



Statistical Process Control Charts

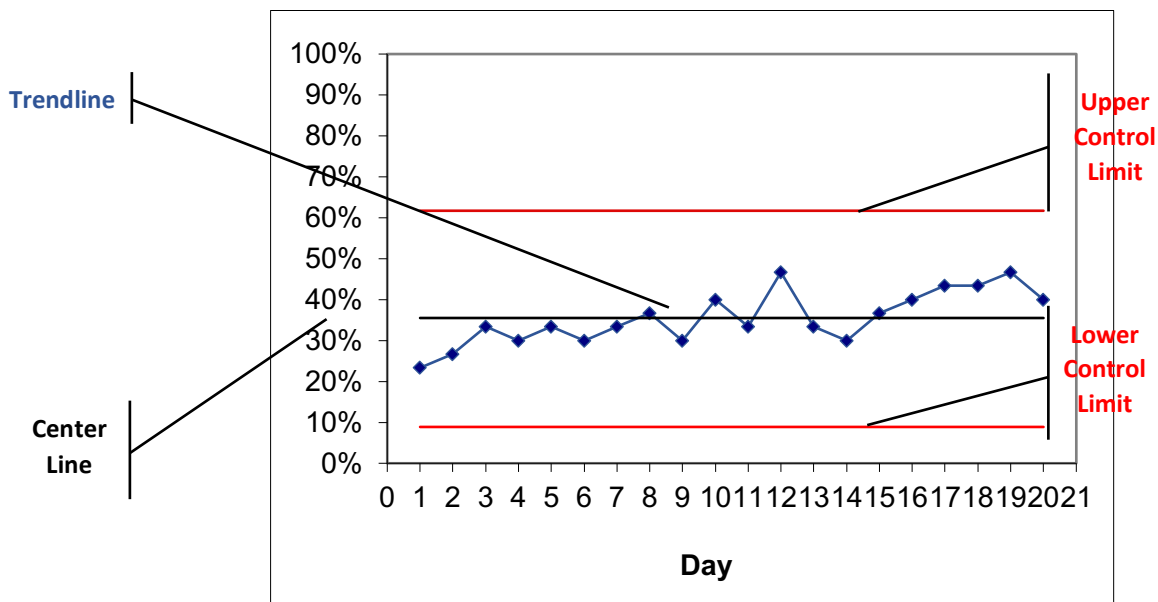
Statistical Process Control (SPC) charts are a useful tool for understanding variation in a process and, like Run Charts, distinguishing changes that occur due to specific circumstances (whether intentional or not) from changes that occur due to chance variation inherent in a system. Specific terminology is used in the analysis of SPC charts to differentiate the causes of these changes.

- **Common Causes:** causes that are inherent in the system or process that are present all the time and lead to chance variation within the system
- **Special Causes:** causes that are not part of the system or process and are only present under specific circumstances, that cause variation outside of the normal play of chance

Special Cause variation is similar to the concept of *statistical significance* in research, but it is not the same thing probabilistically. The mathematical bounds underlying Special Cause Variation were determined empirically, with a view to allowing process improvement efforts to proceed nimbly at the expense of some risk of Type I Error (a false positive, or incorrectly finding Special Cause Variation).

SPC charts are more difficult to construct than Run Charts because they require more data and more robust statistical power, but they are superior to Run Charts in their ability to visualize variation in a process due to their precision in distinguishing special from common cause variation. This makes them superior in determining the stability of a process, the capability of a process, and deciding on the best improvement strategy. They are useful for not only testing for improvements, but for monitoring a process and quickly determining whether an improvement needs to be made nearly in real-time. **SPC charts are preferred over Run Charts if you have enough data to create them.**

Anatomy of a Statistical Process Control Chart

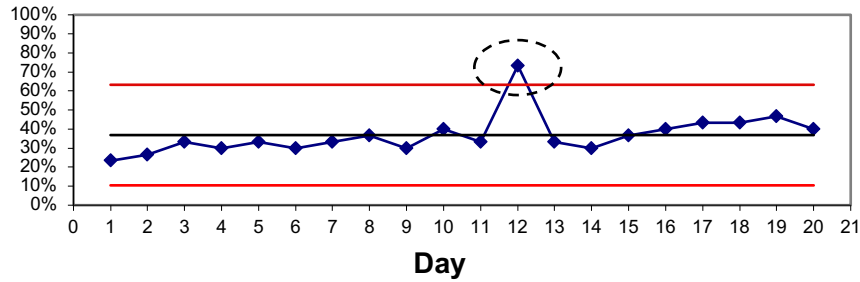


1. Trend line: Just as in a Run Chart, this is the visual representation of the data and its movements in time
2. Center Line: The statistical center of the data, determined by the type of data and sampling used. Most often it is the mean.
3. Upper and Lower Control Limits: Also known as 3-sigma lines, these bars demarcate the bounds of three standard deviations above and below the Center Line. These are the upper and lower bounds of control within which any variation can safely be assumed to be caused by chance alone.

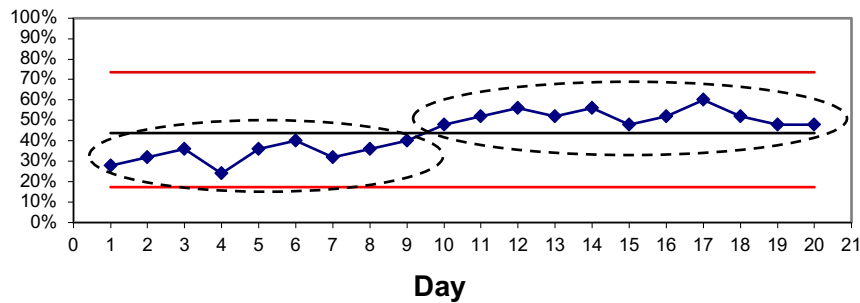


Indicators of Special Cause Variation

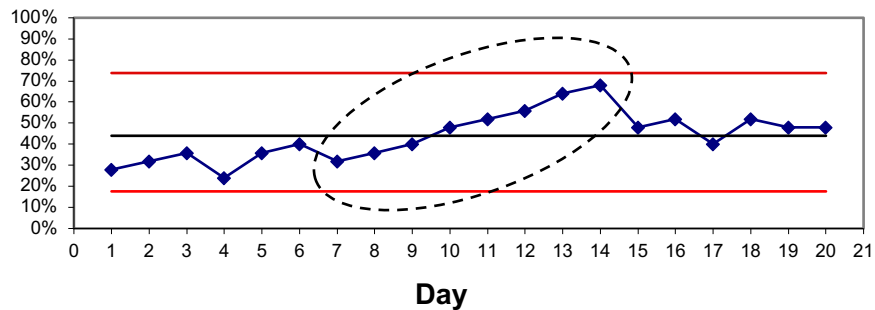
Rule 1: A single point falling outside of the control limits. This rule quickly identifies new changes in a process so they can be promptly investigated.



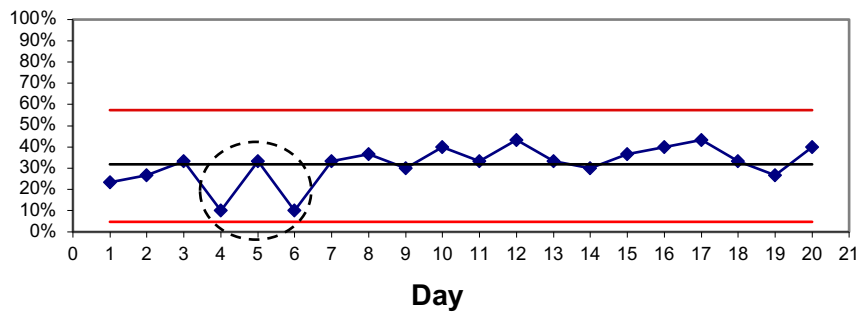
Rule 2: A shift of 8 or more consecutive points above or below the center line. This rule helps identify smaller, sustained changes to a process.



Rule 3: A trend of 6 or more points in one direction, up or down (two consecutive points of equal value count as one). This rule visualizes a consistent drift in a process. Of note, this rule has the least statistical validity but is useful in practice.



Rule 4: Two out of any three consecutive points falling in the outer one third of the control limit. This rule increases the sensitivity to detect changes that do not trigger rules 1 or 2 and can be used as a backup.





Using SPC Charts

SPC Charts can help visualize the variation in a process, and therefore helps inform decisions about what improvements to make to it. Principally, SPC charts help avoid using resources incorrectly when making improvement decisions. Secondly, they can help visualize whether a change led to an improvement.

When a system shows only common cause variation, its processes are stable and its outcomes are the result of the fundamental design of the system. Special cause variation occurs when an aberrant process or action occurs and throws the system out of balance, making it unstable. Depending on whether this change was bad or good, when special cause variation is seen it should prompt investigation into its specific cause and efforts to discourage or encourage that specific cause without the need for a full system overhaul.

	Special Cause Present in System	Only Common Cause Present in System
Act on a specific part of the system while leaving the system fundamentally intact	Correct Action – No resources wasted	Mistake – unlikely to result in meaningful change
Overhaul the whole system	Mistake – Likely overuse of resources	Correct Action – No resources wasted

One can also look for an occurrence of Special Cause Variation after deploying an intervention to see if the intervention has destabilized the system for the better.

Making SPC Charts

Because of the more complex statistics involved in making an SPC chart, we recommend you involve a QI expert or a statistician when creating one. There are different types of SPC charts, each with different underlying calculations, for use with different types and quantities of data. Use of the wrong type for your particular data set may result in erroneous conclusions about the efficacy of your improvement efforts. NOTE: many biostatisticians may not know about these, so be sure to ask!