Curriculum for Outcomes research, Performance Improvement, and Comparative Effectiveness

Lecture 6: Quality Improvement Tools

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Objectives

- Understand how SPC charts are used in quality improvement
- Learn how to produce SPC charts in Minitab
- Understand how to interpret results

Understanding Variation

- To improve any process, it is useful to understand its variation
- All variation is caused by common and/or special causes
- There are two major classifications of causes which help you select appropriate managerial actions:
  - If all variation is due to “common causes,” the result will be a predictable or stable system
  - If some variation is from “special causes,” the result is an unstable or unpredictable system
Consequences of Not Understanding Variation

- See trends where there are no trends
- Blame and give credit to others for things over which they have little or no control
- Build barriers, decrease morale, and create an atmosphere of fear
- Unable to fully understand past performance, make predictions about the future, and/or make significant improvements in processes

Which questions can be answered?

- **Is the process in control?** A process is in control if it is stable and predictable over time. (*Measure*)
- **What factors drive the variation in a process?** Control charts help us quantify this. (*Analyze*)
- **Were our improvement efforts successful?** Control charts help evaluate the effect of changes to a process. (*Improve*)
- **How much did I change the process?** Control Charts help monitor a process to ensure improvement efforts are maintained. (*Control*)

Depicting Variation

- **Static Display**
  - mean, median, mode
  - range, standard deviation, variance, coefficient of variation
  - aggregate display (bar graphs, tables, histograms)

- **Dynamic Display**
  - run or control charts

- **time**
Run Chart

A Run Chart is a graph of a data element over time.

It allows you to study your process over time looking for variation, patterns, trends, or response to changes that have been made to the process.

Example data set

- Central line associated bloodstream infections
Anatomy of a Run Chart

- Central Line Associated Bloodstream Infections
- Measures of Central Tendency
- Chronological observations over time

Interpreting a Run Chart

- **Shift** – 8 or more consecutive points above or below the centerline
- **Trend** – 6 or more consecutive points all going in one direction
- **Pattern** – 8 or more consecutive times

Run Chart Analysis
Run Chart Analysis

Run Chart of CLABSI Rate

Observation

Central Line Associated Bloodstream Infections

Central Line Associated Bloodstream Infections

Control Charts
Basic Control Chart Theory

A phenomenon will be said to be controlled when, through the use of past experience, we can predict, at least within limits, how the phenomenon may be expected to vary in the future. Here it is understood that prediction within limits means that we can state, at least approximately, the probability that the observed phenomenon will fall within the given limits.

Walter A. Shewhart, 1931

Control Chart Features

A control chart typically consists of two different charts: an Individuals or Averages Chart and a Range Chart.

- Individuals or Averages Chart features include:
  - Plotted Data (individual points or averages) in time ordered series
  - Process average
  - Upper Control Limit (UCL)
  - Lower Control Limit (LCL)

- Range Chart features include:
  - Plotted Range Data in time ordered series
  - Range average
  - Upper Control Limit (UCL)
  - Lower Control Limit (LCL) (if one exists)

Elements of a Control Chart
The Normal Distribution and Control Limits

The Normal Distribution and Control Charts

Normalizing a non-normal process

Normal distributions are not the norm.

The Central Limit Theorem:
- implies that the sum of a large number of data points will be normally distributed regardless of the distribution of the individual data points.
- the mean of the samples will be normally distributed. The larger the number of samples, the closer the sum or average distribution is to a normal distribution.
Central Limit Theorem and SPC

It allows you to study the variation in your process and recognize when changes are random or when something new or unusual is present in your data.

Control Chart

Common and Special Cause Variation

Sources of variation come from materials, methods, measurement, machines, and mother nature/environmen, manpower.

Common Cause Variation

Variation in process data which is random.

Special Cause (Assign able) Variation

Variation in process data which is not random. It is associated with a particular part of the process and/or event.
Control Charts

In a stable process, virtually all (99.7%) common cause variation falls within ±3σ of the mean.

Interpreting Control Charts

Interpret Run or Control Chart

Unstable

Stable

Stable

Special Cause Strategy

Root Cause Analysis

Common Cause Strategy

Process Analysis

Things to Look For

• Points outside the control limits
• Trends
• Shifts
• Cycles
Interpreting Control Charts

- **Shift**: 8 or more consecutive points above or below center line
- **Trend**: 6 or more consecutive points going in the same direction
- **Pattern**: 8 or more consecutive times
- A single point outside the control limits
- A run of 7-9 points in a row
- 2 of 3 consecutive points more than 2 sigma from center line
- 15 consecutive points close to the centerline

Is the Process “Out of Control?”

Investigating Special Cause Variation

- Mean = 5.250
- UCL = 5.264
- LCL = 5.236
Investigating Special Cause Variation

Run of 9 Points on One Side of the Centerline

Mean = 5.249
UCL = 5.261
LCL = 5.237

Mean = 5.248
UCL = 5.261
LCL = 5.237

Investigating Special Cause Variation

Six Points Trending in the Same Direction

Mean = 5.249
UCL = 5.261
LCL = 5.237

Mean = 5.248
UCL = 5.261
LCL = 5.237

Process In-Control

No Special Cause Variation Evidenced

PROCESS IN-CONTROL

Mean = 5.249
UCL = 5.261
LCL = 5.238

Mean = 5.248
UCL = 5.260
LCL = 5.238

No Special Cause Variation Evidenced

PROCESS IN-CONTROL

Mean = 5.249
UCL = 5.261
LCL = 5.237

Mean = 5.248
UCL = 5.263
LCL = 5.237
Common Cause Variation

Random variation patterns indicate common cause variation. The following chart illustrates random variation patterns in a process. The points are scattered evenly about the centerline on both charts and detectable patterns in the data are not present.

Identifying Shifts

A sudden shift in level is shown by a change in one direction. A number of points will appear on one side of the Control Chart.

Typical causes are:
- Change in material
- New personnel
- New equipment setting
- Shift change
- New supplies
- Change in process method

Identifying Trends

A long series of points that lack a change of direction. There is a continuous movement of points up or down on this chart. Points will be on one side of centerline followed by points on the other side.

Typical causes are:
- Equipment wear
- Aging
- Seasonal effects
- Operator fatigue
- Inadequate maintenance
- New materials
Short trends that occur in repeated patterns, which become predictable or systematic. There is an indication of assignable cause because characteristic of a random pattern is that it does not repeat.

**Identifying Cycles**

Cycles

Causes that can create this type of pattern could be:

- Seasonal effects
- Worn equipment
- Maintenance
- Measurement differences
- Shifts

**Type of Data?**

- Variable (Continuous)
- Attributes (Discrete)

**Deciding what type of control chart to use**

**X bar and S Chart**

Use a X bar and S Chart when you have variable data and you have a subgroup size of greater than 1. The subgroup can be unequal or equal.

The control limits that are calculated for each subgroup is the standard deviation of the entire subgroup. The subgroup on the S chart is the standard deviation of the measures of the subgroup.
X-bar and S Chart Interpretation

How would you interpret this?

Tests performed with unequal sample sizes
The control limits are calculated for each subgroup. Usually when you have a rate, you will use this chart.

Use a U Chart when you have attributes data when you can count the number of nonconformities but not conformities and you have an unequal area of opportunity.

Tests performed with unequal sample sizes
Control Limits vs. Specification Limits

Control Limits
- Defined based on process performance
- Help determine if your process is “in control” (no special causes)
- Plotted on control charts
- Change when there is a verified, significant change to your process
- Represent the voice of the process

Specification Limits
- Defined based on feedback from the customer(s)
- Help determine if your process is producing defects
- Plotted on histograms
- Change when your customers say they do!
- Represent the voice of the customer

Control Limits vs. Specification Limits

It is possible to have a stable (in control) process that has unacceptable variation. Assume both process A and B are statistically performing “in control”

PROCESS A

PROCESS B

When a process is in statistical control and still has unacceptable variation, work on the reduction of variation due to common causes.

Setting Up Control Charts

- Control limits should be based on common cause variation
  - All special cause variation should be removed
  - Objective is to maximize the chances of detecting special cause variation
- Guideline: use 20-30 data points to construct the control limits
- Question: when, if ever, do we change the limits?
When to recalculate Control Limits

(1) Do the data display a clearly different kind of behavior than in the past?  No  
    No need for new limits

(2) Is the reason for this change known?  No  
    Look for assignable causes rather than tinkering with limits

(3) Do we intend for or expect the new behavior to continue?  Yes  
    OK to revise limits based on data collected since the change in process behavior

Stata Code: p-chart

pchart reject_var unit_var ssize_var [, pchart_options]
Pchart CLABSI Date LineDays

or use interface
Graphics>Quality Control>pchart
Select [pull down menu]: variable containing # rejected; variable containing unit identifier; variable with # inspected in each unit
--Lots of options: title, legend, format lines, etc.; control limits (or use default)
**SPC – Summary**

- Control limits describe “boundaries” of normal process behavior:
  - Control limits are usually set at plus or minus three standard deviations from process mean
  - Set your limits based on your project needs or your customer specifications.
- Special cause variation
  - Points outside control limits
  - Patterns: trends, shifts, cycles
- Common cause variation
  - Random data fluctuations within control limits
  - Process performance will continue as is unless a fundamental process alteration takes place

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**Homework Assignment**

- Using the little CLABSI dataset, try creating other types of control charts in STATA
- Interpret results.