What is normal or not?

J. Benn¹ and I. K. Moppett²*

¹ Centre for Patient Safety and Service Quality, Division of Surgery, Imperial College, London, UK
² Division of Anaesthesia and Intensive Care, Nottingham University Hospitals, University of Nottingham, Nottingham NG7 2UH, UK
* E-mail: iain.moppett@nottingham.ac.uk

The stereotype cartoon of an anaesthetist has a masked individual sat twiddling knobs, and writing things on a chart. Much of an anaesthetist’s role involves monitoring physiological and pharmacological variables across time. In engineering terms, we are monitoring a process. A process is simply a series of inter-related events and actions that produce some result—a widget. In anaesthesia terms, this might be the recorded arterial pressure, a pain-free patient, or an absence of major drug errors. Although the steps are different, it is fundamentally no different to the production of widgets. The potential value of adopting a process view is that if we pursue the same goal, using proven methods, under the same conditions, we may be confined to an overly reactive (and potentially harmful) to investigate or respond to every observation.² Process control charts, on the other hand, are more sophisticated tools that include control limits based upon ‘Sigma’ or standard deviation (σ).

If a process is in control, the only variation that is normally seen is due to causes ‘common’ to the process. It is wasteful (and potentially harmful) to investigate or respond to every common cause variation, yet without understanding variation properly, we may be confined to an overly reactive mode of action. On the other hand, special cause variation should prompt investigation—sometimes a problem will be identified, sometimes an improvement which should be retained. Just as conventional statistical tests are designed to quantify the probability of a type I or type II error, process control can alert us to similar errors in real time. Importantly, control charts describe what the expected variations in a measurement are based upon statistical parameters. They do not stipulate what it should be. To use arterial pressure as an example, a control chart gives information about how much the arterial pressure varies and whether that variation is statistically normal based upon prior observations, but it does not define upper or lower limits for where it should be.
Stemming from work in the 1920s by Shewart, a control chart can be produced, along with a set of statistical rules for their interpretation.\(^2\)\(^-\)\(^5\) There are numerous sub-types of control chart, and controversy over which should be used when. Control chart types vary for different types of data, distributions of data, and different approaches to data collection. Of interest, they are not based on pure statistical theory, but rather on empirical observation. The individuals moving range chart (XMR) is used for individual data and is fairly robust, but mean/SD versions (X-Bar & S) are commonly used. Alternatives include the p-chart, used for proportions (e.g. analysis of death rates by quarter), and u-charts, used for normalized event rates (e.g. drug errors per 100 anaesthetics per year).

To illustrate the analytic process, the first step is to calculate the centre line, based upon either the mean or median value for the data, depending upon the control chart used. Sufficient data are required and authorities differ on their views. Shewart suggested at least 25 data points for control charts, but simpler run charts may yield useful and robust results with as few as 10 data points.\(^4\) Next, the moving range is calculated. This is simply the absolute difference between each pair of values (i.e. for a span of 2)—there will always be one less than the number of data points—and is usually plotted separately. The upper and lower control limits of the original data (roughly equivalent to a 3 SD distance above and below the centre line) are then calculated and plotted. Based upon these simple parameters, a number of robust statistical tests for abnormal variation can be applied.\(^6\)

An important principle about the information obtained from control charts is that the approaches to special cause variation are fundamentally different from those of common cause. With special cause, there is likely to be a specific issue to be addressed—good or bad. With common cause variation, the issue lies in the system itself, and a fundamental change in the system is required. Consider the data from Kim and colleagues (Fig. 1A and B). The figure shows some individual patient data (kindly provided by the authors), not the group means provided in the paper. Several inferences can be drawn from these data.

(i) There is something fundamentally different about the process involved in B compared with A—the control limits are much narrower. The patients are all similar, but the neuromuscular blocking agent regime is different.

(ii) Although the control limits for B are relatively narrow, the first point actually appears to be out of control. It also flags up as having a greater moving range than allowed. There is a plausible special cause—this is the MEP that was recorded at ‘baseline’ when there may well have been some neuromuscular blocking agent effect.

(iii) The technique used in process A has wide control limits and the lower control limit is lower than 50% of baseline MEP—the threshold at which concern about cord function would be raised. It would therefore be a process likely to have a significant number of false positives if solely the 50% threshold is used.

(iv) Process B on the other hand has control limits well above the threshold value, and so might give the opportunity to signal problems earlier if the rules are applied systematically.

(v) The process used in B would therefore seem to be a better process for monitoring of MEPs during spinal surgery.

Improvements to the monitoring of MEPs shown in Figure 1A are unlikely to come from increased vigilance or training of the anaesthetist—the process itself needs to change. An advantage of this approach is the ability to detect significant deviations in ‘real time’. When we have a set of baseline measures of a process organized temporally in a control chart and showing common cause variation, we can detect a significant change in that process in a small number of observations; in some cases, even a single observation. This real-time intelligence affords us the opportunity to respond sooner. Consider the data in Figure 2. The control limits are drawn based on the first 12 observations which are from a random sample of normal distribution (mean 0, SD 1). Points 13–24 are from a new distribution (mean 1, SD 1). Using the rules above, by point 16, special cause variation would be suspected (rule 5—moving range greater than expected) with more confirmation by point 24 (rule 3).

Like all tools, control charts can be misused. If the wrong approach is taken, the wrong answer will ensue. There are
situations where the rules are insufficiently sensitive and real changes are not picked up. It is important to adjust data appropriately, particularly if there are relevant risk factors. Comparing death rates over time should take some account of case-mix, although conversely an unadjusted analysis may flag up an unrecognized change in case-mix. There is a risk of only focusing on special causes and missing the underlying problem with the process. A process may be relatively reliable (demonstrating minimal variation) yet is performing at a poor level.

Anaesthetists might consider whether there are any situations where this approach may be helpful. Settings of alarms, particularly for intermittent monitoring, are straightforward examples. With performance management and revalidation becoming more common, this approach provides a tool to assess variation in a robust and transparent fashion. Aspects of patient safety and quality of care can be addressed with this approach—PONV rates, number of delayed discharges. As Benn and colleagues describe, if it is used on a larger (departmental) scale, then there needs to be a conducive environment to use the data provided in a constructive fashion.

When done correctly, control charts can provide the feedback that enables the clinician to: (i) react where the situation warrants it; (ii) not react where the situation tends to induce over-reaction; or (iii) react quickly, where the situation appears to be superficially ambiguous. We may dislike
comparison with our colleagues in the world of mass production, but we all have the same goal—to produce as good a result as we can with the materials resources we have. Let us not be afraid to borrow their tools.

**Declaration of interest**

I.K.M. is an Editorial Board member of *BJA*.

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