Learning Objectives

At the end of this module, you will be able to:

- Recognize that Six Sigma is a valuable approach for improving process quality
- Interpret a basic Statistical Process Control chart
- Distinguish between process and specified control limits
- Describe a capable process
What is Six Sigma?

• A *Strategy* to improve process quality by identifying and eliminating defects and minimizing variation in process outputs

• A data driven approach based on *Measurement* of the process variation using Statistical Process Control

• A structured *Implementation* approach based on a DMAIC cycle and certified experts

The goal of Six Sigma is to reduce process variation
Some notable qualities of the normal distribution:

- The mean is also its mode and median.
- 68.27% of the area (green) is within one standard deviation of the mean.
- 95.45% of the area (green & yellow) is within two standard deviations.
- 99.73% of the area (green & yellow & red) is within three standard deviations.

Sigma ($\sigma$) = one standard deviation
“Defect” is defined as any process output that does not meet the customer's specifications.

Improving quality means reducing the defects per million opportunities (DPMO). There are two attributes to this metric that can be controlled:

- **Opportunities** – reducing the number of steps, handoffs and other “opportunities” will help improve quality
- **Defects** – reducing the number of defects for each process step through continuous process improvement will help improve quality
Six Sigma – Practical Meaning

99% GOOD (3.8 Sigma)

- 20,000 lost articles of mail per hour
- Unsafe drinking water for almost 15 minutes per day
- 5,000 incorrect surgical operations per week
- Two short or long landings at most major airports each day
- 200,000 wrong drug prescriptions each year
- No electricity for almost seven hours each month

99.99966% GOOD (6 Sigma)

- Seven articles of mail lost per hour
- One unsafe minute every seven months
- 1.7 incorrect operations per week
- One short or long landing every five years
- 68 wrong prescriptions each year
- One hour without electricity every 34 years
Statistical Process Control

• Control charting is the primary tool of SPC
• Control charts provide information about the stability/predictability of the process, specifically with regard to its:
  • Central tendency (to target value)
  • Variation
• SPC charts are time-sequence charts of important process or product characteristics
Class Exercise

- Pharmacy wants to monitor the dispensing of doses of White Bean Medicine
- A 3 cup sample will be taken each day and weighed and recorded on a check sheet
- Data will be entered into two control charts (one for means or averages and one for range)
- Data for the first twenty days will establish the current process capability
- From then on, the pharmacy will monitor the dosages by entering daily samples into the control chart
- Process improvements will be made as needed, based upon data collected.
What To Do
Phase I
Process Capability

- Select three cups with the same sample number (day)
- Weigh each on the digital scale
- Record the data on the check sheet form and calculate the mean (average) and report the results to the instructor
- Also report the lowest and highest weights for each day. Calculate range = highest - lowest
Six Sigma Process - DMAIC

• Define
  • Who are the customers and what are their requirements
  • Identify key characteristics important to the customer

• Measure
  • Categorize key input and output characteristics, verify measurement systems
  • Collect data and establish the baseline performance

• Analyze
  • Convert raw data into information to provide insights into the process

• Improve
  • Develop solutions to improve process capability and compare the results to the baseline performance

• Control
  • Monitor the process to assure no unexpected changes occur
Simple DMAIC Example

- DMAIC is easy to see in process control applications
- The same steps can be used to analyze more complex systems, often in tandem with lean tools
Types of Process Variation

- **Common Cause Variation** is the sum of many "chance causes," none traceable to a single major cause. Common cause variation is essentially the noise in the system. When a process is operating subject to common cause variation it is in a state of statistical control.

- **Special Cause Variation** is due to differences between people, machines, materials, methods, etc. The occurrence of a special (or assignable) cause results in an out of control condition.

Control charts provide a means for distinguishing between common cause variability and special cause variability.
Control Chart Example - Patient Falls

Phase I – Establish Process Capability

Phase II – Monitor the Process

Reference: National Quality Measures Clearing House
What To Do
Phase II Process Monitoring

• Draw control limits on your chart based on the first 20 samples.
• Weigh a new sample (3 cups), record the data on the 2\textsuperscript{nd} check sheet and calculate the average and range.
• Plot the average and range on the charts, and decide if the process is in control.
• If the process goes out of control, stop and investigate the cause using a fishbone diagram.
Control Chart Example - c Chart for Resident Falls

Are our falls on 3A decreasing?

Source: Faten Mitchell, Quality Improvement Advisor, Health Quality Ontario

Courtesy of Faten Mitchell, Quality Improvement Advisor, Health Quality Ontario. Used with permission.
• In early stages, control charts (usually on output variables) are used to understand the behavior of the process
• After corrective actions, place charts on critical input variables
The goal: Monitor and control inputs and, over time, eliminate the need for SPC charts by having preventative measures in place.

If a chart has been implemented, remove it if it is not providing valuable and actionable information.
Process Capability

- "Process Capability is broadly defined as the ability of a process to meet customer expectations" (Bothe, 1997)

- Once we have a process in control then we can answer the question of whether the process is capable of meeting the customer's specifications.
Customer and Process Quality Defined

- **Process Quality** is a measure of the capability of a process to produce to its expected capability
  - *The upper and lower values between which the process must be controlled are known as upper and lower control limits (UCL and LCL)*
- **Customer Quality** is the conformance to customer specifications within a tolerance band
  - *The upper and lower values that the customer is willing to accept are known as upper and lower specification limits (USL and LSL)*

How can we assure Process Capability?
Assessing Process Capability

Cₚ, a term used to define process capability, is mathematically expressed by:

\[ C_p = \frac{USL - LSL}{6\sigma} \]

The figure shows centered distributions with various Cₚ levels. Note Cₚs less than two have visible tails outside the acceptable limits.
Non-Centered Distributions

If the distribution is off center, the probability of a bad result drastically increases. In this case $C_{pk}$ is used. It is the smaller of

$$C_{pk} = \frac{USL - Mean}{3\sigma}$$

or

$$C_{pk} = \frac{Mean - LSL}{3\sigma}$$

This figure shows the same distributions off-center by $1.5\sigma$. The $C_{pk}$s are smaller than the corresponding $C_p$s. This illustrates the need to both control variation and accurately hit the desired mean.
In this case, the shooter (archer) has a good eye, but all the shots are off-center.

- \( C_p \) is high
- \( C_{pk} \) is low

In this case, the shooter (archer) has a bad eye – the shots are widely dispersed and slightly off-center.

- \( C_p \) is low
- \( C_{pk} \) is low

In this case, the shooter (archer) has a good eye, and has now adjusted the gun (bow) sight to bring the shots on target.

- \( C_p \) is high
- \( C_{pk} \) is high
### Implications of a Six Sigma Process

Six Sigma is defined as 3.4 defects per million opportunities, or a first pass yield of 99.9997%.

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<th>Mean On-Target</th>
<th>Process Mean Shifted 1.5 $\sigma$</th>
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With a Six Sigma process even a significant shift in the process mean results in very few defects.
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Wrap Up

• Six Sigma is an effective quality system
  • Widely deployed in manufacturing
  • Actively being pursued in healthcare

• Control charts are an effective visual aid in monitoring process capability
  • Other SPC analysis tools are available

• If “customer” specifications for process quality (USL, LSL) can be established, Six Sigma methods can help achieve desired outcomes.
Reading List


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Contributors

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