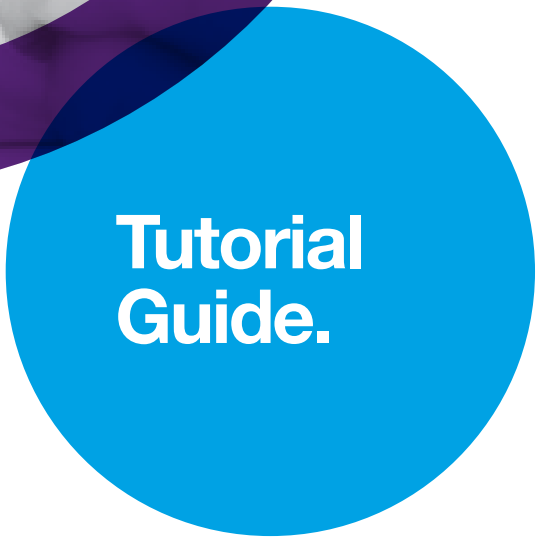




Statistical Process Control

**Monitoring Quality
in Healthcare.**



**Tutorial
Guide.**

**Information Services Division:
Quality Indicators Team**

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Introduction

NHSScotland routinely collects a vast array of data from healthcare processes. The analysis of these data can provide invaluable insight into the behaviour of these healthcare processes.

Statistical Process Control (SPC) techniques, when applied to measurement data, can be used to highlight areas that would benefit from further investigation. These techniques enable the user to identify variation within their process. Understanding this variation is the first step towards quality improvement.

There are many different SPC techniques that can be applied to data. The simplest SPC techniques to implement are the run and control charts. The purpose of these techniques is to identify when the process is displaying unusual behaviour.

The purpose of this guide is to provide an introduction to the application of run charts and control charts for identifying unusual behaviour in healthcare processes. SPC techniques are a tool for highlighting this unusual behaviour. However, these techniques do not necessarily indicate that the process is either right or wrong – they merely indicate areas of the process that could merit further investigation.

History of SPC

Statistical Process Control (SPC) Charts were first introduced in 1928. Commissioned by Bell Laboratories to improve the quality of telephones manufactured, Walter Shewhart developed a simple graphical method – the first of a growing range of SPC Charts.

Understanding the causes of variation within an industrial process proved indispensable as actions could be taken to improve process and output. In the 1950's, with the effective use of SPC, Deming converted post war Japan into the world leader of manufacturing excellence.

This approach is increasingly being applied in healthcare by thinking of healthcare systems as processes. As well as providing a basis for quality improvement within healthcare, SPC Charts also offer alternative methods of displaying data.

Purpose of Guide

The purpose of this tutorial guide is to give a brief overview of the different types of SPC chart, some guidance on the rules that should be applied to the charts, and how to interpret their output.

An [interactive tool](#) has been produced to automate the production of SPC charts for the user. This is an Excel-based tool which is hosted on the Quality Indicators pages of the ISD website.

1 Understanding Variation

1.1 Types of Variation

Variation exists in all processes around us. For example:

- Every person is different
- No two snowflakes are identical
- Each fingerprint is unique

The two types of variation that we are interested in are 'common cause' and 'special cause' variation.

Common Cause

All processes have inherent variation - known as 'common cause variation'. A process is said to be 'in control' if it exhibits only common cause variation i.e. the process is completely stable and predictable, with any variation due to regular, natural or ordinary causes.

Special Cause

Unexpected events/unplanned situations can result in 'special cause variation'. A process is said to be 'out of control' if it exhibits special cause variation i.e. the process is unstable due to irregular or unnatural causes that are not inherent in the design of the process.

1.2 Tools for Identifying Process Variation

Now that we know variation exists in all processes we can proceed to identify which type of variation is present. One method of identifying the type of variation present is by using SPC charts. Originally developed for use in manufacturing, many applications are now involving healthcare processes.

Areas of special cause variation may be of interest to the user for quality control or improvement purposes and can be signals for underlying issues. A signal on an SPC chart does not necessarily mean that something is wrong, nor do they tell the user what may be causing the variation. They should instead be used as a trigger for further investigation.

A lack of a signal on an SPC chart is also, in itself, interesting. Users should be careful not to try and force a signal if one is not present. However, users should be weary of the fact that a lack of a signal does not necessarily mean that there are no underlying issues in the process.

2 Types of Statistical Process Control Chart

SPC charts can be applied to both dynamic process and static processes. The type of SPC chart that should be used depends on the type of data, whether the process is static or dynamic (as described below), and the underlying probability distribution the data is expected to follow.

Dynamic Processes

A process that is observed across time is known as a dynamic process. An SPC chart for a dynamic process is often referred to as a '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. A cross-sectional SPC chart is a good way to compare different institutions. For example, hospitals or health boards can be compared as an alternative to league tables as we will see later.

Choosing the correct chart type is an important step, using the incorrect chart type can lead to misinterpretation and increase the chance of a Type I or Type II statistical error.

Type I Error

Incorrectly flagging a signal when there is no signal present; this is known as a false positive. False positives could lead to a lot of unnecessary work to try and correct a non-existent issue.

Type II Error

Failing to flag a signal when a signal is actually present; this is known as a false negative. False negatives can lead to underlying issues being missed.

This tutorial guide will focus on dynamic processes only.

Two of the most popular SPC tools in use today are the **run chart** and **Shewhart control chart**. They are easy to construct, as no specialist software is required. They are easy to interpret, as there are only a few basic rules to apply in order to identify the variation type without the need to worry too much about the underlying statistical theory.

Run Chart

A time ordered sequence of data, with a centreline drawn horizontally through the chart, usually based on the median. A run chart enables the monitoring of the process level and identification of the type of variation in the process over time.

Shewhart Control Chart

A time ordered sequence of data, with a centreline calculated by the mean. Control charts bring the addition of control limits (and warning limits – optional). A control chart enables the monitoring of the process level and identification of the type of variation in the process over time with additional rules associated with the control (and warning) limits.

2.1 Run Charts

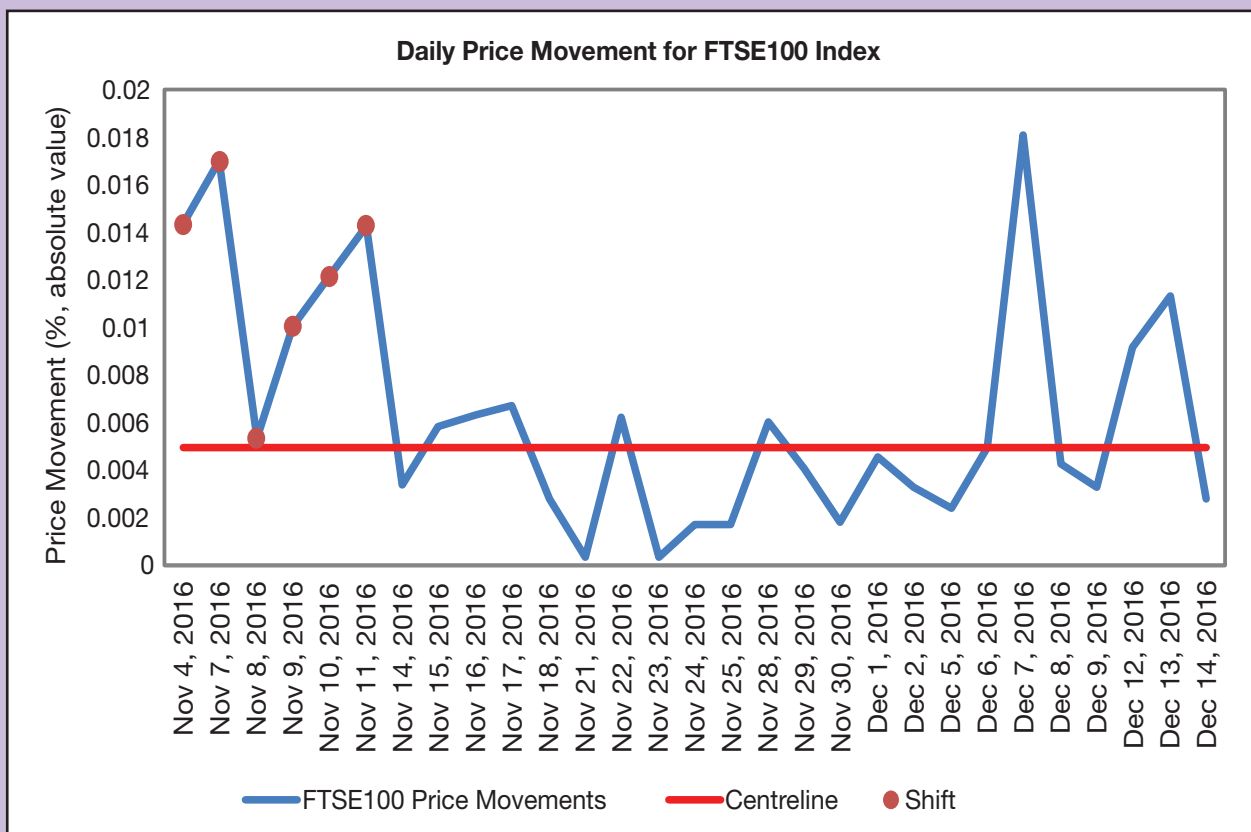
The most basic type of chart that a user can plot is a run chart. A run chart is a simple graph where a process is plotted against time, with a measurement of central tendency, most often based on the median. Run charts have no upper or lower control limits, which can make them easier to produce than typical Shewhart control charts (see [Section 2.2](#)). Their simplicity also means they lack the same level of specific statistical information when compared to a typical Shewhart control chart.

Steps to create a Run Chart

1. Ideally there should be a minimum of 10 to 15 data points.
2. Draw a horizontal line (the x-axis), and label it with the unit of time e.g. year, quarter etc.
3. Draw a vertical line (the y-axis), and scale it to cover the current data, including sufficient room to accommodate future data points. Label it with the outcome.
4. Plot the data on the graph in time order and join adjacent points with a solid line.
5. Calculate the median of the data (the centreline) and draw this on the graph.

Example 1

The chart below shows an example run chart: the absolute value of the daily price movement (%) of the FTSE100 Index from 4 November 2016 to 14 December 2016.



2.1.1 Run Chart Rules

The following definitions are useful before proceeding onto the rules for detecting non-random variation within run charts and later, control charts.

Useful Observations

Those observations that do not fall directly on the centreline are known as “useful observations”. The number of useful observations in a sample is equal to the total number of observations minus the number of observations falling on the centreline.

Run

A sequence of one or more consecutive useful observations on the same side of the centreline. Any observations falling directly on the centreline can be ignored.

Table 1 below lists the rules which can be applied to the run chart for determining the type of variation in the process.

Table 1: Run Chart Rules.

Rule	Description
Shift	A run of 6 or more consecutive data points above or below the baseline. Points on the centreline neither break nor contribute to a shift
Trend	A run of 5 or more consecutive data points which are increasing or decreasing. An observation that is the same as the preceding value does not count towards a trend.
Too many/too few runs	Too many or too few runs: If there are too many or too few runs (i.e. the median is crossed too many or too few times) that's a sign of non-random variation. Table 2 provides a guide based on the number of useful observations in your sample. An easy way to count the number of runs is to count the number of times the line connecting all the data points crosses the median and add one.
Astronomical Data Point	A data point which is distinctly different from the rest of the process. As there are no upper or lower control limits, a judgement should be made by the user on what would constitute an astronomical data point

Table 2: Number of runs which constitute too many/ too few based on useful observations.

Number of Useful Observations	Too Few Runs	Too Many Runs
15	4	12
16	5	12
17	5	13
18	6	13
19	6	14
20	6	15
21	7	15
22	7	16
23	8	16
24	8	17
25	9	17
26	9	18
27	9	19
28	10	19
29	10	20
30	11	20
31	11	21
32	11	22
33	11	22
34	12	23
35	13	23
36	13	24
37	13	25
38	14	25
39	14	26
40	15	26

Source: Perla, RJ., Provost, LP., Murray, SK. 2011. The run chart: a simple analytical tool for learning from variation in healthcare processes. [Online]

Available at: <http://www.wales.nhs.uk/sites3/Documents/841/Run%20charts%20%28August%202011%29.pdf> [Accessed 3 April 2017].

The rules listed above are purely guidelines. Some textbooks may quote different sizes of trends, and shifts. The above are standard to the work that is carried out within the Quality Indicators Team and ISD wide but their primary intention was for applications in industry. Although SPC lends itself well to healthcare processes, healthcare processes deal with lives. With this in mind, common sense is often the best guideline - SPC charts will illustrate the variation within your process but if fewer observations in a trend or shift etc is unusual behaviour in your process then this is just as good an indication of special cause variation and is therefore worth investigating.

Run charts are a good chart to choose if the user is looking for something quick, simple and basic, but their lack of statistical power makes them less able to reliably identify areas of special cause variation (i.e. there will be more type II errors with run charts) than Shewhart charts, so if the user is looking for something that is more robust, a run chart is unlikely to be sufficient. However, as a starting point it is always better to plot a run chart first before any other type of SPC chart.

2.2 Shewhart Control Charts

Shewhart Control Charts enable the monitoring of the process level and identification of the type of variation in the process over time with additional rules associated with the control (and warning) limits. The inclusion of upper and lower control limits allows a degree of measurement of distance from the centreline. Unlike run chart rules, these limits also remove the element of subjectivity in judging whether a point is an astronomical data point or not as points are either outliers or they are not.

There are many different types of chart available, and the correct chart to use depends on the type of data being collected.

Types of Data

Continuous data

Occupy any value within a range. Typically a measurement of some kind, they are unrestrained by “categories”, and can be infinite in range. Examples of continuous data would be measurements of height, weight or length; monetary values and anything which could be considered workload or throughput.

Discrete data

Observations where each possible observation is distinct from one another. It can be categorical e.g. different colours of balloons handed out at a fair; or numeric, typically count data e.g. the number of falls in a care home each month; or binomial data e.g. the number of red balloons handed out at a fair out of all the balloons handed out that day. Typically, when putting a binomial process into an SPC chart, the data should be presented as a proportion of a success, or a proportion of failures.

Type I Error

Incorrectly flagging a signal when there is no signal present; this is known as a false positive.

Type II Error

Failing to flag a signal when a signal is actually present; this is known as a false negative.

Types of Distribution**Poisson**

Data that has a Poisson distribution is discrete and is based on events occurring over time (or space) at a fixed rate on average, but where each event occurs independently and at random. For example, the number of new hip fracture admissions.

Binomial

Data that has a Binomial distribution is discrete and is based on data with only two possibilities e.g. the probability of being dead or alive, male or female etc.

Geometric

Data that has a Geometric distribution is discrete and is based on the number of Bernoulli trials until the first observation with a particular characteristic of interest, where trials are independent and an occurrence is equally likely on each trial. For example, the number of days between needles sticks.

A list of chart types and a brief summary of the types of data they serve is found in Table 3 (see [section 2.2.2](#) for examples of their application). This is not an exhaustive list and is not intended to be prescriptive. A judgement on the type of chart to use should be made depending on what is appropriate for the data and what measures stakeholders are tracking. This should be used as a guide only.

Table 3: Types of Shewhart Control Chart.

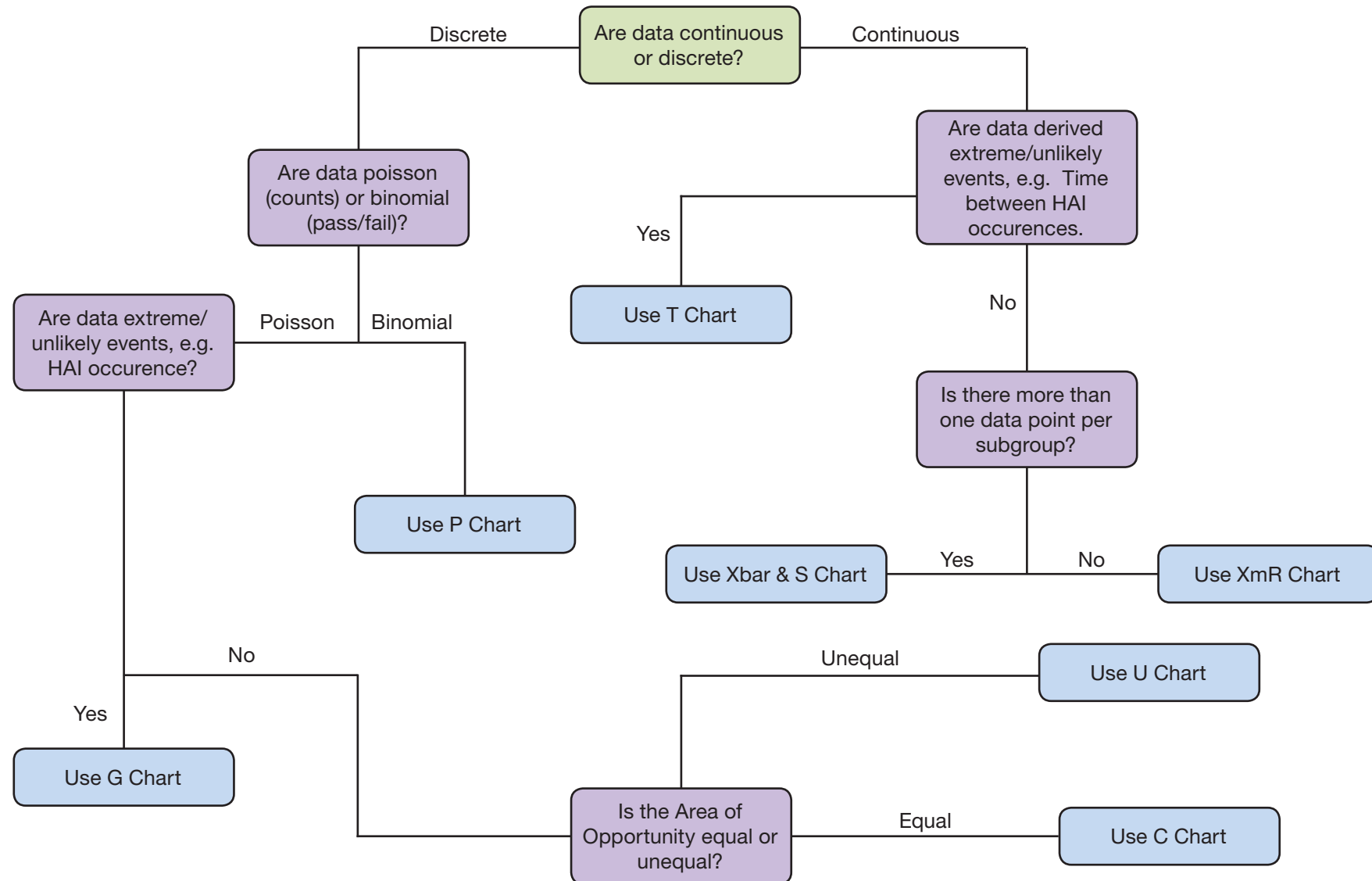
Chart Name	Appropriate For
XmR Chart	Continuous data, where each data point is an individual measurement and not an aggregate or average of multiple data points
Xbar & S Charts	Continuous data, where each data point is an average of multiple data points
P Chart	Discrete data. Data should be a proportion/percentage of successes/failures
C Chart	Count data, where the “area of opportunity” is equal for each data point
U Chart	Count data, where the “area of opportunity” is unequal for each data point
T Chart	For rare events data, recorded as time between rare events (continuous).
G Chart	For rare events data, recorded as the number of events between rare events (discrete).

Figure 1 is a flow chart which illustrates the decision making process for choosing the correct chart type.

Steps to create a Control Chart

1. First, select the most appropriate control chart for your data, which is dependent on the properties of your data. Use the flow chart in Figure 1 and Table 3 to help with this.
2. Proceed as for the run chart, this time using the mean as the centreline.
3. Calculate the upper and lower control (and optionally warning limits) using the formulas provided in [Appendix A](#) (for the appropriate chosen chart)

Figure 1: Flow chart illustrating the decision-making process for choosing the most appropriate type of Shewhart Control Chart.



2.2.1 Shewhart Control Chart Rules

In order to interpret data from a control chart correctly, a set of consistent rules must be applied to highlight any special cause variation. These rules highlight data points which may be of interest in order to prompt the user of the data to investigate further. These rules should be agreed upon before creating the control chart based on the user's knowledge of the data, as creating the chart first could lead to a bias from the user who may feel compelled to choose a set of rules which show something more in line with what they want to see.

Table 4 contains standard **Shewhart Control Chart Rules** for identifying special cause variation agreed for Improvement Programmes in NHS Scotland.

Table 4: Shewhart Control Chart Rules.

Rule	Description
Outlier	Data point(s) exceeding the upper or lower control limits (at 3 standard deviations)
Shift	A run of 8 or more consecutive data points above or below the centreline
Trend	A run of 6 or more consecutive data points. An observation that falls directly on the centreline, or is the same as the preceding value is not counted.
Outer One – Third	Two out of three consecutive data points which sit close to one of the warning or control limits (within 2 and 3 standard deviations)
Inner One - Third	15 or more consecutive data points that lie close to the centreline (within 1 standard deviation).

These are standard rules which should be sufficient for the vast majority of charts but they can be adapted accordingly **only if** it is appropriate for the data and any changes have been agreed beforehand.

2.2.2 Shewhart Control Chart Examples

This section will include four examples of SPC charts. Each example will present a dataset, and follow the flow chart for deciding which chart to use step-by-step.

Example 1

Hospital Standardised Mortality Ratios are calculated for all SPSP-participating hospitals in Scotland. SPC charts can be very useful for this measure to identify areas of unnatural variation.

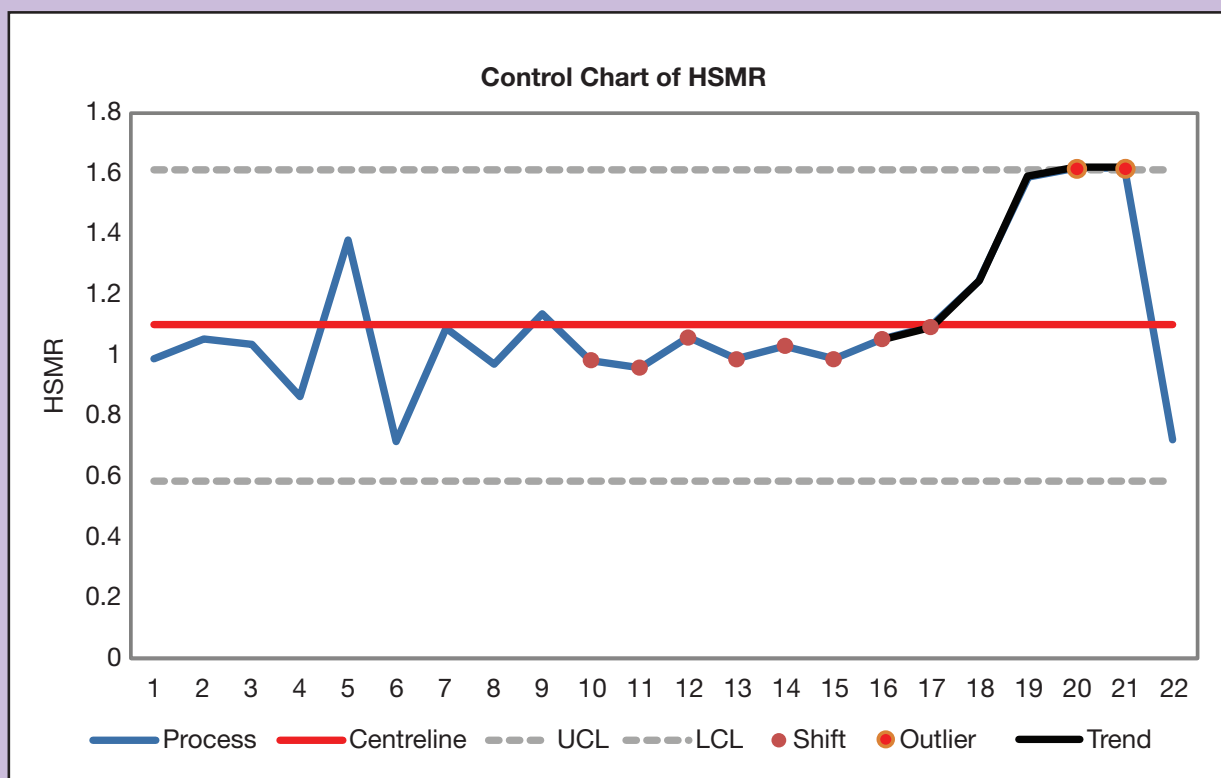
Is the data discrete? – No.

HSMR is a calculated measure which can take any value greater than 0.

Is there more than one observation per subgroup? – No.

There is only one measurement each quarter calculated for each hospital.

As the data are continuous and consist of individual measurements, the preferred chart for this would be an XmR chart. If HSMR was being calculated and then averaged for multiple hospitals each quarter, then an Xbar chart would be suitable, with the process being the average of each measurement across all sites (note: the number of sites should remain constant).



The chart above shows that the process looked relatively stable until quarter 19, where there was a large spike, followed by two outlying quarters. This will have influenced the centre line, in turn attributing to the downward shift in the centre. So, additional investigation of the outlying quarters would be necessary.

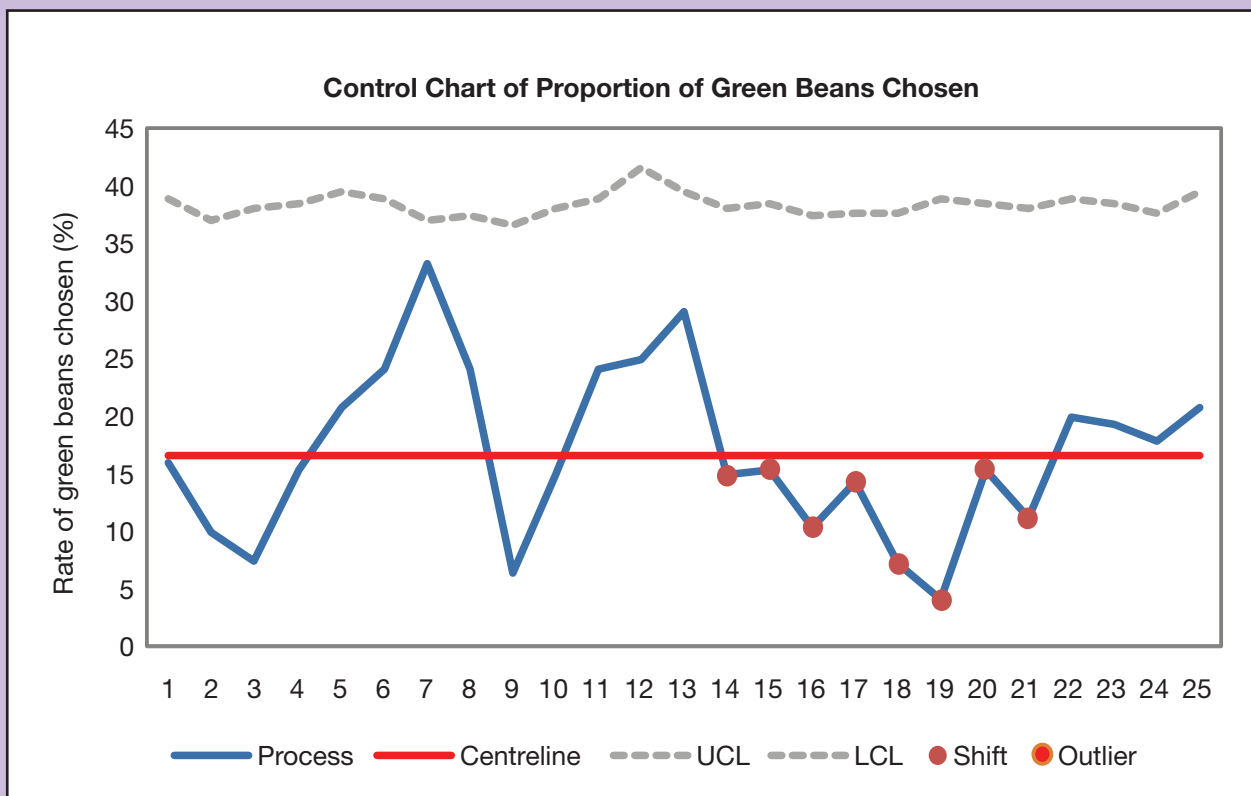
Example 2

You have a large jar of jelly beans, and from the jar you take 25 scoops of beans. You measure the number of green beans, classifying each bean as green or not-green, and total number of beans in each scoop and wish to monitor this process with an SPC chart.

Is the data discrete? – Yes.

Are there only two possible outcomes? – Yes (green or not green).

As the data are binomial (acceptable/unacceptable), then the best chart for this type of data is a P chart. The best way to plot this process is with the proportion of successes to the number of overall beans. In this case, the process will be the proportion (percentage) of green beans in each scoop.



The variable control limits come from the variable size of each sample. Scoops with more beans will have tighter limits as the predicted proportion of green beans obtained by random chance should tend towards the true mean (which the centreline is an estimate of) when the sample size increases.

The above P chart shows no outliers, but does show a downward shift. There is also no lower control limit as the calculated limit was less than 0, and a negative percentage is impossible to achieve in this context.

Example 3

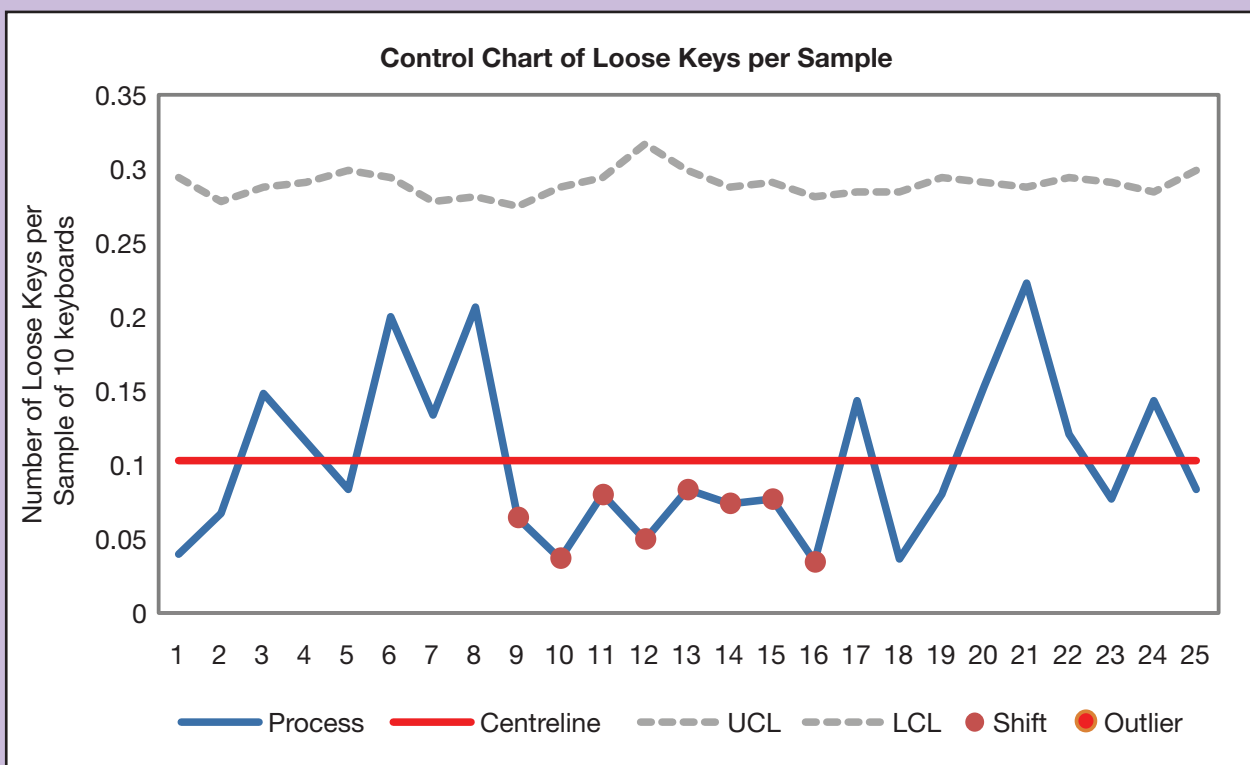
A factory that produces computer accessories takes a sample of 10 keyboards every hour and counts the number defects per keyboard (e.g. loose keys, scratches), but they take a random sample across all models of keyboard they produce.

Is data discrete? – Yes.

Are there only two possible outcomes? – No. The data is a count of defects, not a classification of whether or not the keyboard had a defect or not.

Is the area of opportunity variable? – Yes. Different models have different numbers of keys which could be loose, and each keyboard has variable scope for further defects.

As the data in this example are poisson counts, a C or U chart would be suitable. As there is room for one keyboard to have more defective keys than another, the chart used should be a U chart.



The mean number of defects (unadjusted for sample size) found per sample is 2.7 (~0.1 per 100 keys per sample). Most samples fluctuate closely around this number and no samples are outliers, however there is a downward shift from sample 9 to sample 16, indicating that further investigation is required to determine what was happening there.

Example 4

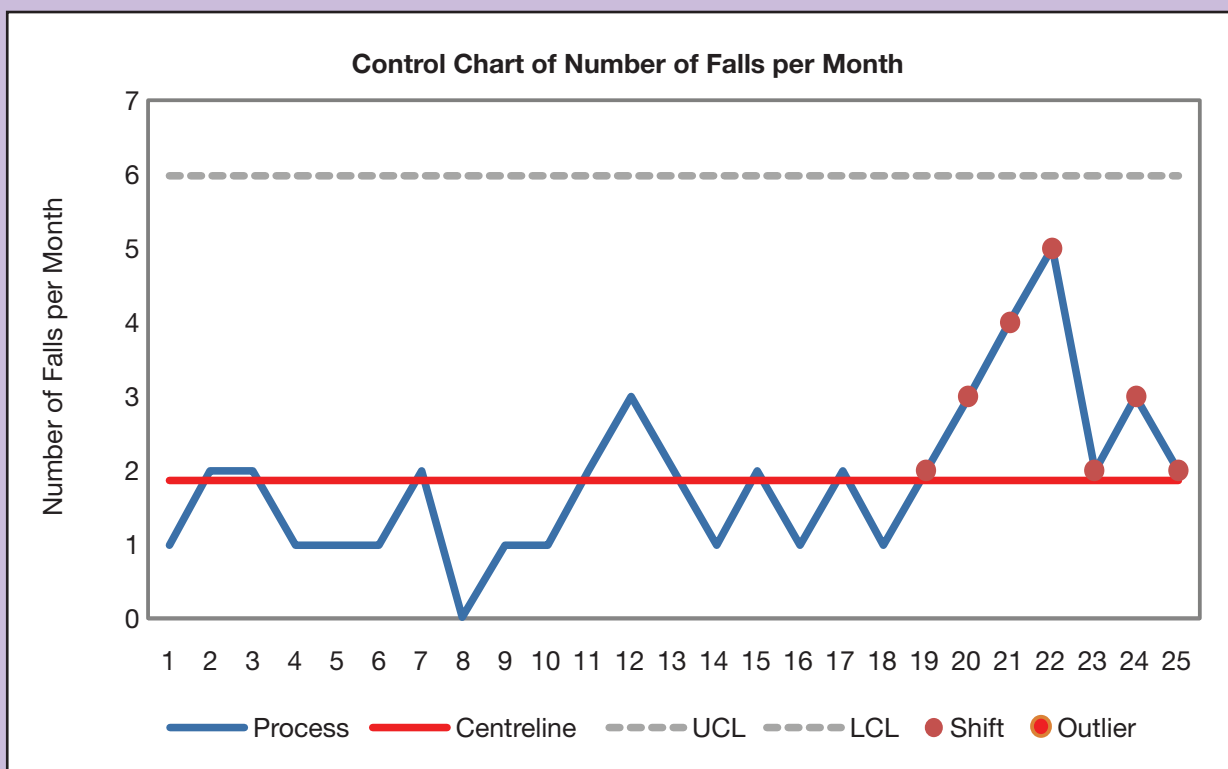
A care home monitors how many times its residents have had a fall each month, and wants to produce an SPC chart to monitor the numbers.

Is data discrete? – Yes.

Are there only two possible outcomes? – No. The data is a count of the number of falls in the care home.

Is the area of opportunity variable? – No. The number of residents in this example is constant each month.

As the data in this example are Poisson counts, a C or U chart would be suitable, and as the number of residents in the home is constant month-to-month, a C chart is appropriate here.



The mean number of defect falls found per month is around 2. Most months fluctuate closely around this number or below, however an downward shift is present in the first 11 data points.

The table below provides further examples.

Data	Flow Chart Process	Type of SPC to use
Number of patients that go through a GP surgery each week	Is data discrete? No. Data are throughput which, by convention, are considered continuous. Is there more than one data point per subgroup? No. Data are single measurements.	XmR chart.
Percentage of patients that died within 30 days of admission to hospital	Is data discrete? Yes. Is data poisson or binomial? Binomial (patients can only be dead or alive after 30 days)	P chart.
Number of morbidities patients report when admitted to A&E departments each day	Is data discrete? Yes. Is data poisson or binomial? Poisson (data are counts of morbidities) Is the area of opportunity equal? No. The number of patients may vary day-to-day and the number of morbidities each patient can report is theoretically infinite.	U chart.
Average daily spend on antibiotics prescribed by GP practices across a health board	Is data discrete? No. Monetary values are continuous. Is there more than one datapoint per subgroup? Yes. Each GP practice contributes towards the health board average.	Xbar & S chart.
Percent of hospitals across the UK which make the target of 95% of patients seen within 4 hours in A&E	Is data discrete? Yes. Is data poisson or binomial? Binomial.	P chart, but data must first be expressed as a proportion.
The number of days between hospital acquired infections (HAI) for a single hospital site	Is data discrete? No. Data are time measurements. Are data unlikely events? Yes.	T chart.
The number of patients prescribed a certain drug between two adverse drug events	Is data discrete? Yes. Are data unlikely events? Yes.	G chart.

2.2.4 The XMR chart

There is an alternative school of thought around Shewhart chart selection which proposes only an XmR chart is necessary. This section lays out the arguments for and against this approach. The decision over which approach to take is entirely down to the user and the decision should be made before producing any SPC chart.

	Wider range of Shewhart Charts	XmR Charts
Advantages	<p>When applied properly, these charts are correct and provide more statistically appropriate results</p> <p>The control limits vary according to the size of each individual sample</p>	<p>They are simple to understand</p> <p>In most improvement situations, the results can be deemed 'appropriate enough'</p> <p>Does not require any assumptions about underlying data distributions</p> <p>Quick and easy to apply to practical situations</p> <p>They are recommended by influential members of the quality improvement communityⁱ</p>
Disadvantages	<p>Assumptions about underlying data distributions may not be metⁱⁱ</p> <p>Lack of understanding of these probability distributions can lead to errors or lack of user confidence in choice of chart</p> <p>The greater complexity of these charts makes understanding and automation more difficult</p>	<p>They are not correct for all types of data</p> <p>A large portion of the quality improvement community does not recommend them over the wider range of Shewhart Charts.</p>

These advantages and disadvantages are for information purposes only and are not intended to try and sway a user towards one approach or the other. The decision to use just an XmR chart is down to the user(s) and should be agreed upon before production of any chart begins.

i Stauffer (2010), Balestracci (2014)

ii Wheeler (1996)

Summary

Choosing the correct chart is an important step in monitoring a process, and ensures that incorrect conclusions around process stability are not drawn. However, chart selection is not an exact science and there is room for manoeuvrability. It is also important that any decisions regarding chart selection and rules are made prior to producing the chart, as making these decisions retrospectively can lead to a bias towards a chart which is more agreeable with what the user would like to see.

Run charts and Shewhart control charts are not the only type of SPC chart available, and a process over time is not the only type of data which can be put into an SPC chart. Data which are point-in-time comparisons, e.g. crude mortality rates by hospital for one quarter in Scotland could be put into an appropriate funnel plot to be compared against the national average. Like Shewhart control charts, there are a number of approaches to funnel plots (based on \bar{X} +S, P or U charts) depending on the data.

Further Information

There are a wide range of online resources on the use and calculation of SPC charts. As mentioned in the introduction, the Quality Indicators team has produced an [interactive tool](#) in producing SPC charts. The tool takes the user through the selection process step-by-step and decides what the best chart is to use.

The NHS Education for Scotland digital platform, Turas Learn has pages dedicated to [Shewhart control charts](#) and [run charts](#). The Healthcare Data Guideⁱⁱⁱ is also an excellent reference guide for this type of analysis.

Acknowledgments

This document was prepared by the Quality Indicators Team from both knowledge of the topic within PHI and reference material. This document was circulated to individuals with Quality Indicators and wider PHI for comments and feedback. Their input was much appreciated and we are grateful for their advice. Any error or lack of clarity that remains is, however, our responsibility.

Contact Information

If after reading this document you have any unanswered queries on SPC charts, or would like to discuss any aspects further, please contact the Quality Indicators Team, via [NSS. isdQualityIndicators@nhs.net](mailto:isdQualityIndicators@nhs.net).

We would also welcome any feedback from you on this document.

iii See <http://eu.wiley.com/WileyCDA/WileyTitle/productCd-0470902582.html>

Appendix A: Formula for calculating Control Charts limits

XmR Chart

$$\bar{x} = \frac{\sum_{i=1}^m x_i}{m}$$

$$MMR = \frac{\sum_{i=2}^m |x_i - x_{i-1}|}{m - 1}$$

$$\text{Control Limits} = \bar{x} \pm 2.66 * MMR$$

Where x_i is the i th datapoint and m is the number of datapoints.

Xbar and S Chart

$$\bar{\bar{x}} = \frac{\sum_{i=1}^m \sum_{j=1}^n x_{ij}}{mn}$$

$$\text{Control Limits} = \bar{\bar{x}} \pm 3 \frac{\sum_{i=1}^m \sqrt{\frac{\sum_{j=1}^n (x_{ij} - \bar{\bar{x}})^2}{n - 1}}}{m}$$

Where x_{ij} is the i th datapoint from group j and m is the number of groups and n is the number of data points per group.

P Chart

$$\bar{p} = \frac{\sum_{i=1}^m \sum_{j=1}^n \begin{cases} 1 & \text{if } x_{ij} \text{ is defective} \\ 0 & \text{otherwise} \end{cases}}{\sum_{i=1}^m n_i}$$

$$\text{Control Limits} = \bar{p} \pm 3 \sqrt{\frac{\bar{p}(1 - \bar{p})}{n_i}}$$

Where x_{ij} is the i th datapoint from group j and m is the number of groups and n is the number of data points per group.

C Chart

$$\bar{c} = \frac{\sum_{i=1}^m x_i}{m}$$

$$\text{Control Limits} = \bar{c} \pm 3\sqrt{\bar{c}}$$

Where x_i is the total number of “defects” from group j and m is the number of groups.

U Chart

$$\bar{u} = \frac{\sum_{i=1}^m x_i}{mn}$$

$$\text{Control Limits} = \bar{u} \pm 3\sqrt{\frac{\bar{u}}{n}}$$

Where x_i is the total number of “defects” from group j , m is the number of groups and n is the sample size for each group.

T Chart

$$T_i = t_i^{(1/3.6)}$$

$$MMR = \frac{\sum_{i=2}^n |T_i - T_{i-1}|}{n}$$

$$\bar{T} = \frac{\sum_{i=1}^n T_i}{n}$$

$$\bar{t} = \bar{T}^{3.6}$$

$$\text{Upper Control Limit} = (\bar{T} + (2.66MMR))^{3.6}$$

$$\text{Lower Control Limit} = (\bar{T} - (2.66MMR))^{3.6}$$

Where t_i is the time between the i th event and n is the number of events.

G Chart

$$\bar{g} = \frac{\sum_{i=1}^k g_i}{k}$$

$$\text{Upper Control Limit} = \bar{g} + 3\sqrt{\bar{g}(1 + \bar{g})}$$

$$\text{Lower Control Limit} = \bar{g} - 3\sqrt{\bar{g}(1 + \bar{g})}$$

Where g_i is the number of occurrences between the i th event and k is the number of events.