyota introduced and refined the use of kanban in a relay system to standardize the flow of parts in their just-in-time (JIT) production lines in the 1950s.

"A visual system used to manage and keep track of work as it moves through a process"

Kanban Card

Part Description				Part Number	
Smoke-shifter, left handed.				14613	
Qty	20	**Lead Time**	1 week	**Order Date**	9/3
Supplier	Acme Smoke-Shifter, LLC			**Due Date**	9/10
Planner	John R.	Card 1 of 2			
		Location	Rack 1B3		

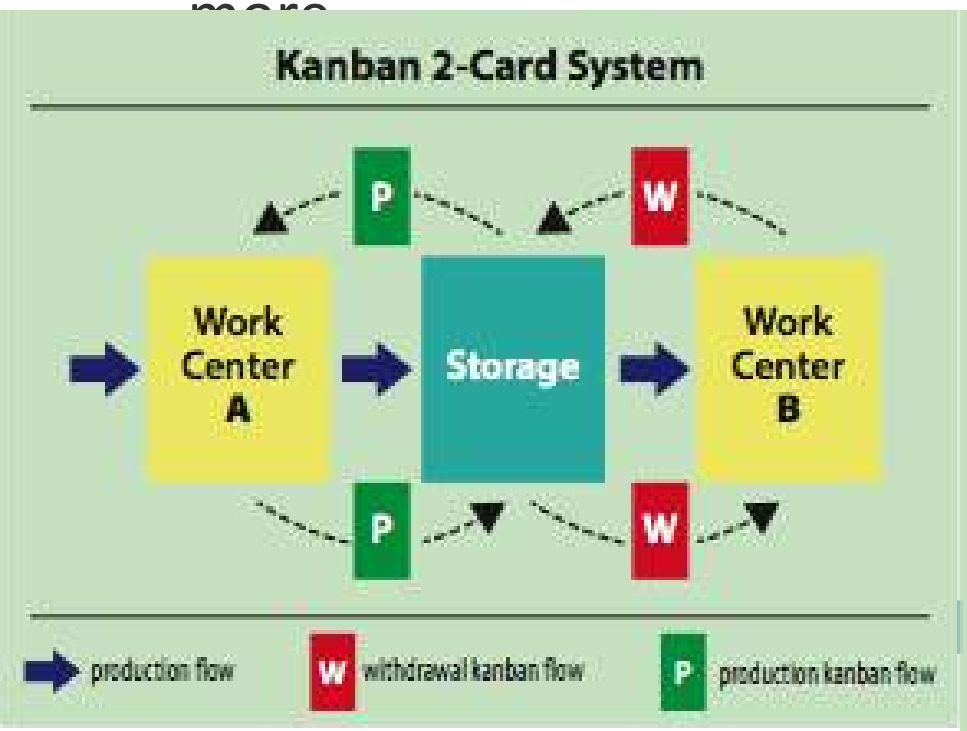
RULES FOR KANBAN

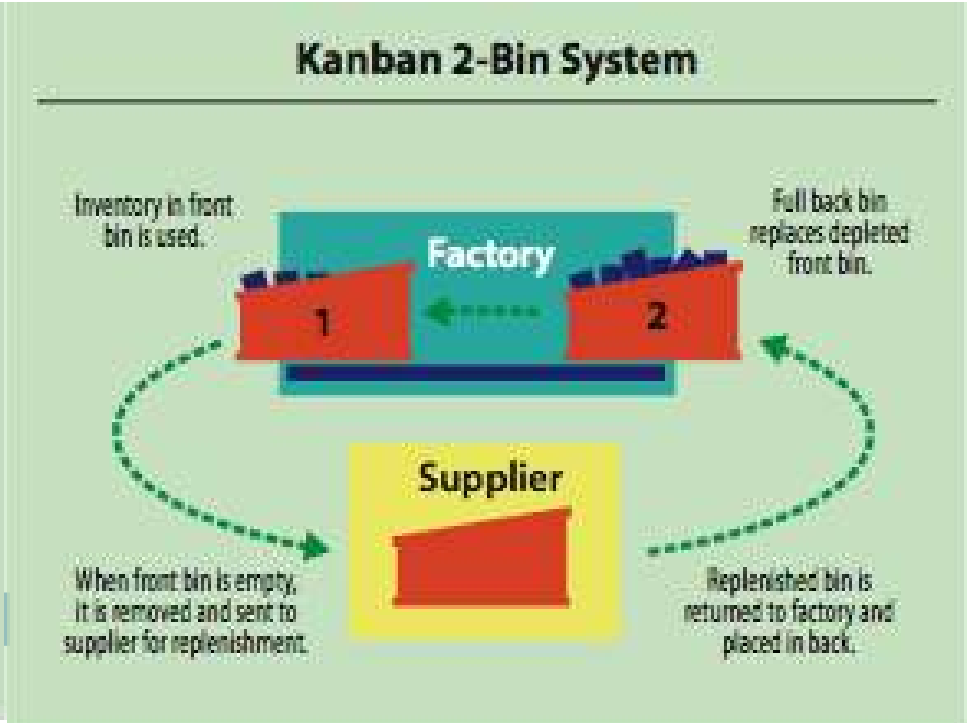
Toyota has formulated six rules for the application of kanban:

1. Each process issues requests (kanban) to its suppliers when it consumes its supplies.
2. Each process produces according to the quantity and sequence of incoming requests.
3. No items are made or transported without a request.
4. The request associated with an item is always attached to it.
5. Processes must not send out defective items, to ensure that the finished products will be defect-free.
6. Limiting the number of pending requests makes the process more sensitive and reveals inefficiencies.

2-Bin system of Kanban

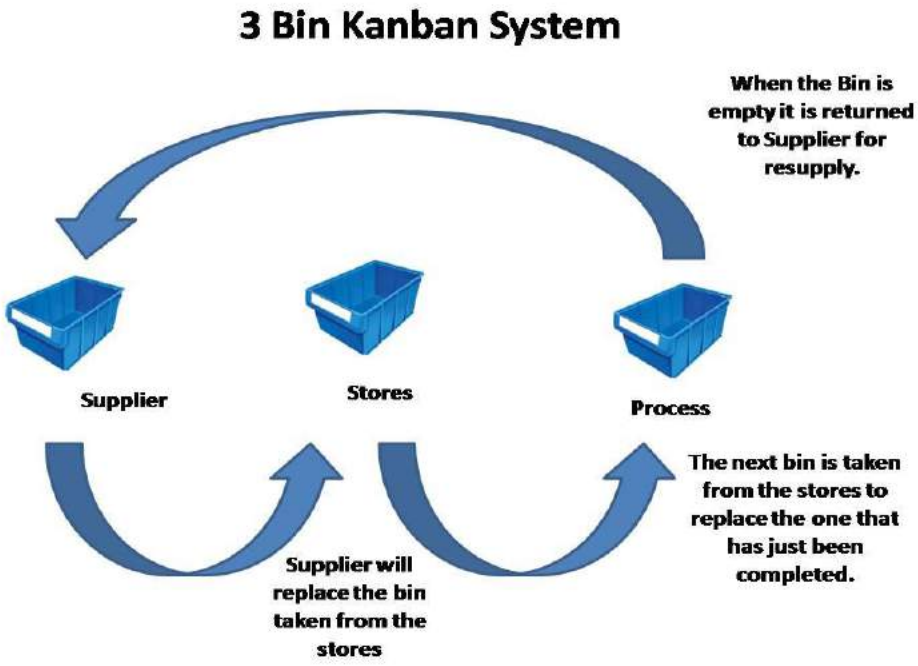
- System which uses two physical bins to manage inventory, usually of small but critical parts
- Used in warehouses, supply rooms at hospitals, places where ingredients are stored in restaurants or bakeries, and more

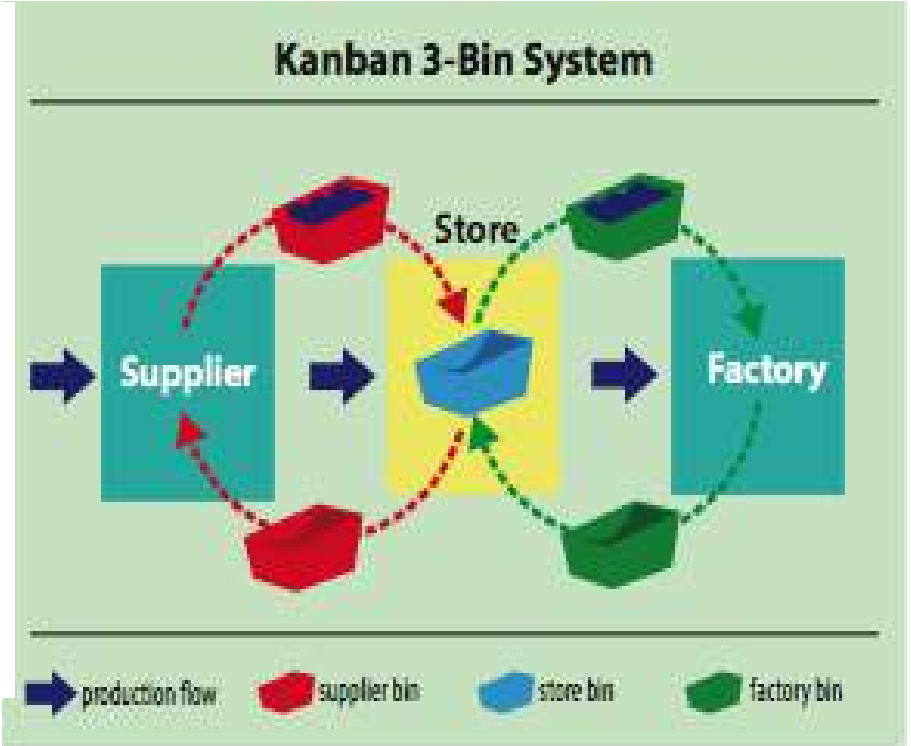




3-bin system of Kanban

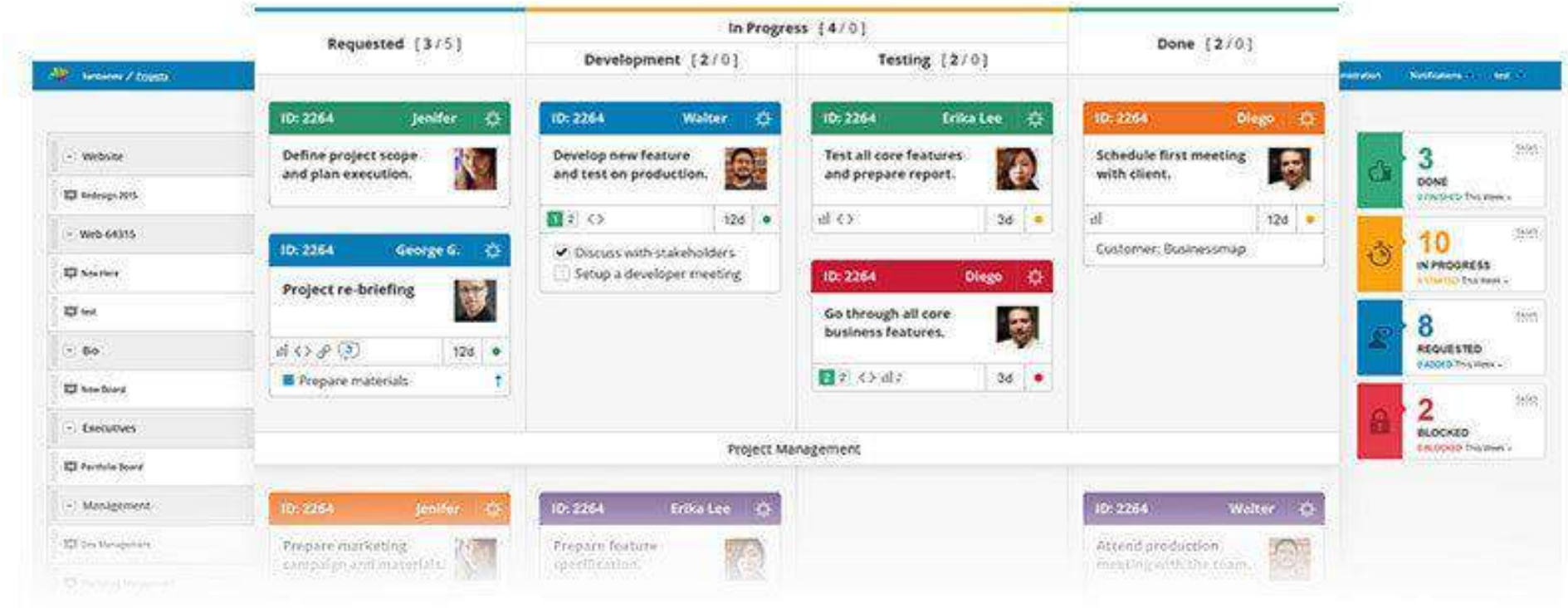
- One bin at the factory where products are made, one at the store where parts/materials are held, and one at the supplier.
- Used in blood banks , medical organ parts, grocery warehouses, automotive parts





Digital Kanban

In electronic Kanban systems, barcodes are placed on items, on materials, or in specific locations. Scanning the barcodes sends a signal to the correct person or department to fill the request. Some systems even generate emails when certain barcodes are scanned that send orders to external suppliers.



PUSH vs PULL

- **A pull system initiates production as a reaction to present demand, while a push system initiates production in anticipation of future demand**.

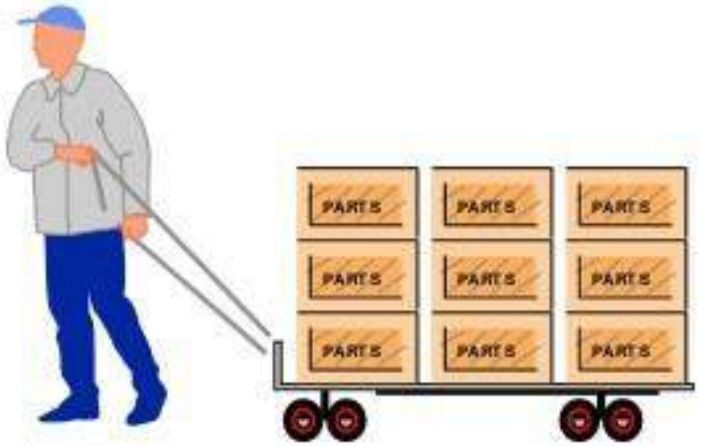
- In a pull system, production is triggered by actual demands for finished products, while in a push system, production is initiated independently of demands.

Push vs. Pull

Make all we can just in case.

- Production Approximation
- Anticipated Usage's
- Large Lots
- High Inventories
- Waste
- Management by Firefighting
- Poor Communication

Make what's needed when we need it



- Production Precision
- Actual Consumption
- Small Lots
- Low Inventories
- Waste Reduction
- Management by Sight
- Better Communication

PUSH vs PULL

- Dell pre-orders and stocks up on raw materials and components.
- However, from this point on, they do not produce their computers until an order is actually placed. They initially "push", but then switch to "pull'' in the production and assembly process.

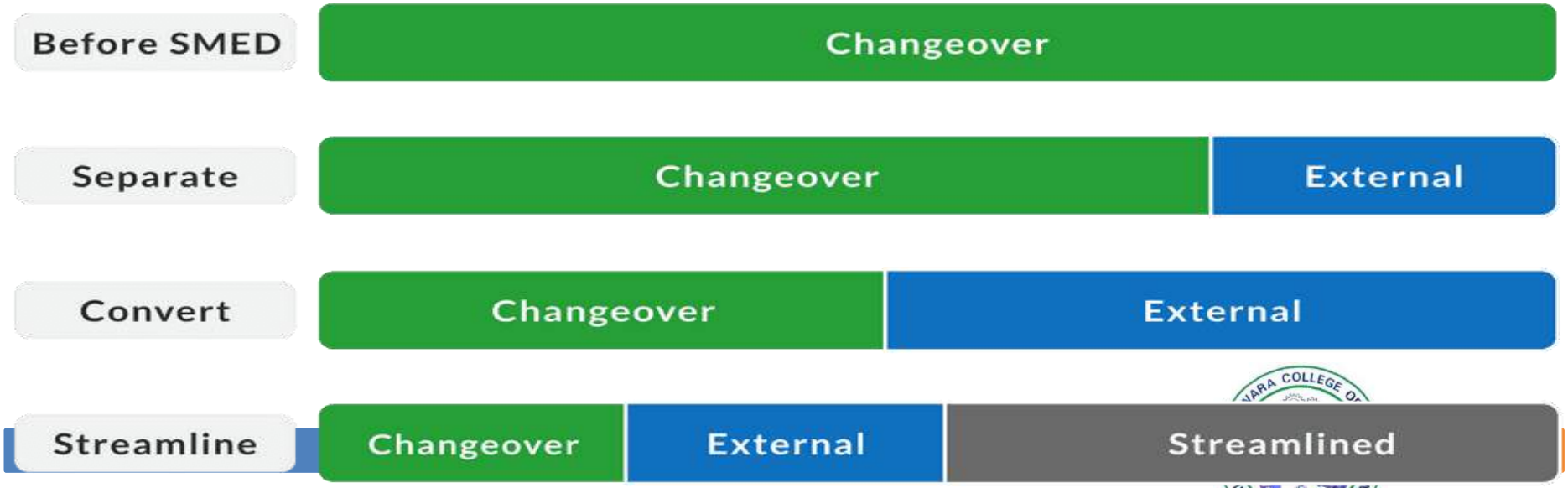
The push-pull strategy (hybrid) is usually suggested for products with high demand uncertainty and high importance of economies of scale.

PUSH – PULL SYSTEM

- Let's say a high-end wooden furniture manufacturer knows that they sell three tables per week on average but there have also been weeks when customers have bought six or seven.
- As one table takes them one and a half workdays to finish, they could respond to their average demand week-by-week without holding any extra stock.
- To respond to the spikes in demand, however, they need to have some safety stock.
- In this case, the push system creates a surplus of tables that are expected to be sold, and the pull system replenishes the safety stock when items are sold.

SINGLE MINUTE EXCHANGE OF DIES (SMED)

- **The process of reducing changeover or setup time**.
- It involves identifying and eliminating any unnecessary part of the changeover process.
- Goal of reducing changeover times to the “single” digits (i.e., less than 10 minutes).



SMED PROCEDURE

1. Identify Pilot Area
2. Identify Elements
3. Separate External Elements
4. Convert Internal Elements to External
5. Streamline Remaining Elements

SMED - Example

SMED Example 1		
Changeover	Switching from lunch to dinner	
Equipment	Kitchen and staff	
Time Equipment is Running	when guests are being served	
Time Equipment is Stopped	when the restaurant is closed	
Elements:		
bring out ingredients for dinner menu meals	clean the kitchen / prepare stations (throwing out oil, clearing chopping boards, etc.)	ensure second shift (or dinner shift) servers are ready

Step 1: Separate	
Internal	**External**
• clean the kitchen / prepare stations (throwing out oil, clearing chopping boards, etc.) • ensure second shift (or dinner shift) servers are ready	• bring out ingredients for dinner menu meals

Step 2: Convert	
Internal	**External**
• clean the kitchen / prepare stations	• bring out ingredients for dinner menu meals • second shift servers come in already prepared or prepare while the first shift servers are almost done

Step 3: Streamline	
Internal Streamlined	optimized kitchen preparation and cleaning flow
SMED Technique	using 5S Lean method to organize the kitchen

Introduction to Hypothesis Testing

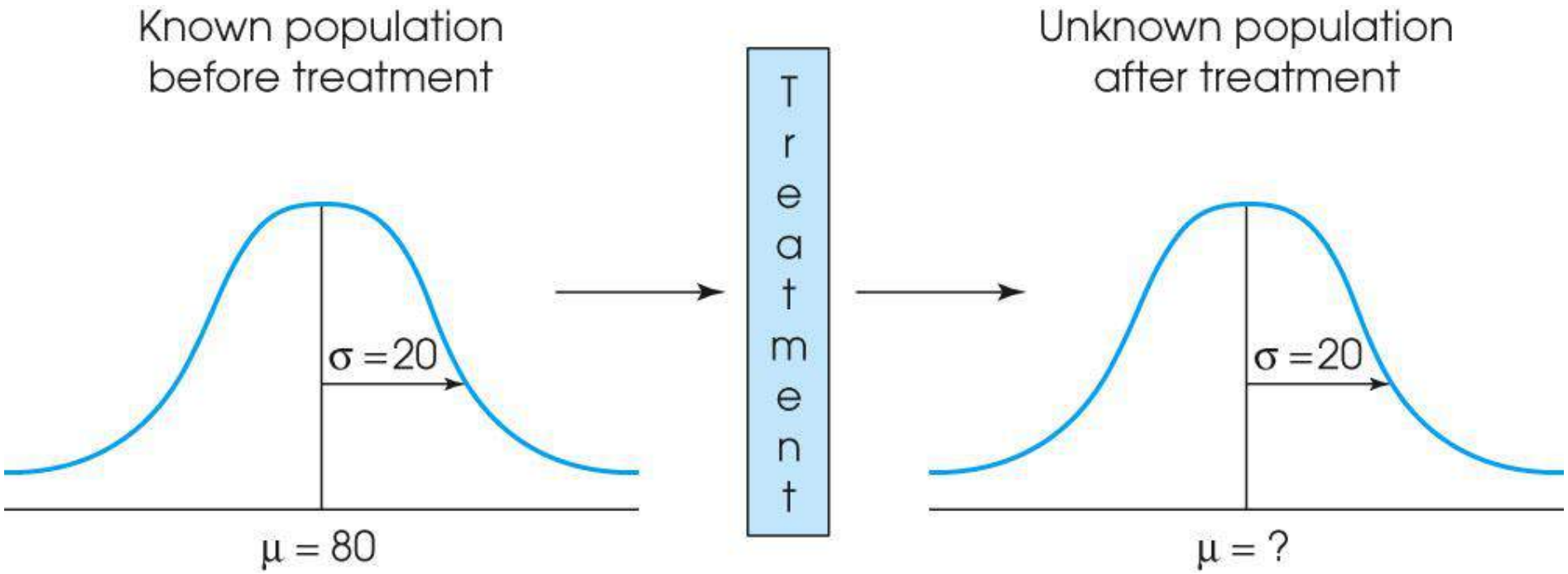
Hypothesis Testing

- The general goal of a hypothesis test is to rule out chance (sampling error) as a plausible explanation for the results from a research study.
- Hypothesis testing is a technique to help determine whether a specific treatment has an effect on the individuals in a population.

Hypothesis Testing

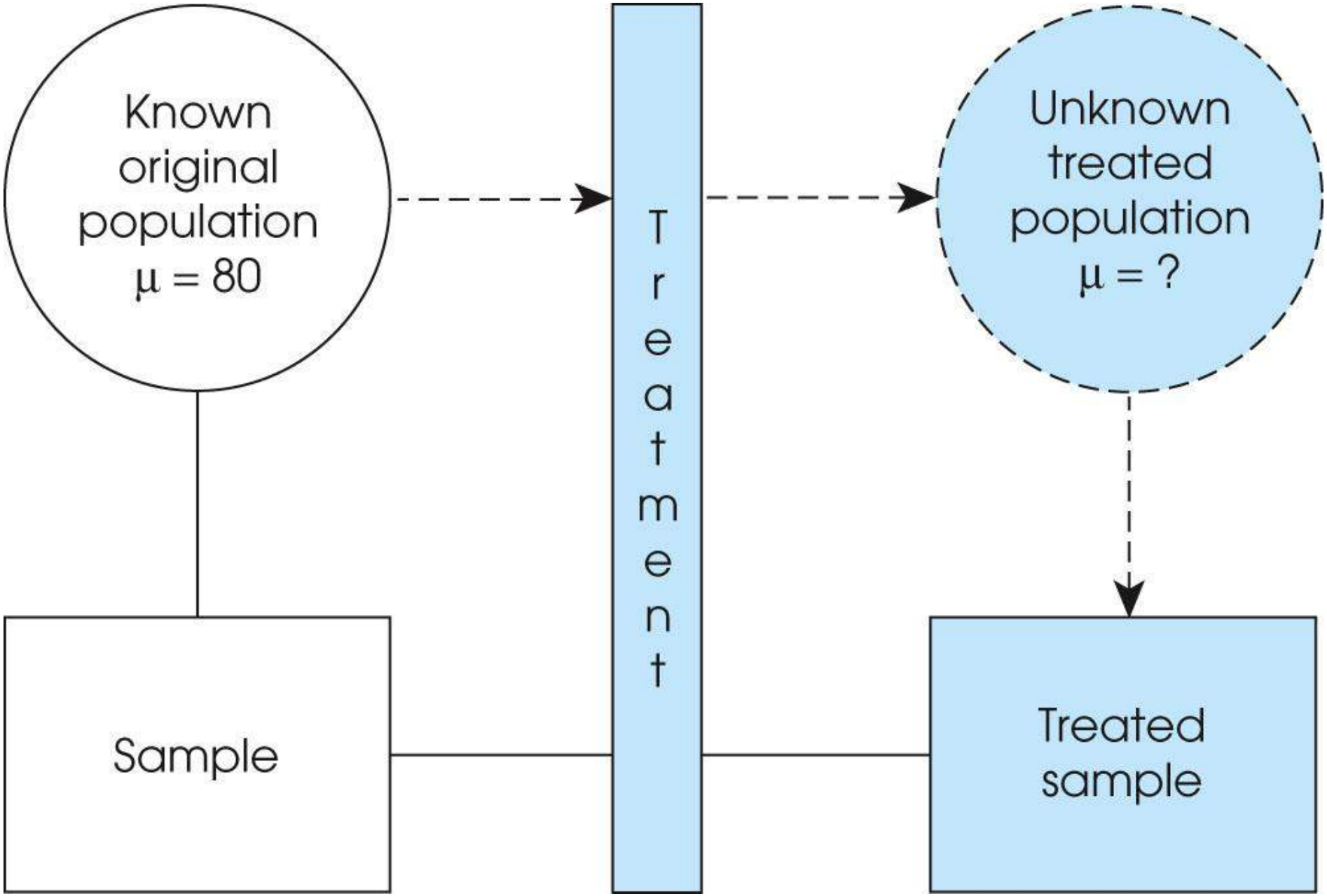
The hypothesis test is used to evaluate the results from a research study in which

1. A sample is selected from the population.
2. The treatment is administered to the sample.
3. After treatment, the individuals in the sample are measured.


Known population
before treatment
σ = 20
μ = 80
Treatment
Unknown population
after treatment
σ = 20
μ = ?

Hypothesis Testing (cont.)

- If the individuals in the sample are noticeably different from the individuals in the original population, we have evidence that the treatment has an effect.
- However, it is also possible that the difference between the sample and the population is simply sampling error


Known original population μ = 80
Treatment
Unknown treated population μ = ?
Sample
Treated sample

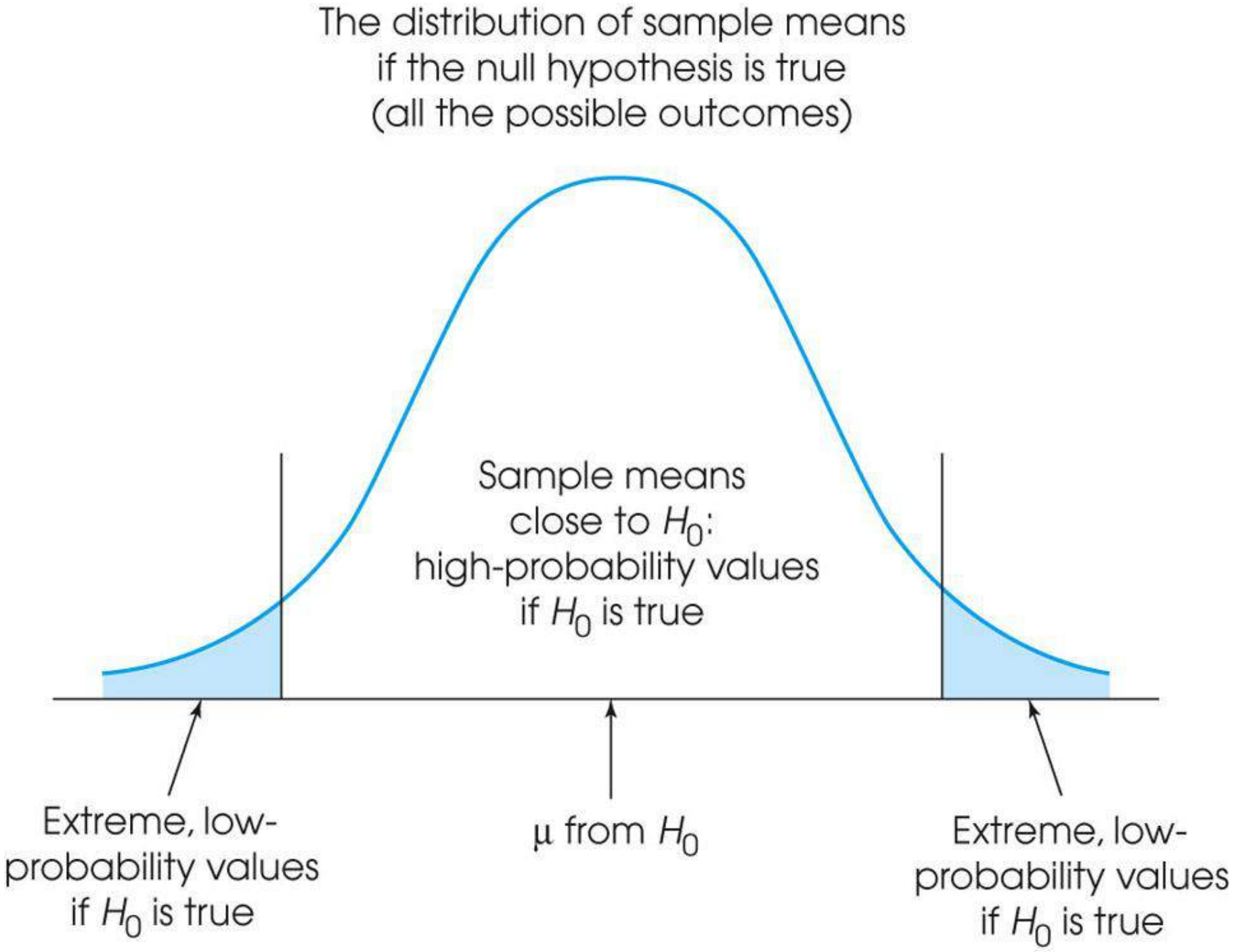
Hypothesis Testing (cont.)

- The purpose of the hypothesis test is to decide between two explanations:

  1. The difference between the sample and the population can be explained by sampling error (there does not appear to be a treatment effect)

  2. The difference between the sample and the population is too large to be

  explained by sampling error (there does appear to be a treatment effect).

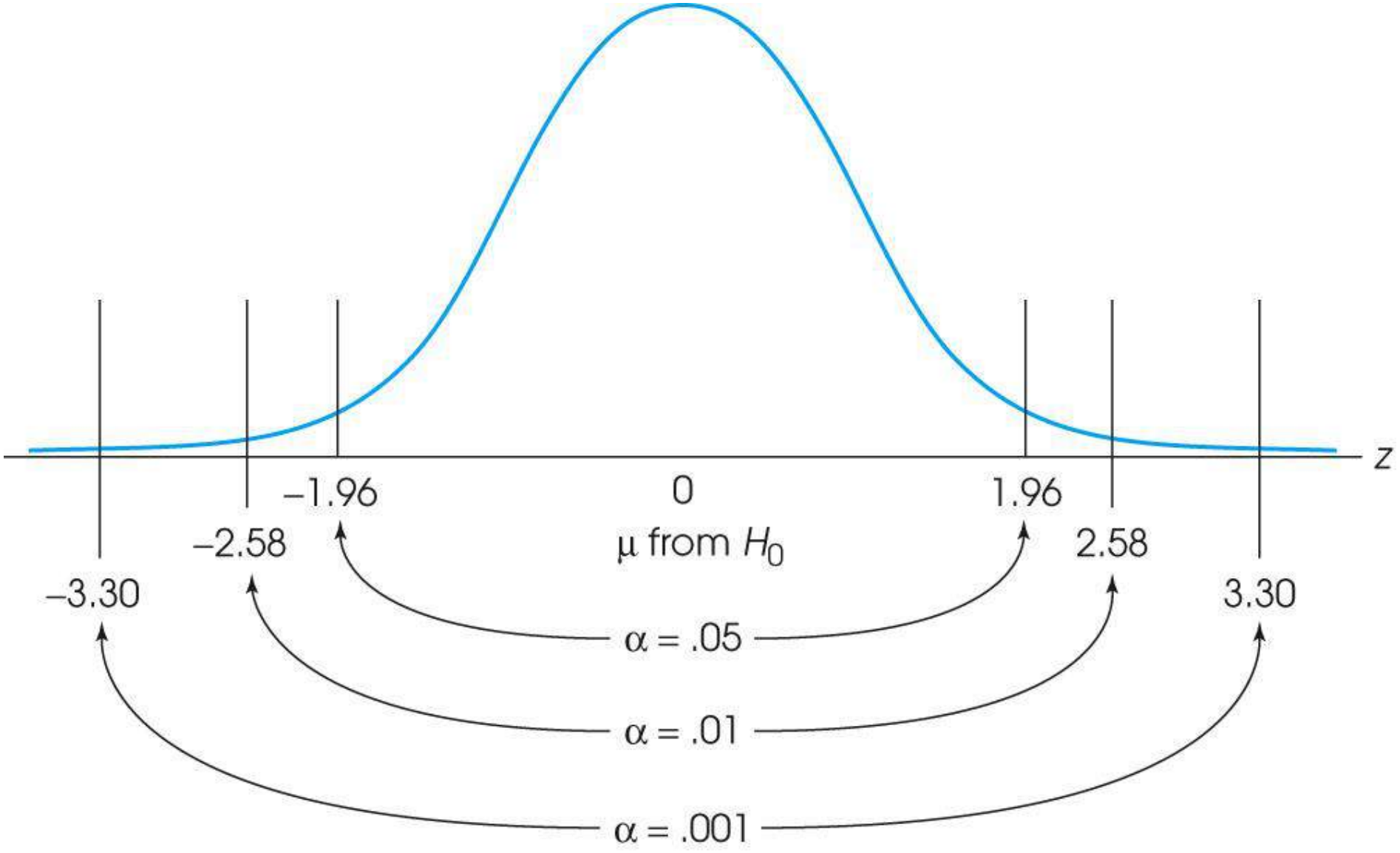

The distribution of sample means
if the null hypothesis is true
(all the possible outcomes)
Sample means
close to H_0:
high-probability values
if H_0 is true
Extreme, low-
probability values
if H_0 is true
μ from H_0
Extreme, low-
probability values
if H_0 is true

The Null Hypothesis, the Alpha Level, the Critical Region, and the Test Statistic

- The following four steps outline the process of hypothesis testing and introduce some of the new terminology:

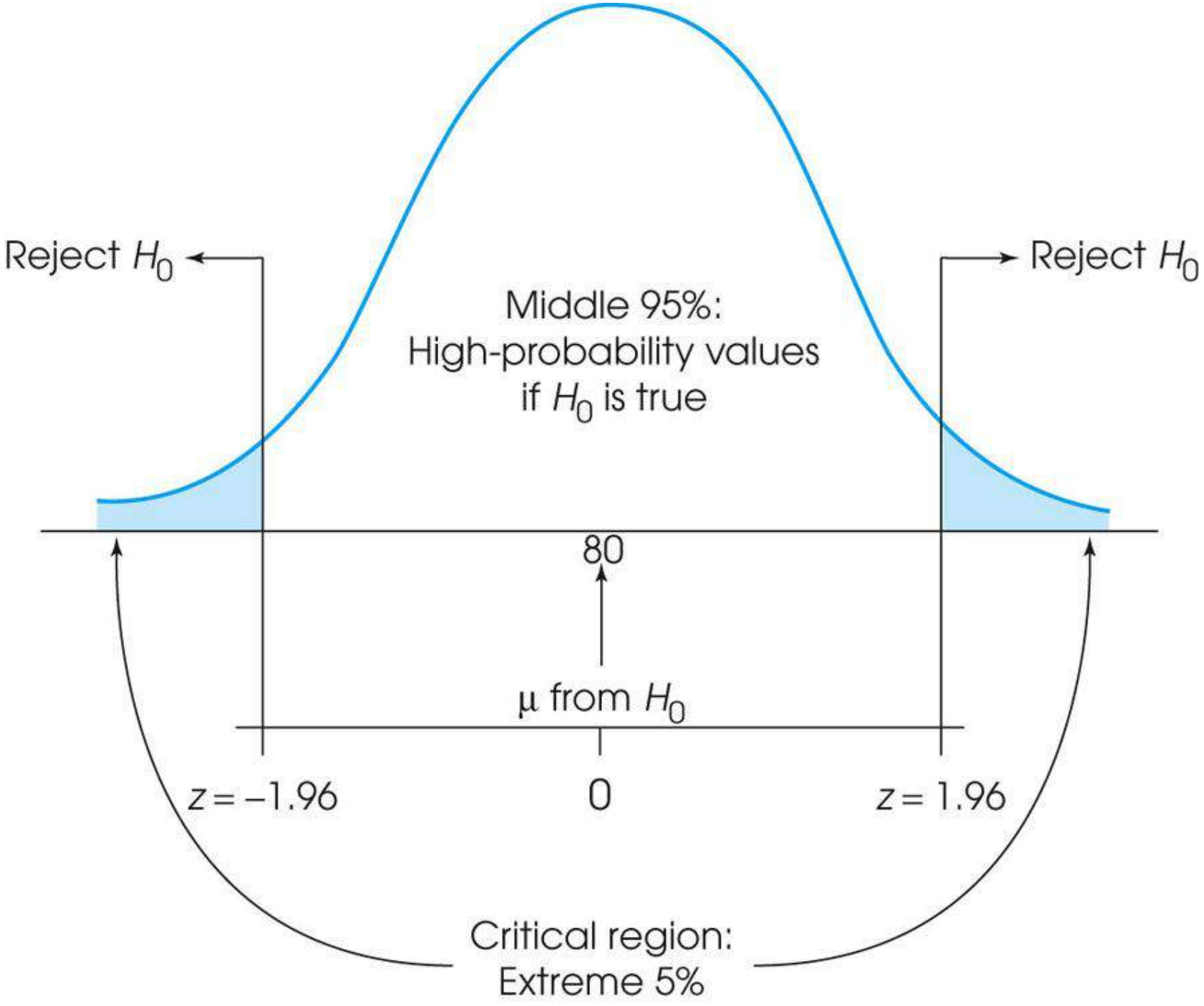
Step 1

State the hypotheses and select an α level. The **null hypothesis**, H**0**, always states that the treatment has no effect (no change, no difference). According to the null hypothesis, the population mean after treatment is the same is it was before treatment. The **α level** establishes a criterion, or "cut-off", for making a decision about the null hypothesis. The alpha level also determines the risk of a Type I error.


z
–1.96
0
1.96
–2.58
μ from H_0
2.58
–3.30
3.30
α = .05
α = .01
α = .001

Step 2

Locate the critical region. The **critical region** consists of outcomes that are very unlikely to occur if the null hypothesis is true. That is, the critical region is defined by sample means that are almost impossible to obtain if the treatment has no effect. The phrase “almost impossible” means that these samples have a probability (p) that is less than the alpha level.

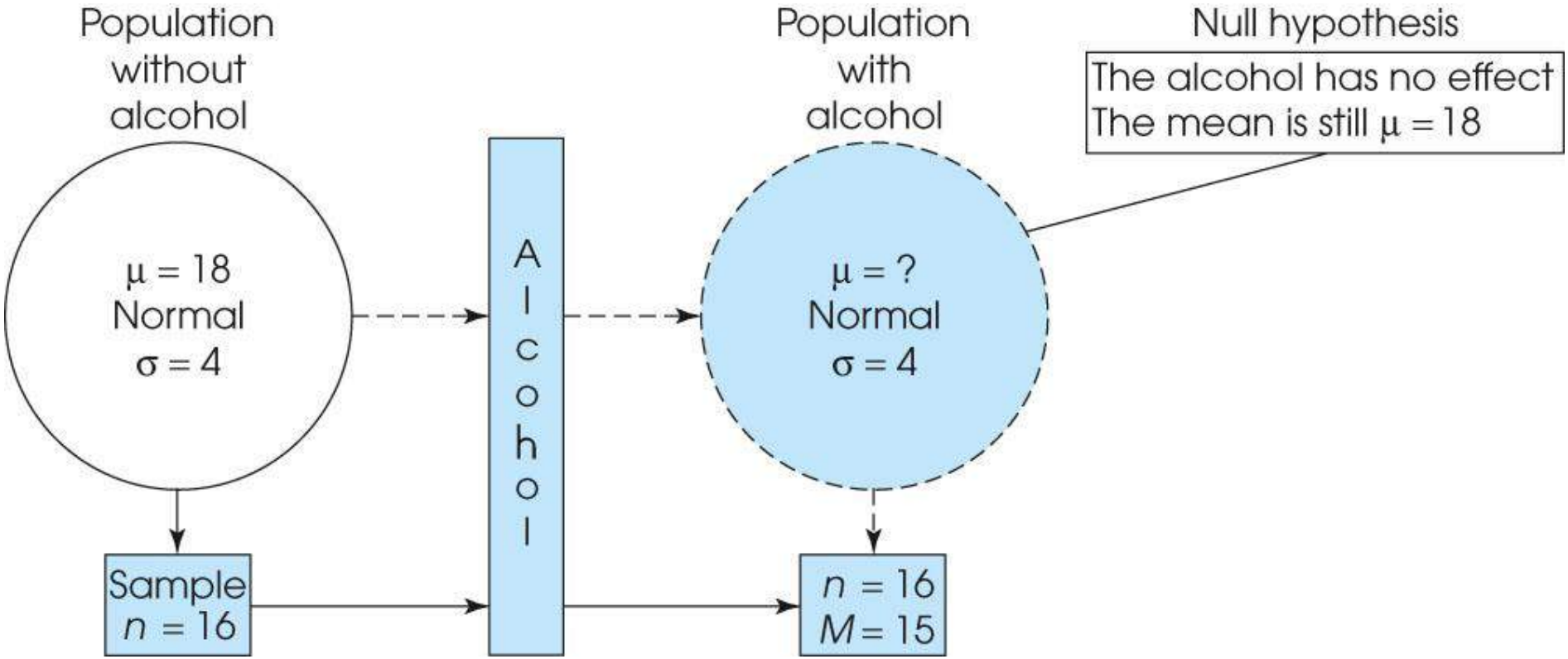

Reject H_0
Reject H_0
Middle 95%:
High-probability values
if H_0 is true
80
μ from H_0
$z = -1.96$
0
$z = 1.96$
Critical region:
Extreme 5%

Step 3

Compute the test statistic. The **test statistic** (in this chapter a z-score) forms a ratio comparing the obtained difference between the sample mean and the hypothesized population mean versus the amount of difference we would expect without any treatment effect (the standard error).

Step 4

A large value for the test statistic shows that the obtained mean difference is more than would be expected if there is no treatment effect. If it is large enough to be in the critical region, we conclude that the difference is **significant** or that the treatment has a significant effect. In this case we reject the null hypothesis. If the mean difference is relatively small, then the test statistic will have a low value. In this case, we conclude that the evidence from the sample is not sufficient, and the decision is fail to reject the null hypothesis.


Population without alcohol
μ = 18
Normal
σ = 4
Sample
n = 16
Alcohol
Population with alcohol
μ = ?
Normal
σ = 4
n = 16
M = 15
Null hypothesis
The alcohol has no effect
The mean is still μ = 18

Errors in Hypothesis Tests

- Just because the sample mean (following treatment) is different from the original population mean does not necessarily indicate that the treatment has caused a change.
- You should recall that there usually is some discrepancy between a sample mean and the population mean simply as a result of sampling error.

Errors in Hypothesis Tests (cont.)

- Because the hypothesis test relies on sample data, and because sample data are not completely reliable, there is always the risk that misleading data will cause the hypothesis test to reach a wrong conclusion.
- Two types of error are possible.

Type I Errors

- A **Type I error** occurs when the sample data appear to show a treatment effect when, in fact, there is none.
- In this case the researcher will reject the null hypothesis and falsely conclude that the treatment has an effect.
- Type I errors are caused by unusual, unrepresentative samples. Just by chance the researcher selects an extreme sample with the result that the sample falls in the critical region even though the treatment has no effect.
- The hypothesis test is structured so that Type I errors are very unlikely; specifically, the probability of a Type I error is equal to the alpha level.

Type II Errors

- A **Type II error** occurs when the sample does not appear to have been affected by the treatment when, in fact, the treatment does have an effect.
- In this case, the researcher will fail to reject the null hypothesis and falsely conclude that the treatment does not have an effect.
- Type II errors are commonly the result of a very small treatment effect. Although the treatment does have an effect, it is not large enough to show up in the research study.

TABLE 8.1

Possible outcomes of a statistical decision

		Actual Situation	
		No Effect, H_0 True	Effect Exists, H_0 False
EXPERIMENTER'S DECISION	Reject H_0	Type I error	Decision correct
	Retain H_0	Decision correct	Type II error

Directional Tests

- When a research study predicts a specific direction for the treatment effect (increase or decrease), it is possible to incorporate the directional prediction into the hypothesis test.
- The result is called a **directional test** or a **one-tailed test**. A directional test includes the directional prediction in the statement of the hypotheses and in the location of the critical region.

Directional Tests (cont.)

- For example, if the original population has a mean of $\mu = 80$ and the treatment is predicted to increase the scores, then the null hypothesis would state that after treatment:

$$H0: \ \mu \leq 80 \quad \text{(there is no increase)}$$

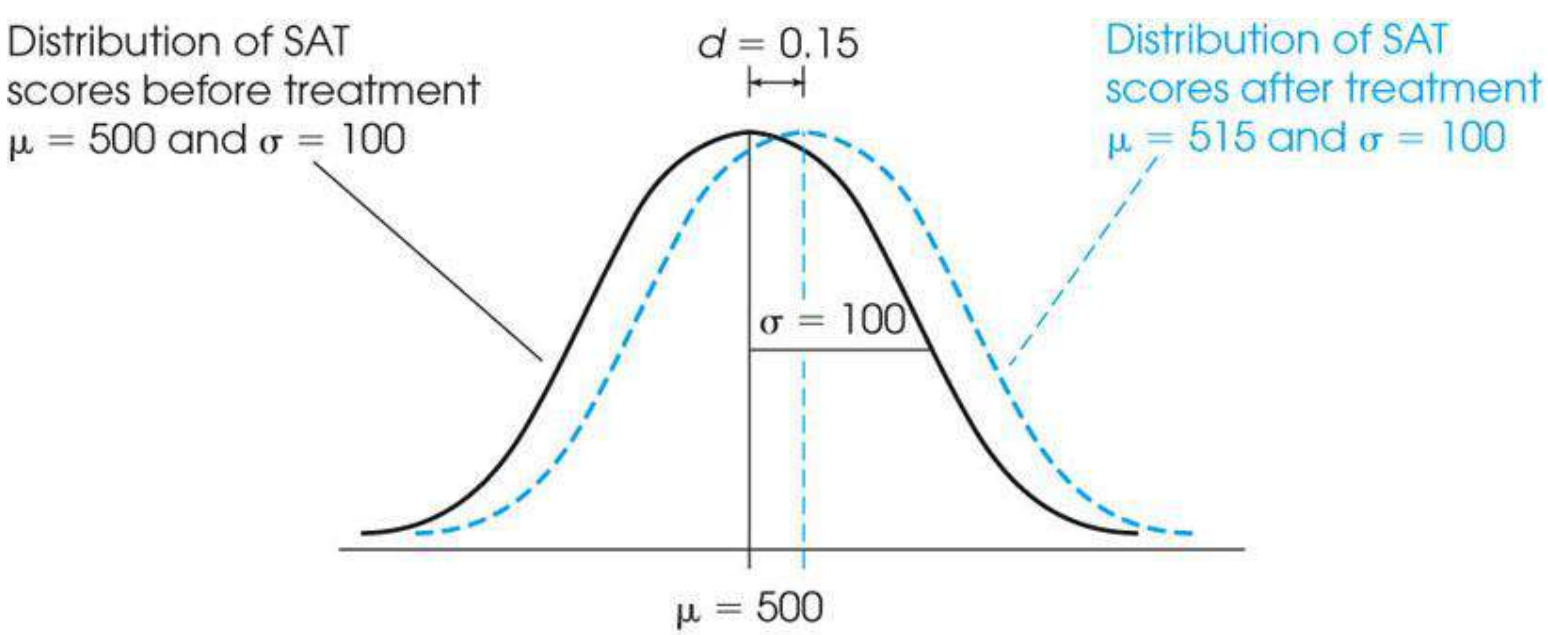
- In this case, the entire critical region would be located in the right-hand tail of the distribution because large values for M would demonstrate that there is an increase and would tend to reject the null hypothesis.

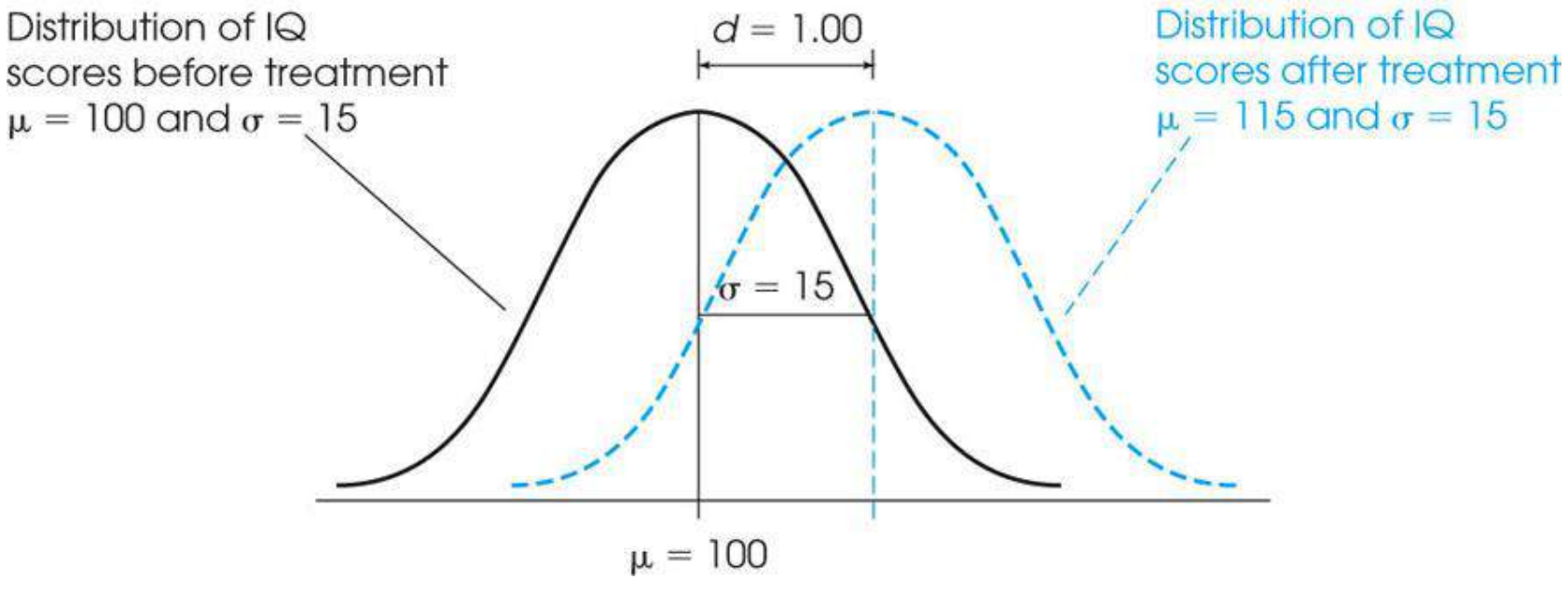
Measuring Effect Size

- A hypothesis test evaluates the *statistical significance* of the results from a research study.
- That is, the test determines whether or not it is likely that the obtained sample mean occurred without any contribution from a treatment effect.
- The hypothesis test is influenced not only by the size of the treatment effect but also by the size of the sample.
- Thus, even a very small effect can be significant if it is observed in a very large sample.

Measuring Effect Size

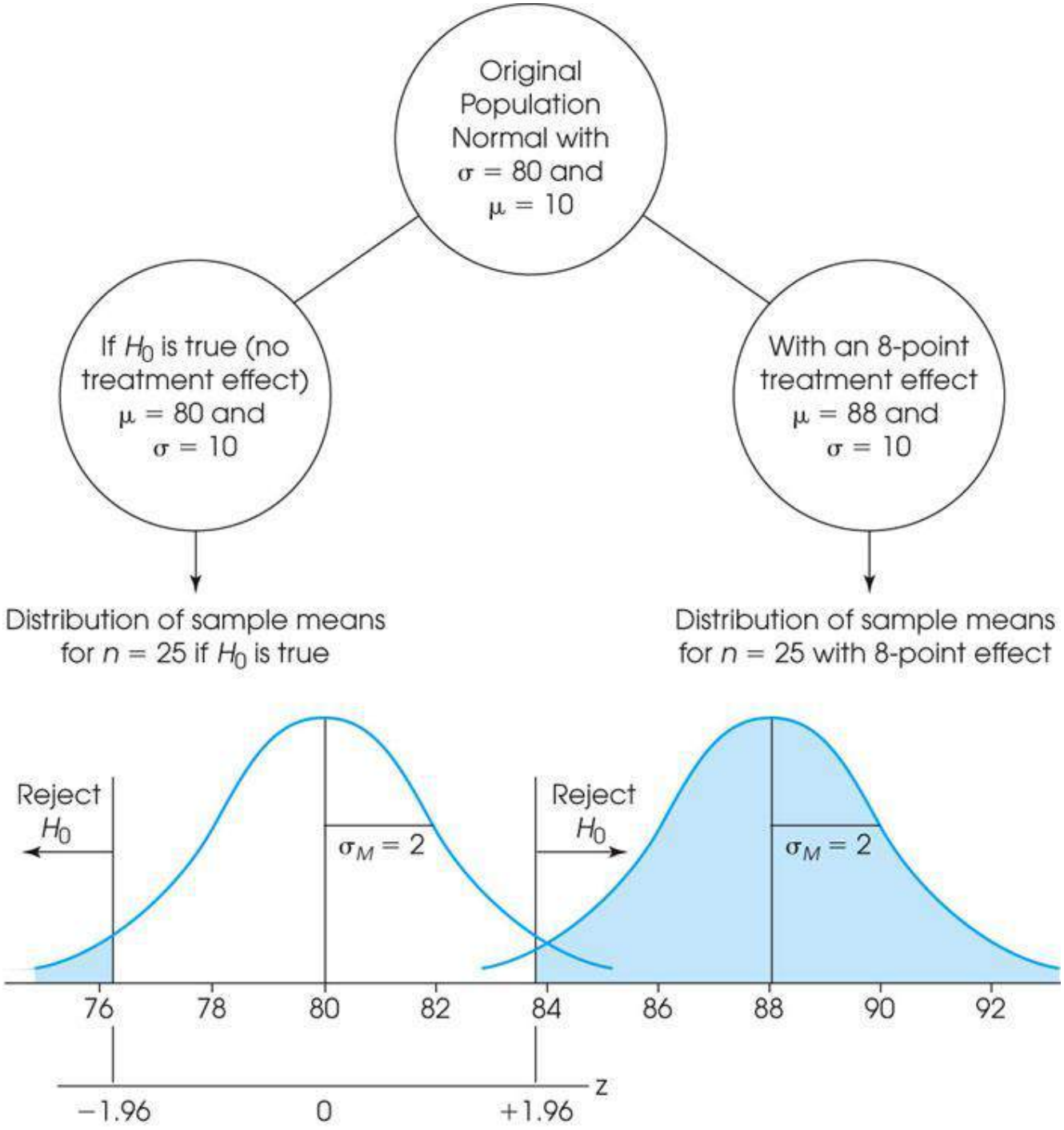
- Because a significant effect does not necessarily mean a large effect, it is recommended that the hypothesis test be accompanied by a measure of the **effect size**.
- We use Cohen=s d as a standardized measure of effect size.
- Much like a z-score, **Cohen=s d** measures the size of the mean difference in terms of the standard deviation.


Distribution of SAT
scores before treatment
μ = 500 and σ = 100
d = 0.15
Distribution of SAT
scores after treatment
μ = 515 and σ = 100
σ = 100
μ = 500


Distribution of IQ
scores before treatment
μ = 100 and σ = 15
d = 1.00
Distribution of IQ
scores after treatment
μ = 115 and σ = 15
σ = 15
μ = 100

Power of a Hypothesis Test

- The **power** of a hypothesis test is defined is the probability that the test will reject the null hypothesis when the treatment does have an effect.
- The power of a test depends on a variety of factors including the size of the treatment effect and the size of the sample.


Original Population Normal with σ = 80 and μ = 10
If H_0 is true (no treatment effect) μ = 80 and σ = 10
With an 8-point treatment effect μ = 88 and σ = 10
Distribution of sample means for n = 25 if H_0 is true
Distribution of sample means for n = 25 with 8-point effect
Reject H_0
$\sigma_M = 2$
Reject H_0
$\sigma_M = 2$
76
78
80
82
84
86
88
90
92
z
−1.96
0
+1.96

STATISTICAL PROCESS CONTROL

STATISTICAL PROCESS CONTROL (SPC)

•Is the application of Statistical Methods to monitor and control a process to ensure that it operates at its full potential to produce conforming product.

OR

•Is an analytical decision making tool which allows you to see when a process is working correctly and when it is not.

•Variation is present in any process, deciding when the variation is natural and when it needs correction is the key to quality control.

HISTORY

•Was Pioneered By Walter .A. Shewhart In The Early 1920s.

•W. Edwards Deming Later Applied SPC Methods In The US During World war II, Successfully Improved Quality In The Manufacture Of Munitions And Other Strategically Important Products.

•Deming introduced SPC Methods to Japanese Industry After The War Had Ended.

•Resulted high quality of Japanese products.

•Shewhart Created The Basis For The Control Chart And The Concept Of A State Of Statistical Control By Carefully Designed Experiments.

•Concluded That While Every Process Displays Variation, Some Processes Display Controlled Variation That Is Natural To The Process (Common Causes Of Variation), While Others Display Uncontrolled Variation That Is Not Present In The Process Causal System At All Times (Special Causes Of Variation).

•In 1988, The Software Engineering Institute Introduced The Notion That SPC Can Be Usefully Applied To Non-manufacturing Processes

TRADITIONAL METHODS VS STATISTICAL PROCESS CONTROL

- The quality of the finished article was traditionally achieved through post-manufacturing inspection of the product; accepting or rejecting each article (or samples from a production lot) based on how well it met its design specifications

- SPC uses Statistical tools to observe the performance of the production process in order to predict significant deviations that may later result in rejected product.

TYPES OF VARIATION

Two kinds of variation occur in all manufacturing processes

1. Natural or Common Cause Variation
   - consists of the variation inherent in the process as it is designed.
   - may include variations in temperature, properties of raw materials, strength of an electrical current etc.

2. Special Cause Variation or Assignable-cause Variation

   With sufficient investigation, a specific cause, such as abnormal raw material or incorrect set-up parameters, can be found for special cause variations.

‘In Control’ and ‘Out Of Control’

❖ **Process is said to be ‘in control’ and stable**

If common cause is the only type of variation that exists in the process

It is also predictable within set limits i.e. the probability of any future outcome falling within the limits can be stated approximately.

❖ **Process is said to be ‘out of control’ and unstable**

Special cause variation exists within the process

Statistical process control -broadly broken down into 3 sets of activities

1. Understanding the process

2. Understanding the causes of variation

3. Elimination of the sources of special cause variation.

Understanding the process

- Process is typically mapped out and the process is monitored using control charts.

Understanding the causes of variation

- Control charts are used to identify variation that may be due to special causes, and to free the user from concern over variation due to common causes.
- It is a continuous, ongoing activity.
- When a process is stable and does not trigger any of the detection rules for a control chart, a process capability analysis may also be performed to predict the ability of the current process to produce conforming product in the future.

•When excessive variation is identified by the control chart detection rules, or the process capability is found lacking, additional effort is exerted to determine causes of that variance.

• The tools used include

- **Ishikawa diagrams**
- **Designed experiments**
- **Pareto charts**

•Designed experiments are critical -only means of objectively quantifying the relative importance of the many potential causes of variation.

Elimination of the sources of special cause variation

•Once the causes of variation have been quantified, effort is spent in eliminating those causes that are both statistically and practically significant.

•includes development of standard work, error-proofing and training.

•Additional process changes may be required to reduce variation or align the process with the desired target, especially if there is a problem with process capability.

ADVANTAGES OF SPC

• Reduces waste

• Lead to a reduction in the time required to produce the product or service from end to end

due to a diminished likelihood that the final product will have to be reworked, identify bottlenecks, wait times, and other sources of delays within the process.

•A distinct advantage over other quality methods, such as inspection - its emphasis on early detection and prevention of problems

•Cost reduction

•Customer satisfaction

SPC CHARTS

- One method of identifying the type of variation present.

- Statistical Process Control (SPC) Charts are essentially:
  - ❖ Simple graphical tools that enable process performance monitoring.
  - ❖ Designed to identify which type of variation exists within the process.
  - ❖ Designed to highlight areas that may require further investigation.
  - ❖ Easy to construct and interpret.

- 2 most popular SPC tools
  - ❖ **Run Chart**
  - ❖ **Control Chart**

•SPC charts can be applied to both dynamic processes and static processes.

Dynamic Processes

- A process that is observed across time is known as a dynamic process.
- An SPC chart for a dynamic process - „time-series‟ or a „longitudinal‟ SPC chart.

Static Processes

- A process that is observed at a particular point in time is known as a static process.
- An SPC chart for a static process is often referred to as a „cross sectional‟ SPC chart.

Control charts

- Show the variation in a measurement during the time period that the process is observed.

- Monitor processes to show how the process is performing and how the process and capabilities are affected by changes to the process. This information is then used to make quality improvements.

- A time ordered sequence of data, with a centre line calculated by the mean.

- Used to determine the capability of the process.

- Help to identify special or assignable causes for factors that impede peak performance.

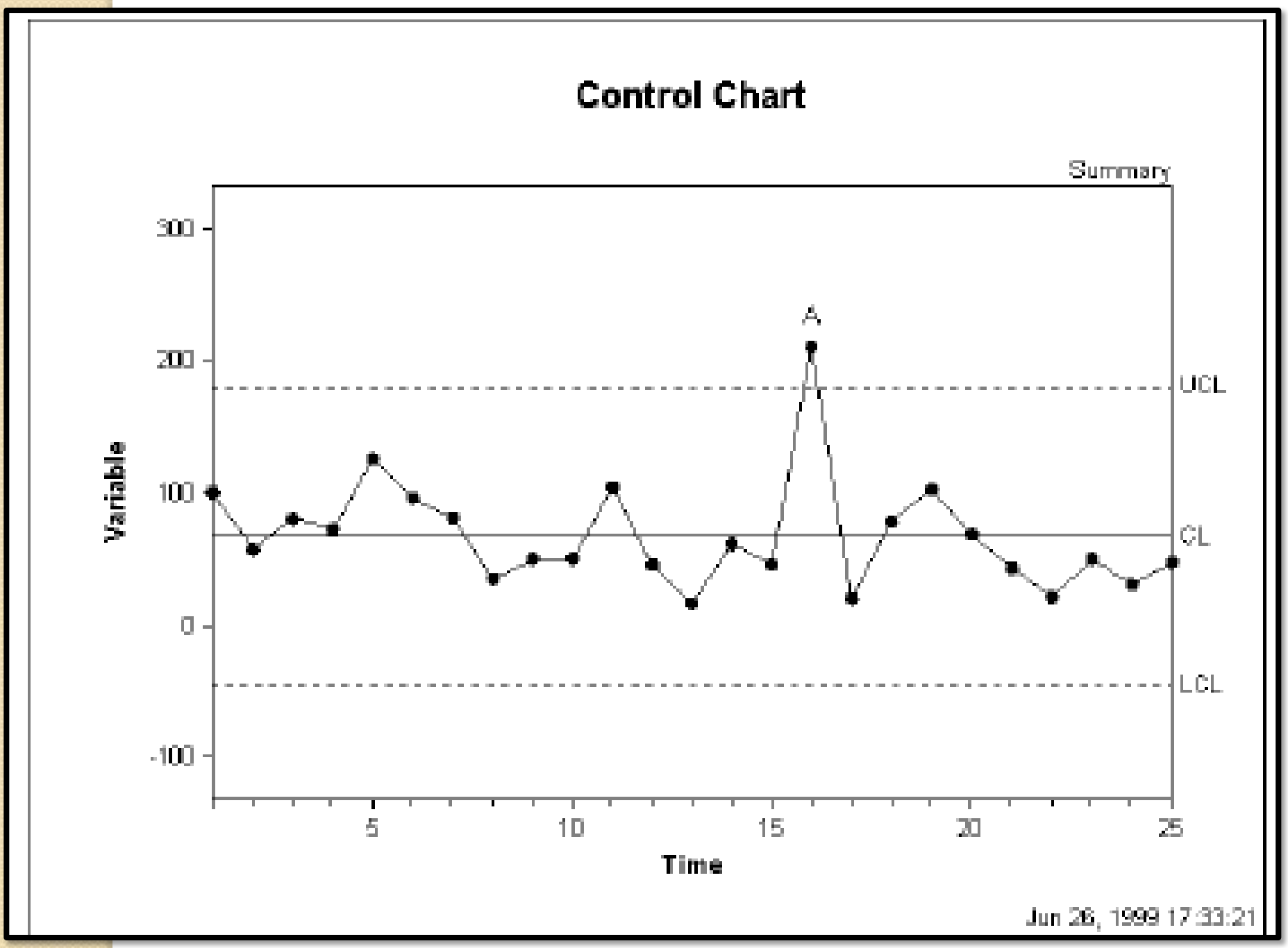
Control charts have four key features:

1) **Data Points:**
   Either averages of subgroup measurements or individual measurements plotted on the x/y axis and joined by a line. Time is always on the x-axis.

2) **The Average or Center Line**
   The average or mean of the data points and is drawn across the middle section of the graph, usually as a heavy or solid line.

3) **The Upper Control Limit (UCL)**
   Drawn above the centerline and annotated as "UCL". This is often called the “+ 3 sigma” line.

4) **The Lower Control Limit (LCL)**
   Drawn below the centerline and annotated as "LCL". This is called the “- 3 sigma” line.


Control Chart
Summary
300
200
100
0
-100
Variable
A
UCL
CL
LCL
5
10
15
20
25
Time
Jun 26, 1999 17:33:21

- Control limits define the zone where the observed data for a stable and consistent process occurs virtually all of the time (99.7%).

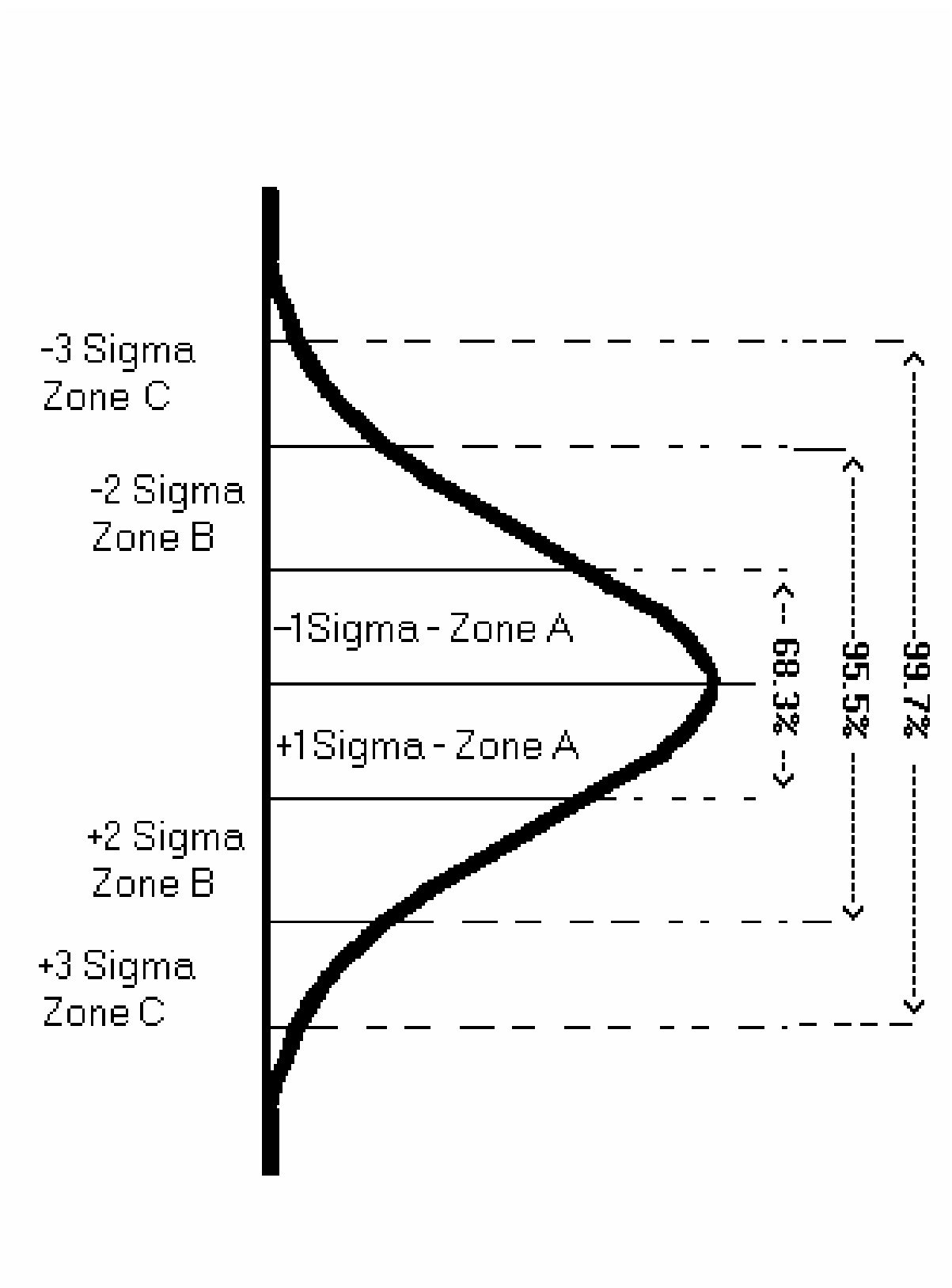
- Any fluctuations within these limits come from common causes inherent to the system, such as choice of equipment, scheduled maintenance or the precision of the operation that results from the design.

- An outcome beyond the control limits results from a *special cause.*

- The automatic control limits have been set at 3-sigma limits.

•The area between each control limit and the centerline is divided into thirds.

1) Zone A - "1-sigma zone“
2) Zone B - "2-sigma zone"
3) Zone C - " 3-sigma zone “

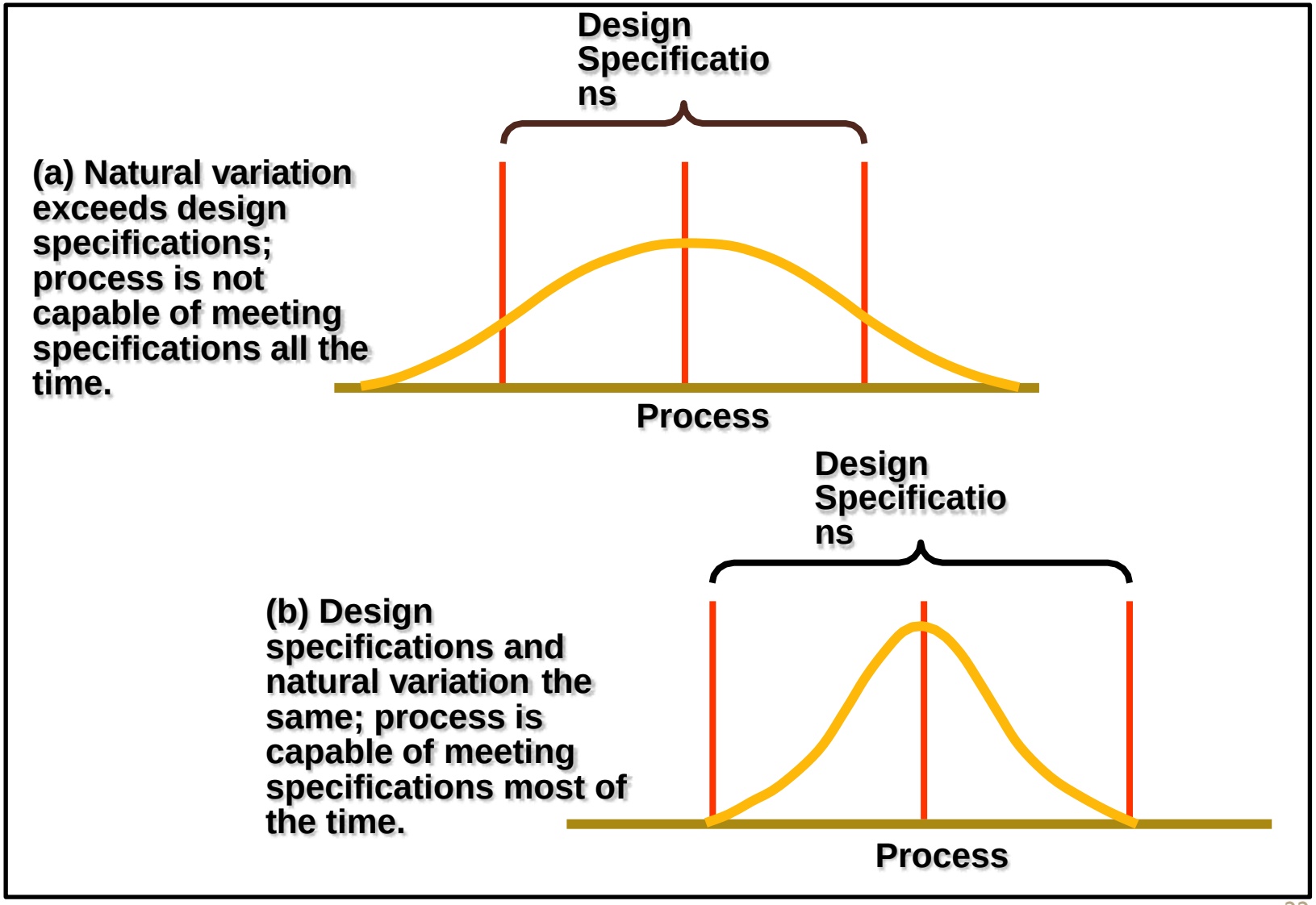

-3 Sigma
Zone C
-2 Sigma
Zone B
-1Sigma - Zone A
+1Sigma - Zone A
+2 Sigma
Zone B
+3 Sigma
Zone C
68.3%
95.5%
99.7%

PROCESS CAPABILITY ANALYSIS

- Examines
  - whether the process is capable of producing products which conforms to specifications
  - range of natural variability in a process what we measure with control charts

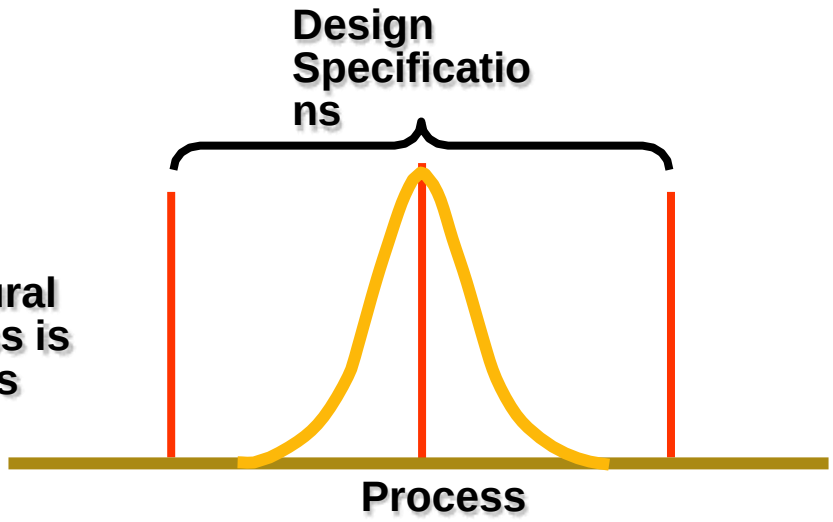
- Process capability studies distinguish between conformance to **control limits** and conformance to **specification limits** (also called **tolerance limits**)
  - if the process mean is in control, then virtually all points will remain within control limits
  - staying within control limits does not necessarily mean that specification limits are satisfied
  - specification limits are usually dictated by customers

Process Capability analysis cont.

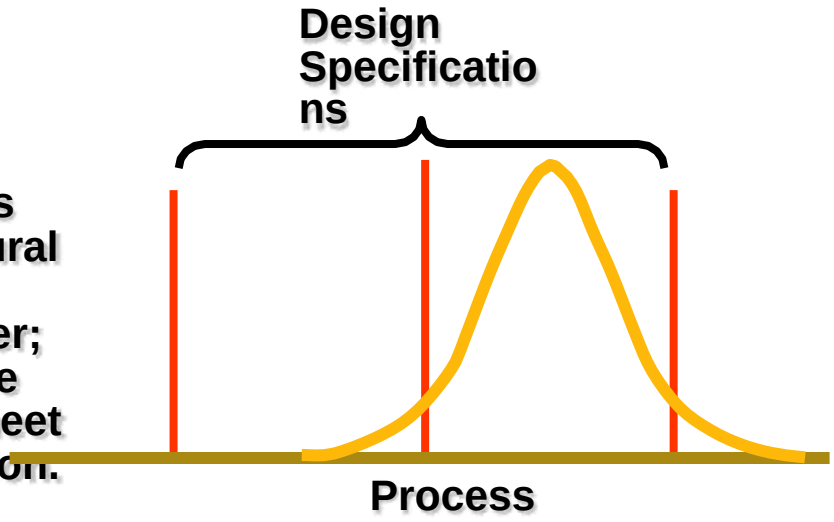


Process Capability (cont.)

(c) Design specifications greater than natural variation; process is capable of always conforming to specifications.



(d) Specifications greater than natural variation, but process off center; capable but some output will not meet upper specification.



INTRODUCTION TO SURVIVAL ANALYSIS

What is Survival Analysis?

- **Survival Analysis is referred to statistical methods for analyzing survival data**
- **Survival data could be derived from laboratory studies of animals or from clinical and epidemiologic studies**
- **Survival data could relate to outcomes for studying acute or chronic diseases**

What is Survival Time?

- **Survival time refers to a variable which measures the time from a particular starting time (e.g., time initiated the treatment) to a particular endpoint of interest (e.g., attaining certain functional abilities)**
- **It is important to note that for some subjects in the study a complete survival time may not be available due to censoring**

Censored Data

Some patients may still be alive or in remission at the end of the study period

The exact survival times of these subjects are unknown

These are called *censored observation* or *censored times* and can also occur when individuals are lost to follow-up after a period of study

Random Right Censoring

- **Suppose 4 patients with acute leukemia enter a clinical study for three years**
- **Remission times of the four patients are recorded as 10, 15+, 35 and 40 months**
- **15+ indicate that for one patient the remission time is greater than 15 months but the actual value is unknown**

Important Areas of Application

- **Clinical Trials (e.g., Recovery Time after heart surgery)**
- **Longitudinal or Cohort Studies (e.g., Time to observing the event of interest)**
- **Life Insurance (e.g., Time to file a claim)**
- **Quality Control & Reliability in Manufacturing (e.g., The amount of force needed to damage a part such that it is not useable)**

Survival Function or Curve

Let *T* denote the survival time

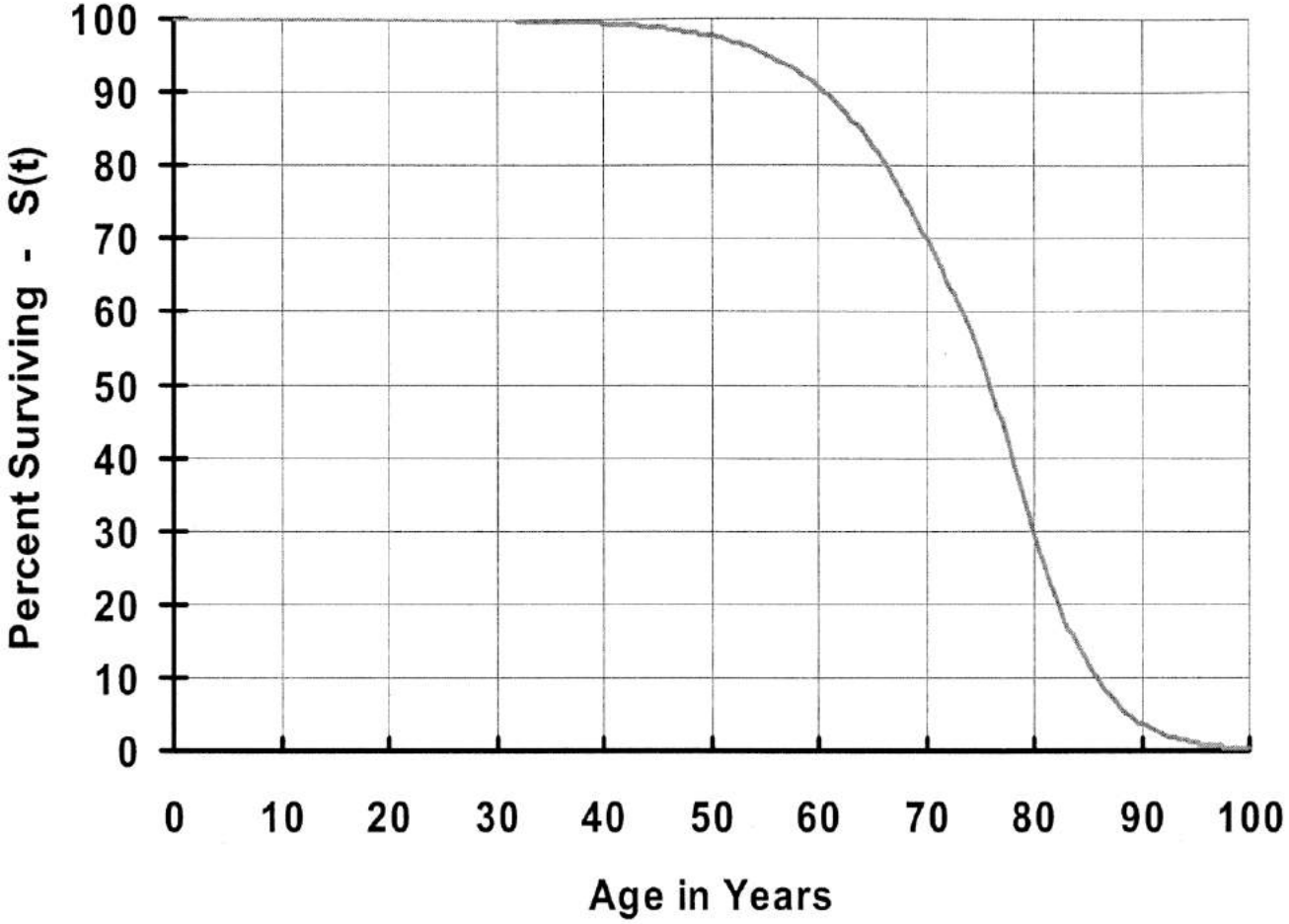
S(t) = P(surviving longer than time t)

= *P(T > t)*

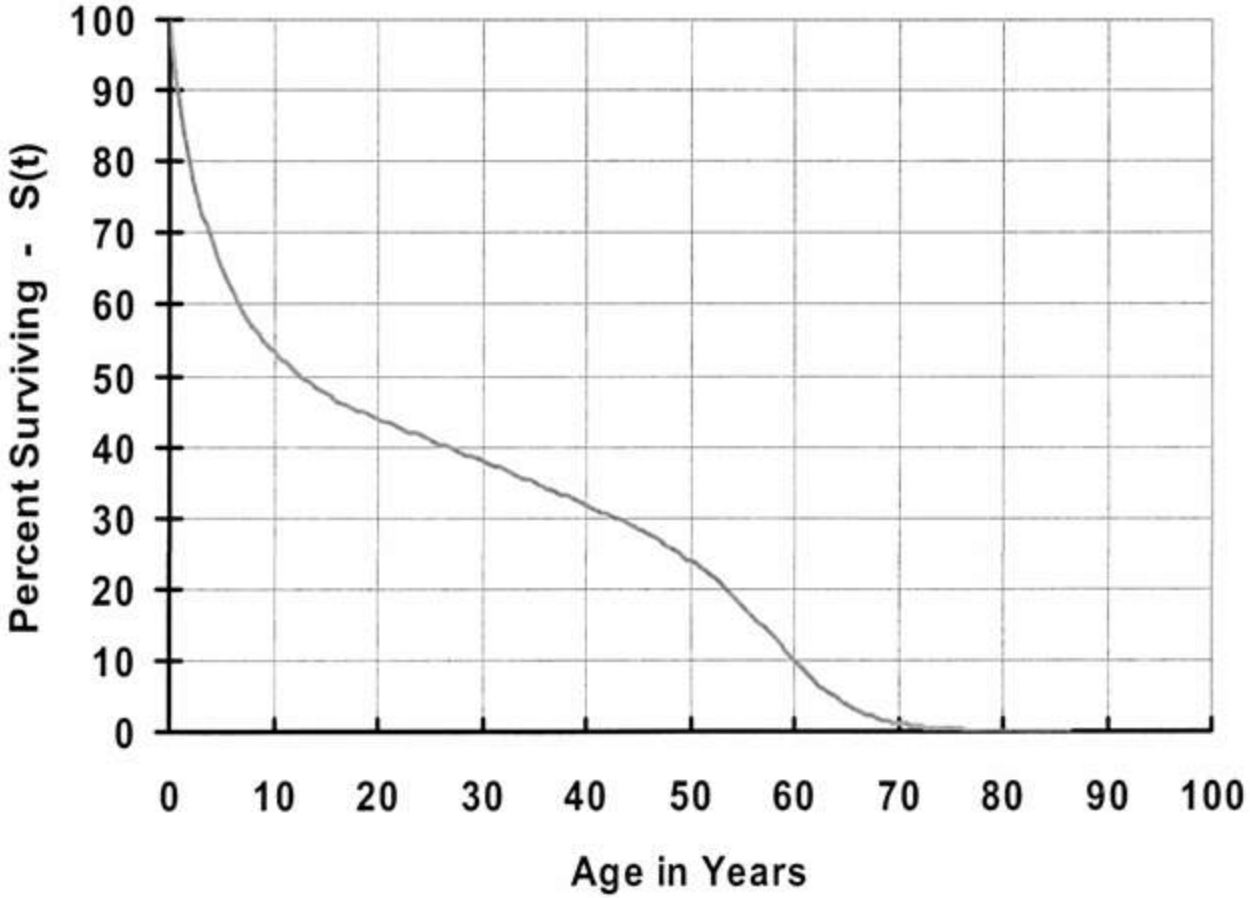
The function S(t) is also known as the cumulative survival function. 0 ≤ S(t) ≤ 1

$$\hat{S}(t)=\frac{\text{number of patients surviving longer than } t}{\text{total number of patients in the study}}$$

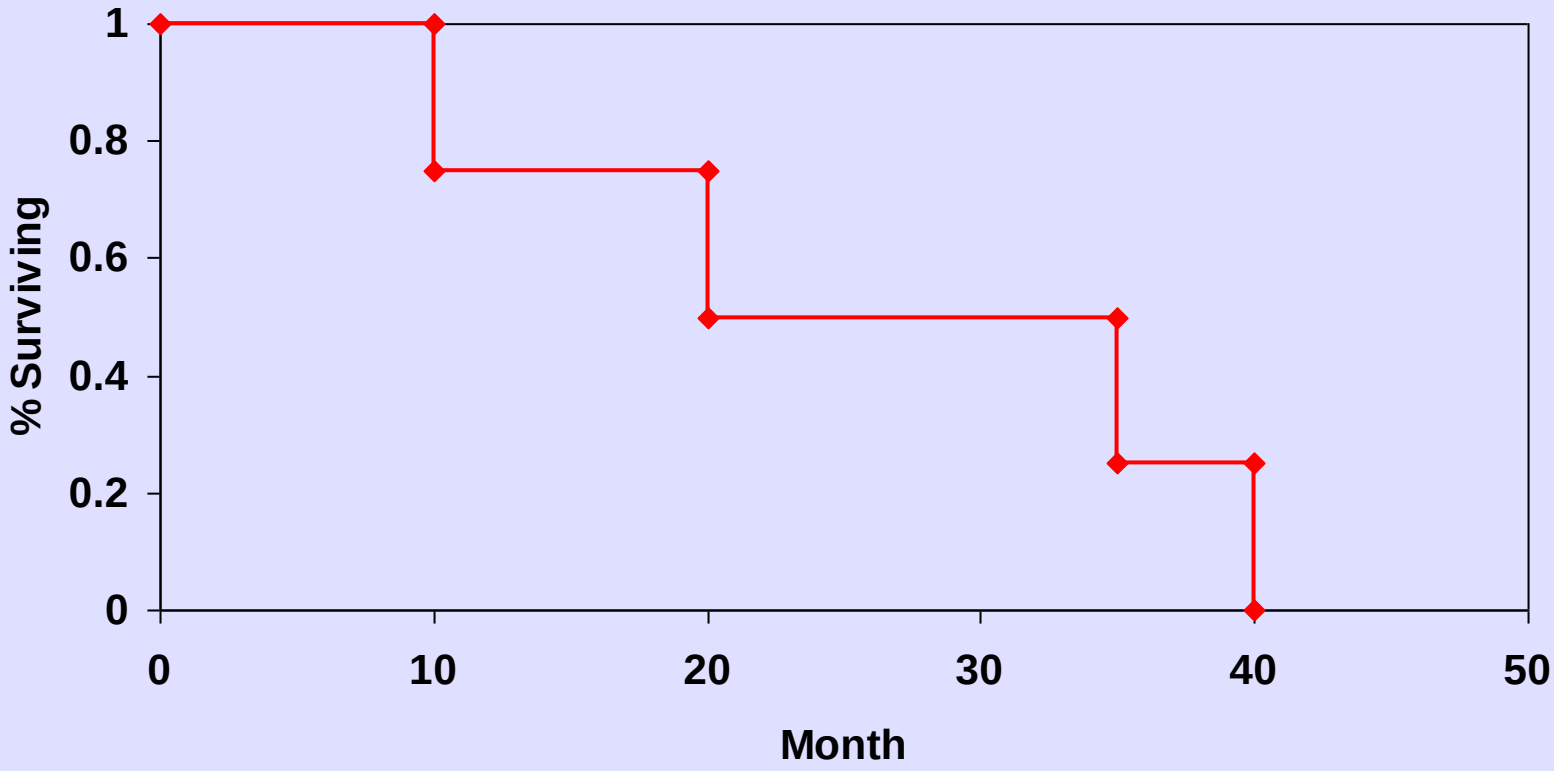
Western Countries – All Cause Mortality



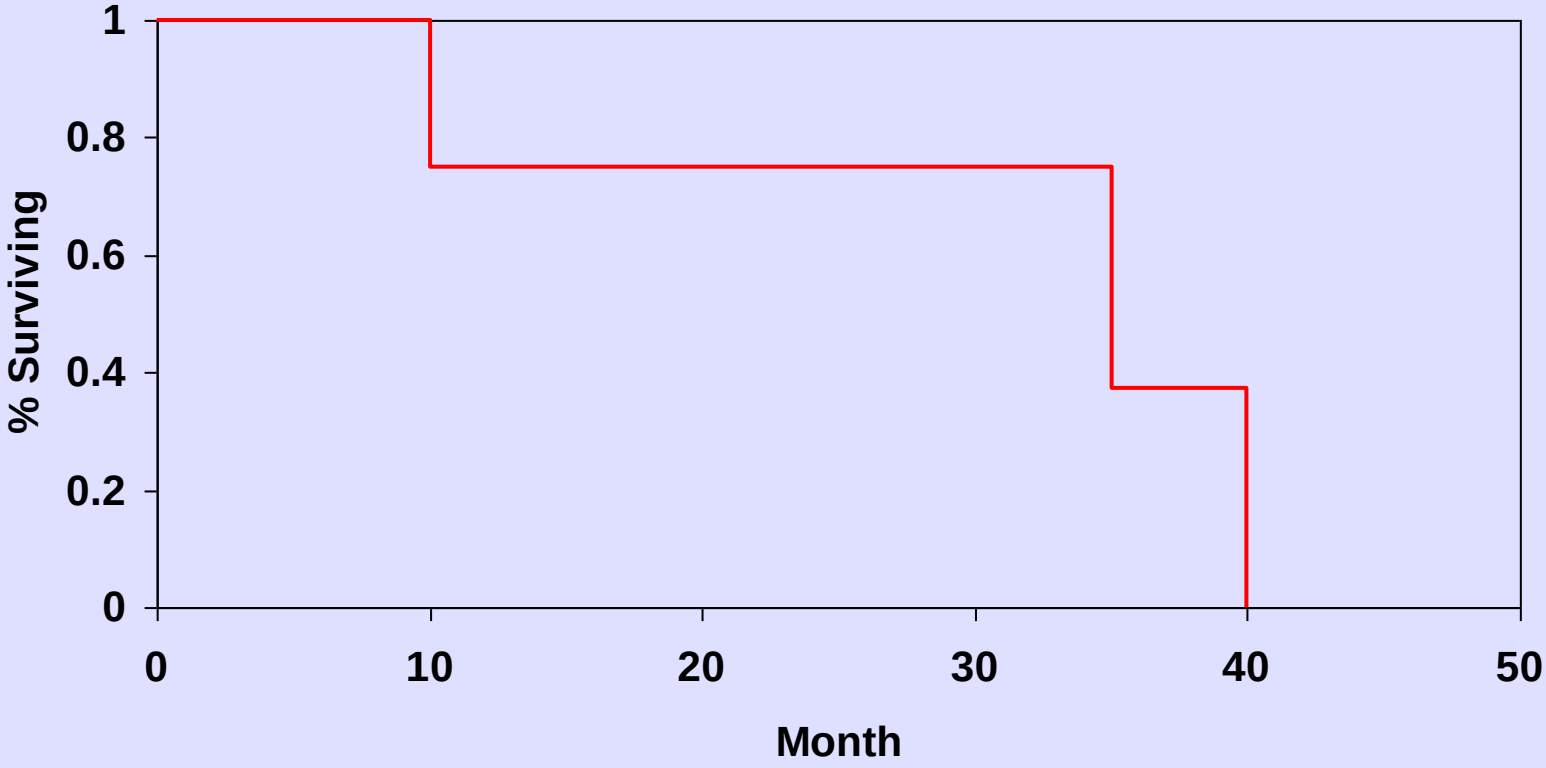
Third World Countries – All Cause Mortality



E.g: Four patients' survival time are 10, 20, 35 and 40 months. Estimate the survival function.



Example: Four patients' survival data are 10, 15+, 35 and 40 months. Estimate the survival function



In 1958, Product-Limit (P-L) method was introduced by Kaplan and Meier (K-M)

- As you move from left to right in estimation of the survival curve first assign equal weights to each observation. Do not jump at the censored observations
- Redistribute equally the pre-assigned weight to the censored observations to all observations to the right of each censored observation

- Median survival is a point of time when S(t) is 0.5
- Mean is equal to the area under the survival curve

A few critical features of P-L or K-M Estimator

- **The PL method assumes that censoring is independent of the survival times**
- **K-M estimates are limited to the time interval in which the observations fall**
- **If the largest observation is uncensored, the PL estimate at that time equals zero**

Comparison Of Two Survival Curves

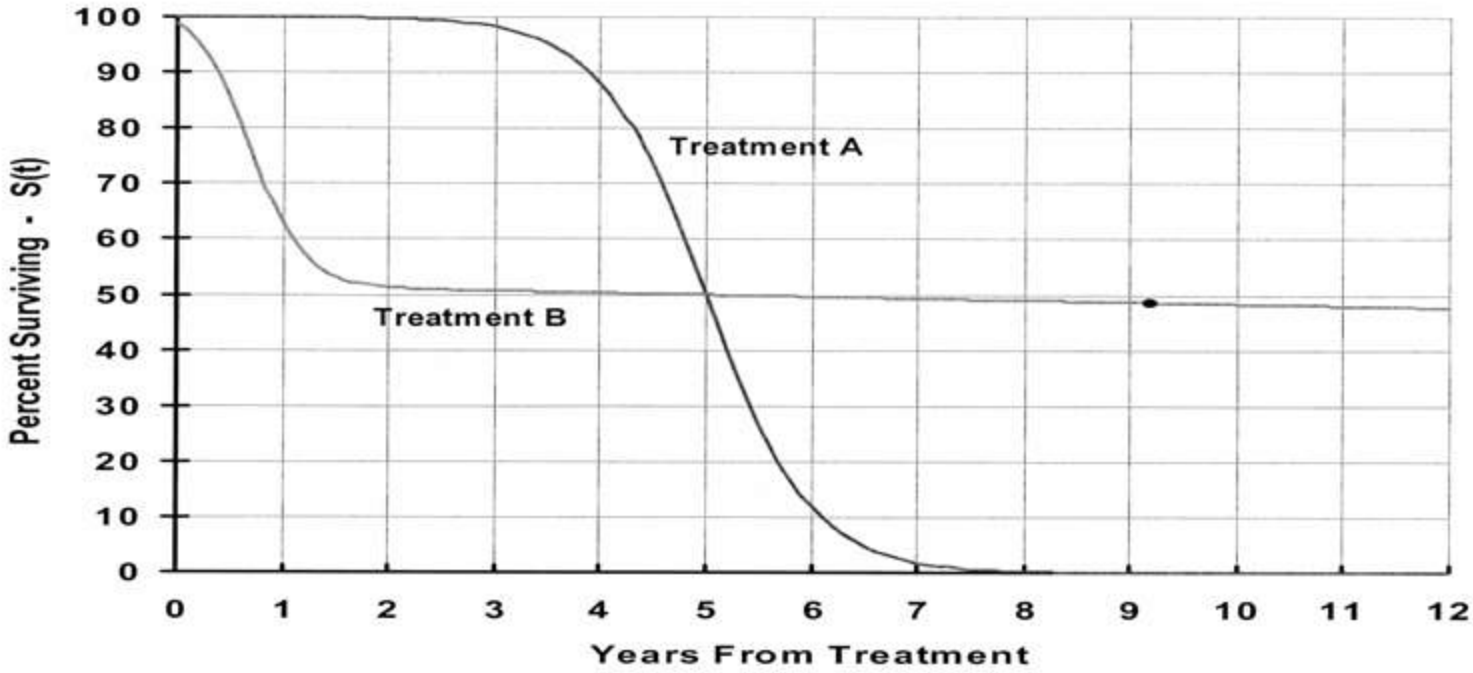
- Let $S_1(t)$ and $S_2(t)$ be the survival functions of the two groups.
- The null hypothesis is

$$H_0: S_1(t) = S_2(t), \text{ for all } t > 0$$

- The alternative hypothesis is:

$$H_1: S_1(t) \neq S_2(t), \text{ for some } t > 0$$

TWO DIFFERENT SURVIVAL CURVES

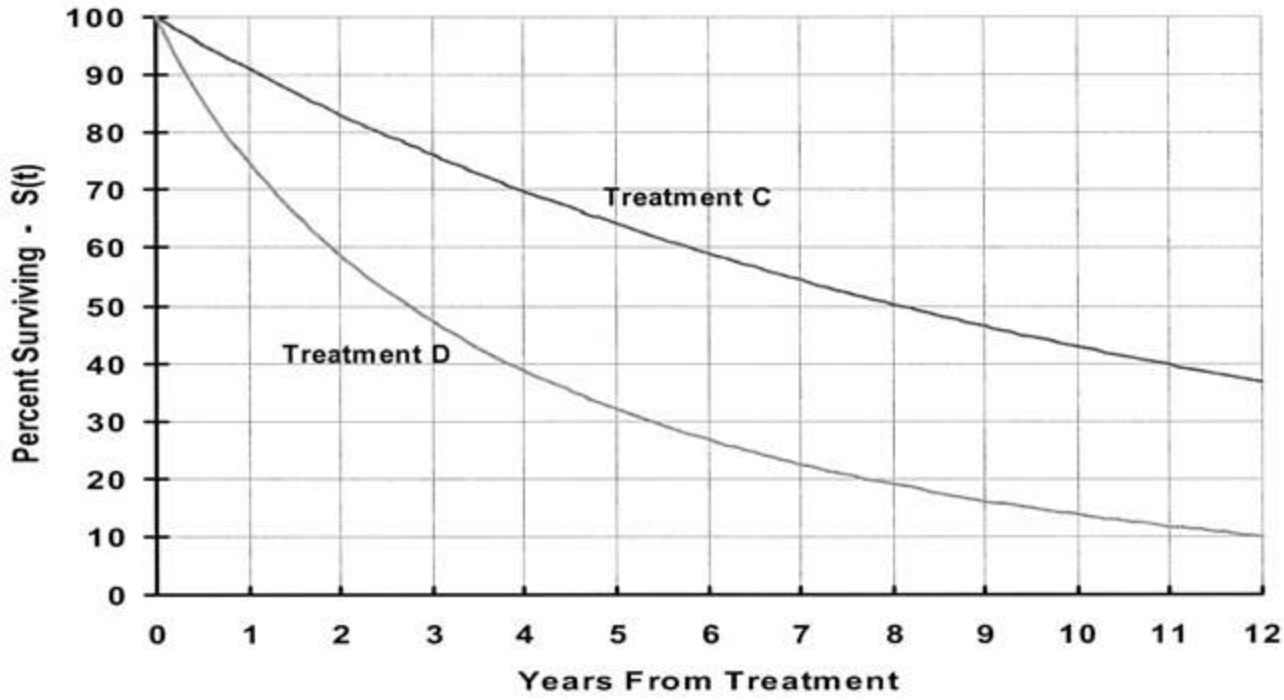


These two survival curves have the same 5-year survival rate of 50%.

The interpretation of the curves is substantially different, however.

Which treatment is preferable will be a subjective judgement.

TWO DIFFERENT SURVIVAL CURVES



These two curves never have the same survival rate.

The interpretation of the curves differs only in magnitude.

Which treatment is preferable will be a simple judgement.

The Logrank Test

- **SPSS, SAS, S-Plus and many other statistical software packages have the capability of analyzing survival data**
- **Logrank Test can be used to compare two survival curves**
- **A p-value of less than 0.05 based on the Logrank test indicate a difference between the two survival curves**

EXAMPLE

- **Survival time of 30 patients with Acute Myeloid Leukemia (AML)**

- **Two possible prognostic factors**

Age = 1 if Age of the patient ≥ 50

Age = 0 if Age of the patient < 50

Cellularity = 1 if cellularity of marrow clot section is 100%

Cellularity = 0 otherwise

Format of the DATA

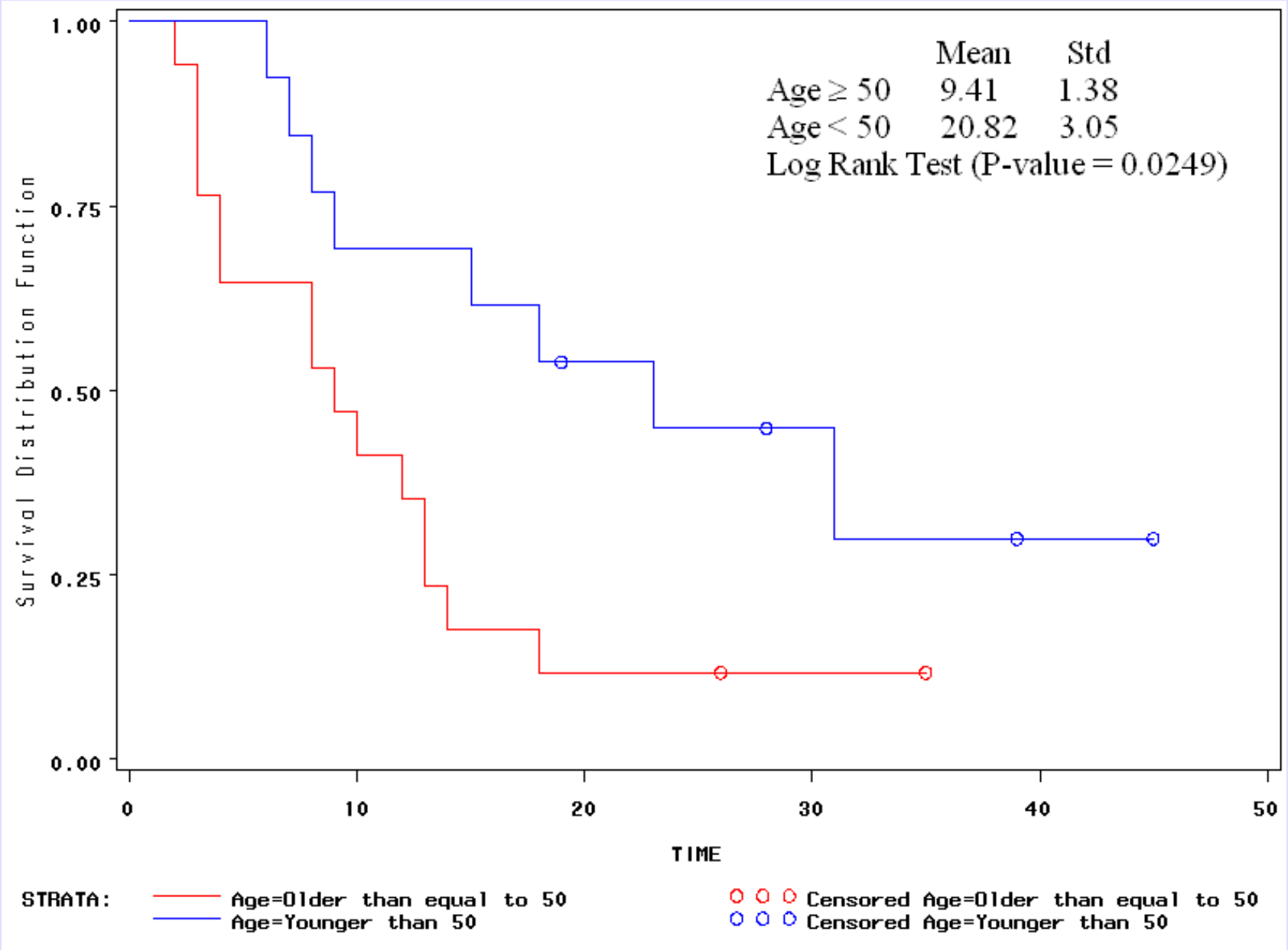
Survival Times and Data of Two Possible Prognostic Factors of 30 AML Patients

Survival Time	Censored	Age	Cellularity
18	0	0	0
9	0	0	1
26	1	1	0
28	1	0	0
8	0	1	0
31	0	0	1

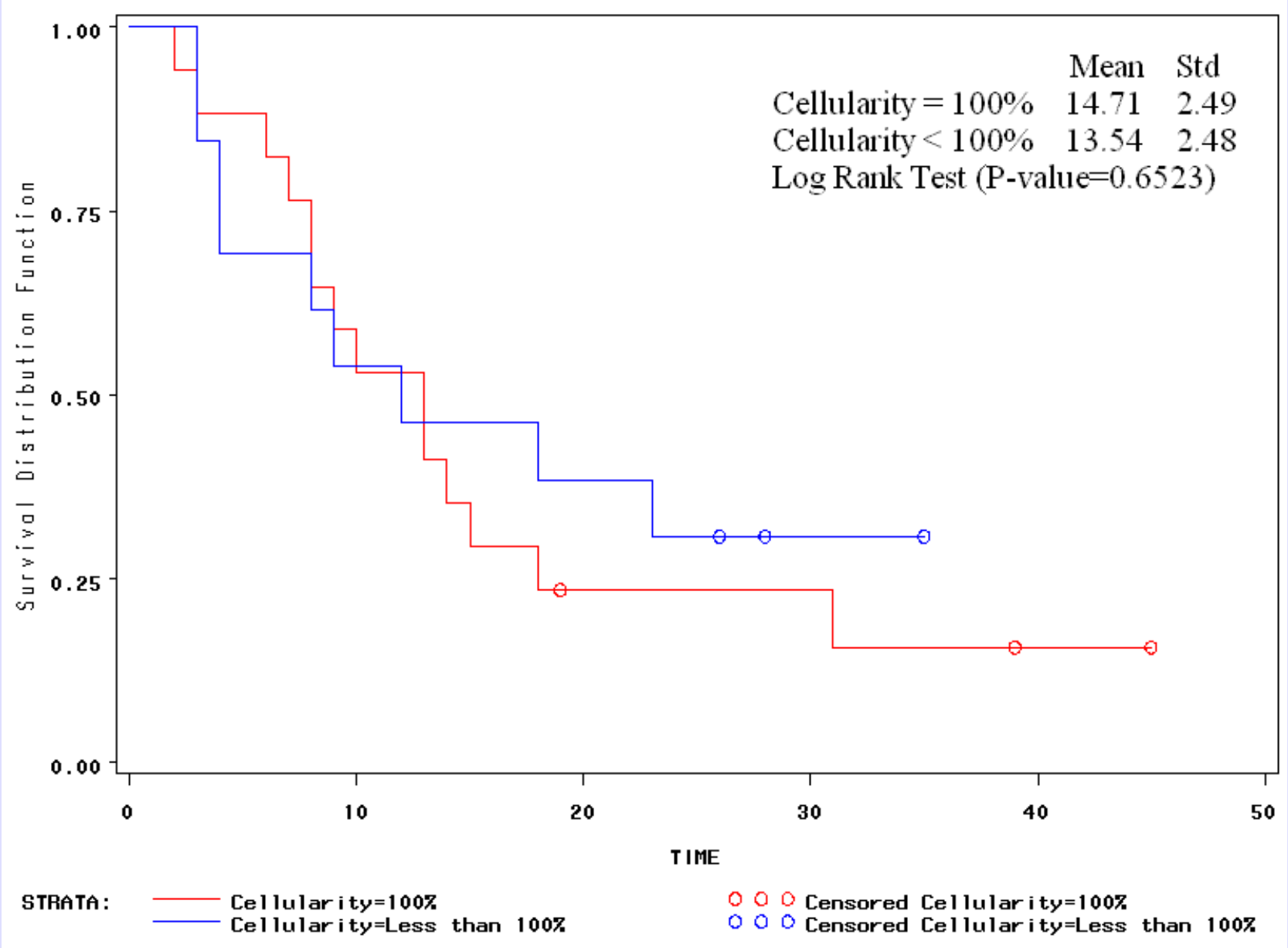
*** Censored = 1 if Lost to follow-up**

Censored = 0 if Data is Complete

Comparing the survival curves by Age Groups using Logrank Test



Comparing the survival curves by Cellularity using Logrank Test



Hazard Function

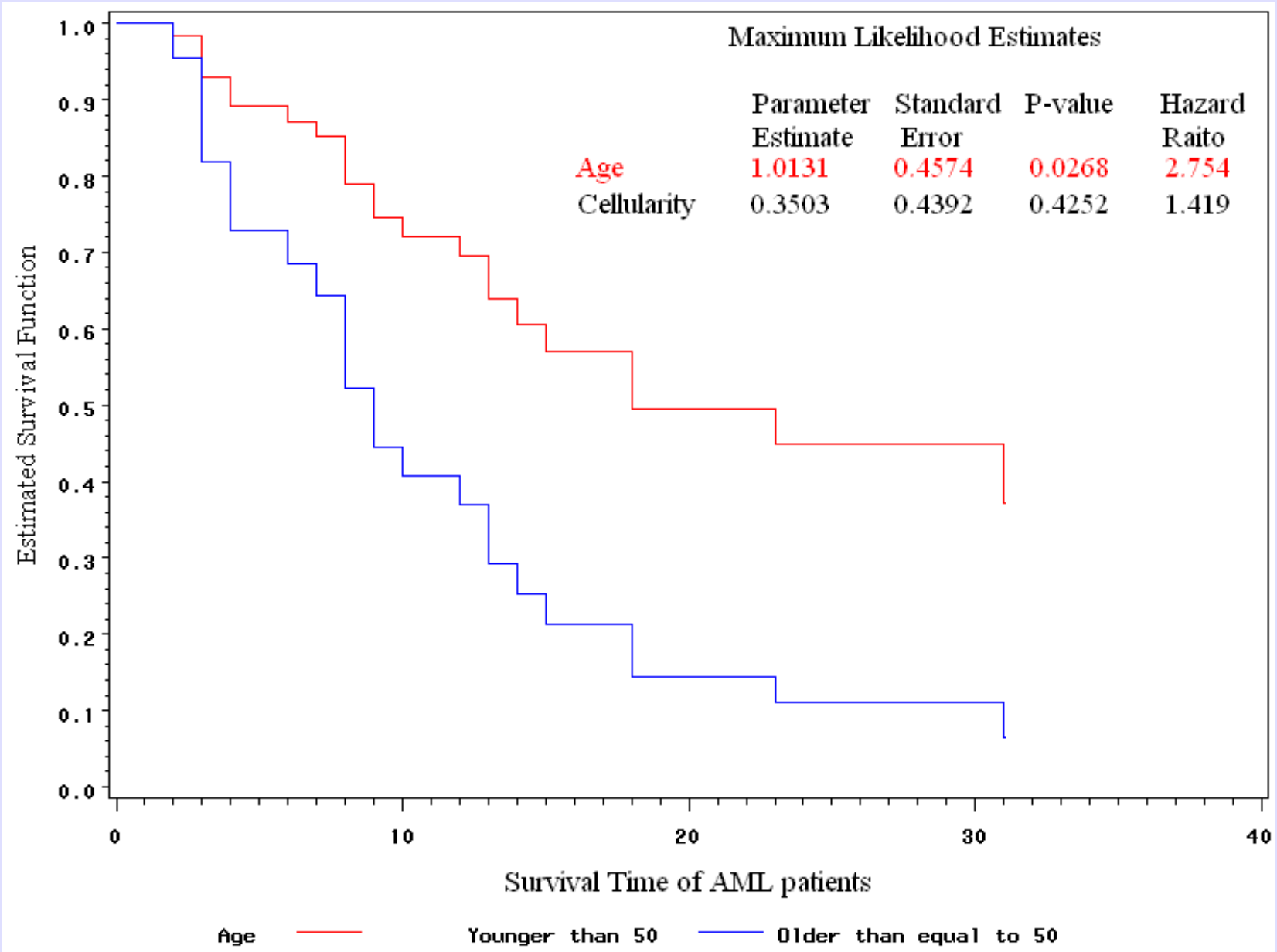
- **The hazard function *h(t)* of survival time *T* gives the *conditional failure rate***
- **The hazard function is also known as the *instantaneous failure rate, force of mortality,* and *age-specific failure rate***
- ***The hazard function gives the risk of failure per unit time during the aging process***

Multivariate Analysis: (CPHM) Cox's Proportional Hazards Model

- **CPHM is a technique for investigating the relationship between survival time and independent variables**

- **A PHM possesses the property that different individuals have hazard functions that are proportional to one another**

Comparing the survival curves by Age Groups after Adjusting Cellularity using CPHM



Comparing the survival curves by Cellularity Groups after Adjusting Age using CPHM