NHS Improvement

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Statistical process control

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Statistical process control

What is it?

There are two methods to support the robust statistical interpretation of measures presented over time and to understand if your process has special cause and/or common cause variation. These are **run charts** and statistical process control (SPC) charts. SPC can help you understand the scale of any problem, gather information and identify possible causes when used in conjunction with other investigative tools, eg **process mapping** and **spaghetti diagrams**. You will then be able to measure the impact of any change and evaluate its worth.

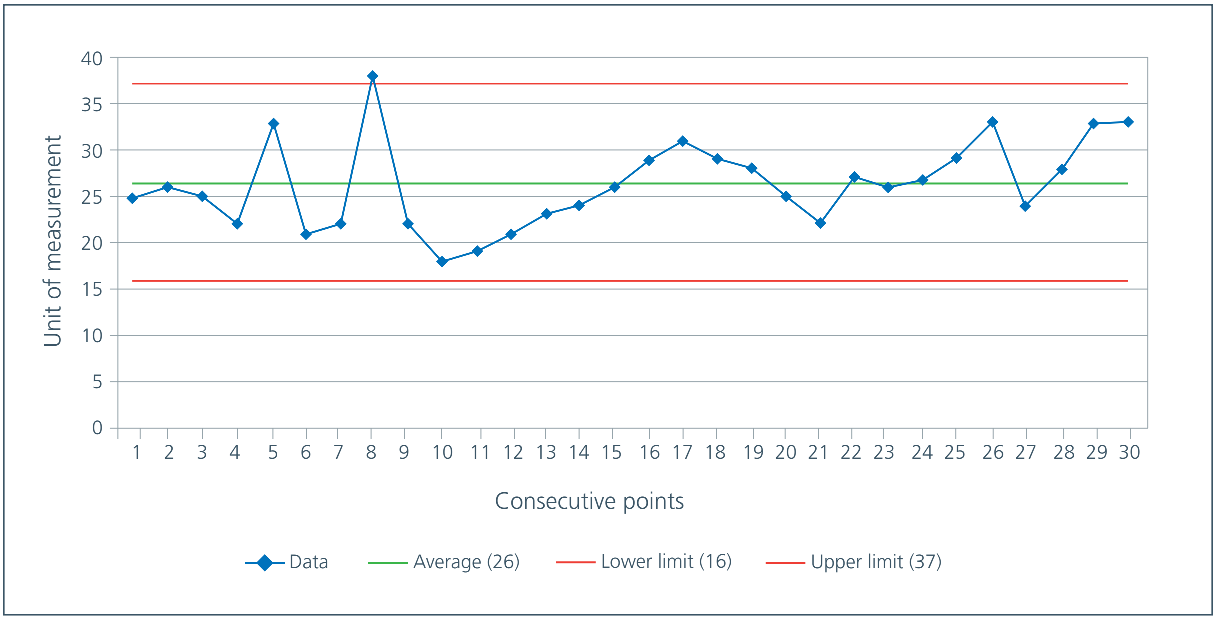
When to use it

SPC should be used throughout the life cycle of the project to help you identify a project, get a baseline and evaluate how you are currently operating. SPC will also help you to assess whether your project has made a sustainable difference.

How to use it

An SPC chart has an average line (mean or median – the mean is most often used in SPC charts) and two control lines above and below the average line, both of which allow more statistical interpretation.

Figure 1: Example of an SPC chart



SPC tells us about the variation that exists in the systems that we are looking to improve.

S – statistical, because we use some statistical concepts to help us understand processes.
P – process, because we deliver our work through processes ie how we do things.
C – control, by this we mean predictable.

SPC charts are constructed by plotting data (we suggest a minimum of 25 data points or more ideally) in time order, calculating and displaying the average (the mean) and some data comparisons known as the upper and lower control limits as lines. These limits, which are a function of the data, give an indication by means of chart interpretation rules as to whether the process exhibits common cause (predictable) variation or whether there are special causes. After plotting your chart, the next stage is therefore analysing the chart by looking at how the values fall around the average and between the control limits.

Generally we use specialist software to create SPC charts, but charts can also be easily created using MS Excel. There are four rules to interpret SPC charts and if you use specialist software, these rules will be flagged so you don't need to remember them. If one of the rules has been broken, this means that special cause variation exists in the system and once identified, can be removed. It is also perfectly normal for a process to show no signs of special cause variation. This means that only common cause variation is present and therefore by reducing variation you can improve the process further to deliver standard results – ie it is necessary to ensure that only common cause variation is present before you make a change.

Figure 2: Rule 1 – any single point outside the control limits:

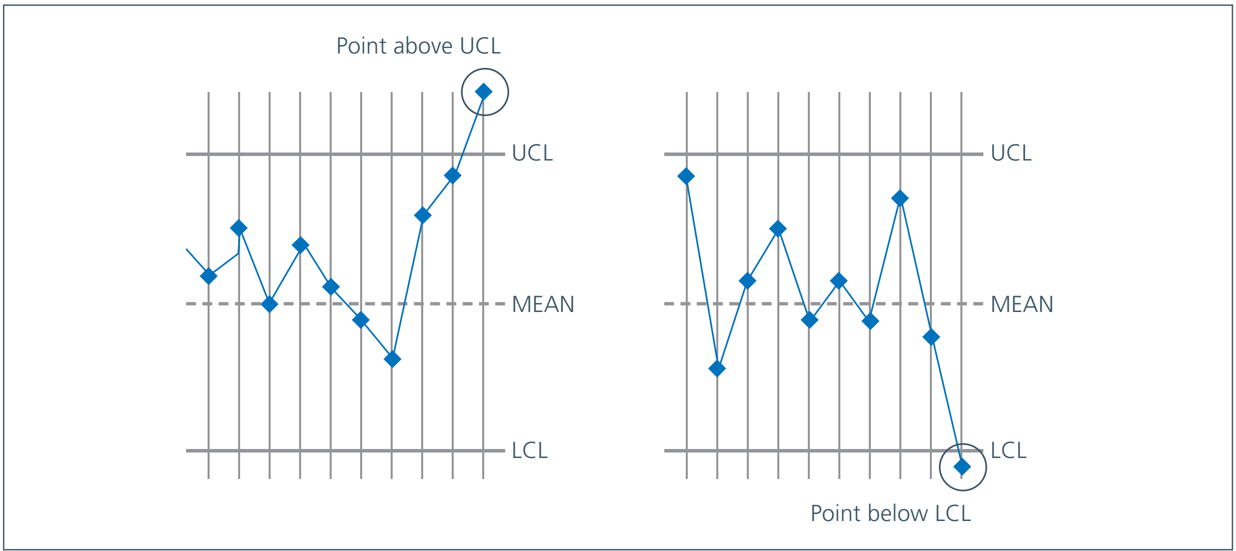


Figure 3: Rule 2 – a run of seven points all above or all below the centre line (a shift), or a run of seven points all consecutively ascending or descending (a drift):

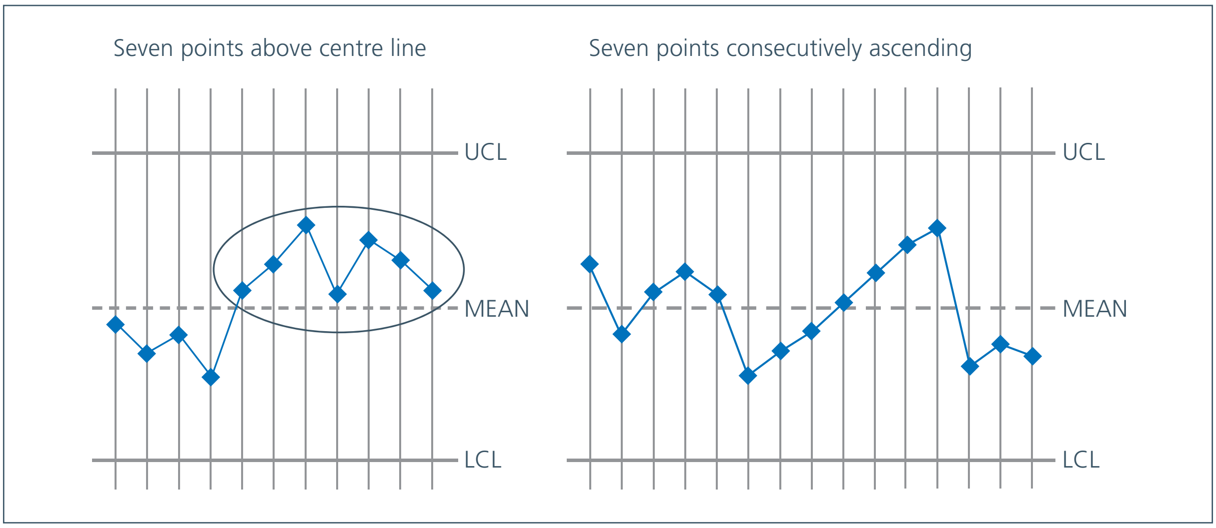


Figure 4: Rule 3 – any unusual pattern or trends within the control limits:

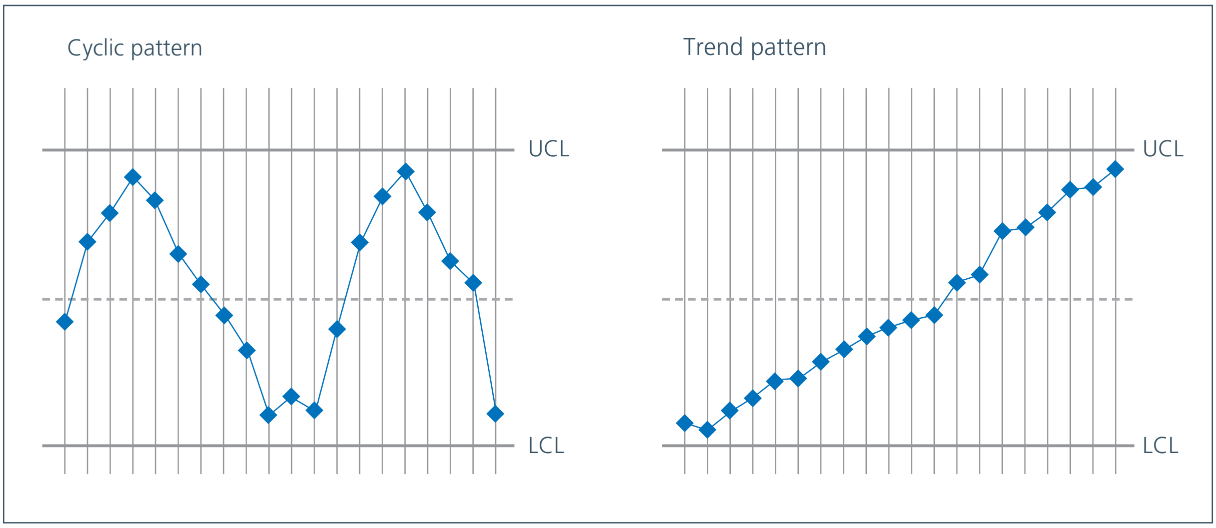
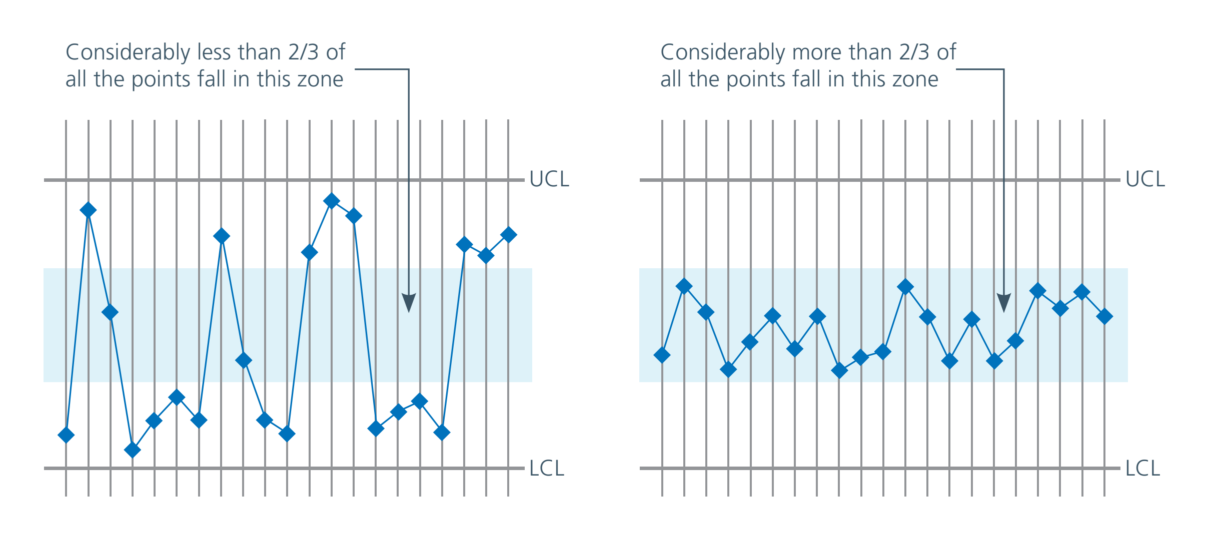


Figure 5: Rule 4 – the number of points within the middle third of the region between the control limits differs markedly from two thirds of the total number of points:



If you want a more efficient system, you need to reduce variation. Common and special causes of variation indicate the need for two different types of improvement. If controlled variation (common cause) is displayed in the SPC chart, the process is stable and predictable, which means the variation is inherent in the system.

If you want to improve the process, you will have to change the whole system. If uncontrolled variation (special cause) is displayed in the SPC chart, the process is unstable and unpredictable.

Variation may be caused by factors outside the process. In this case, you need to identify these sources and resolve them, rather than change the system itself.

There are three issues that you should be aware of when using SPC charts to improve a process:

1. You should not react to special cause variation by changing the process, as it may not be the system at fault
2. You should not ignore special cause variation by assuming that it is part of the process. It is usually caused by outside factors, which you need to understand in order to remove
3. You should ensure that the chart is not comparing more than one process and displaying false signals. An example of this would be data covering two hospital sites, or two procedures that are very different.

TIPS

- **You may need to collect the data for analysis as it may not be available. To be statistically rigorous, the more frequently you record your observations the better. Weekly or daily is better than monthly.**
- **Aggregate data is discouraged (ie the use of percentages) as this often hides the pattern of the data).**
- **The problem you are observing may be the means by which you are measuring, not what is really happening. Sometimes it is better not to act if you are unsure; investigate further instead.**
- **Sometimes the process that you are looking to improve will display seasonal variation and if this is the case you can split the chart to understand what is normal for the different time periods (for example winter and summer) based on where the data runs start and end.**
- **Remember that when you change something in the process, the data points after the change will be from a new system. When you have a run of points that break a rule, you will need to recalculate the SPC control limits to show an improvement (showing the control limits of the new system).**

What next?

Common cause variation is the desirable state of a system prior to undertaking a **PDSA** cycle. If the system is unstable and unpredictable then we are not confident about assigning improvement to the PDSA, it could be external factors affecting the result. Undertaking analysis before improvement allows you to develop a strong baseline and using weekly or daily data is a good starting point for understanding the baseline. The following other tools will be helpful:

- **Managing variation** – essential reading for using SPC charts.
- **Process mapping** – useful for understanding variation revealed by SPC charts.
- **Root cause analysis using five whys** – useful for understanding variation revealed by SPC charts.

Additional resources

Berwick, DM (1991) Controlling Variation in Healthcare: A Consultation from Walter Shewhart, *Med Care: 29*: p1212–25

Bicheno, J and Catherwood, P (2005) *Six Sigma and the Quality Toolbox: For Service and Manufacturing*, Picsie Books

Deming, WE (1986) *Out of the Crisis*, MIT: Massachusetts

Esain, A (2006) Problem Solving, TQM and Six Sigma in Rich, N, Bateman, N, Esain, A, Massey, L and Samuel, D (Eds) *Lean Evolution: Lessons from the Workplace*

Rich, N *et al* (2006) *Lean Evolution: Lessons from the Workplace*, Cambridge University Press

Shewhart, WA (1980) *Economic Control of Quality of Manufactured Product: 50th Anniversary Commemorative Reprint*, SAQC/Quality Press, Reissue Edition

Wheeler, D (2000) *Understanding Variation: The Key to Managing Chaos*, SPC Press, 2nd edition

Wheeler, D (2003) *Making Sense of Data: SPC for the Service Sector*, SPC Press: Knoxville

Thor *et al* (2007) Application of statistical process control in healthcare improvement: systematic review. *Quality Safety in Health Care* (2007)16: 387–399.

Background

The method of SPC was created by Walter Shewhart during the 1920s when he was investigating the production of faulty telephones for Bell Telephones. He found that the company continually changed the production line when faulty handsets were produced. This resulted in the production of different formats of handset – telephones that wouldn't talk to each other!

Through Shewhart's work, Bell Telephones understood the importance of reducing the variation in the manufacturing process to ensure Lean production. Shewhart framed problems as 'assignable cause' and 'chance cause' and introduced the SPC chart to differentiate between the two.

1920s: First control charts developed by the communications industry.

1930s: Adopted by other industries.

POST WAR: Shewhart tried to introduce the principles of SPC in American manufacturing but was unsuccessful and so took his ideas to Japan.

1950s: Japan began to widely use the principles of SPC in industry.

1980s: Ford Motor Company adopted SPC principles due to pressure on the US market from Japanese imports.

2000s: SPC adopted in the NHS.

Data should always be presented in a way that preserves the evidence. Shewhart (1931) suggested that displaying data using averages and aggregates loses the richness of the individual data points. SPC displays the individual data points (in the NHS these are often individual patients), then provides analysis to interpret what the user sees.

SPC and PDSAs were created by the same person, intended to be used together. **PDSA** improvement cycles should only be implemented in a system that displays common cause variation. If special cause variation is present, then the system is not stable enough to ensure the information is a result of the PDSA change.