Statistical process control part 1: a primer for using statistical process control in health care process improvement

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QUALITY IMPROVEMENT is increasingly important for health care organisations both nation-wide and internationally. There is greater recognition of both the variances in patient care and the gaps between evidence-based research and current practice. At the same time, demand, not only for the quantity of services, but for higher quality services, continues to grow. Realising this, most major hospitals across Australia are initiating the redesign of hospital processes in order to maximise the timeliness and quality of patient care. But changing a process does not always result in an improvement.[1,2] For this reason, a key component of any quality improvement effort is the robust measurement, analysis, and interpretation of appropriate clinical outcomes and processes, to ensure beneficial changes occur.

Measuring improvement in health care

Demonstrating that an improvement has actually taken place is not always simple. Health care outcomes represent the complex interaction of diverse patient casemix with imperfect hospital processes, and often show some variation with repeated measurements, even when there is no change to the process.[1,3] Comparing isolated observations of process performance is therefore of little value in quality improvement decision making, as differences may result from chance alone rather than any real change in the process.[3] Simply looking at the numerical difference between average scores of performance before and after an intervention can lead to invalid conclusions for the same reason; it is highly likely that one number will be higher than the other purely due to random fluctuations in the process.[4] In the absence of statistical methods to test for significance, decision makers cannot be certain whether outcomes have changed or not.

Further complicating the measurement of process improvement and redesign in health care is the fact that structured research trials (for example, randomised controlled trials and other robust study designs) are often too expensive and impractical at the front line of health care service delivery; randomisation is generally not possible and identification of an appropriate control group can be difficult. Health services research is therefore typically action research implemented at the local hospital level as part of a quality improvement initiative. Within this setting, individual hospitals and health professionals require a tool simple to use, with the capability of tracking process performance over time to provide real-time, regular feedback on whether an implemented change appears to be improving the process.

A set of management tools proven successful in industry, termed statistical process control (SPC), are proving to be the ideal technique for this specific purpose (that is, providing regular feedback for, and consistent tracking of, local quality improvement efforts). Two features common to all SPC methods justify their usefulness. Firstly, SPC techniques take into account the time-ordered sequence of observations so that

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each test is iteratively applied to the most recent "run" of data. This allows real-time testing of each new observation, and consequently enables timely detection of any change in the outcomes of the process. The second strength of SPC techniques is their simplicity; SPC can be learnt and applied with relatively limited training. These techniques can therefore be easily adopted and interpreted by non-statistical end-users to inform local improvement decision making.

Statistical process control — the theory and tools

SPC methods were pioneered in the 1920s by Dr Walter Shewart for improving processes in industrial manufacturing, and in recent years have been applied in health care in much the same way (for example, in emergency medicine,[5-7] anaesthesia care,[3,8] and even hospital-wide processes[9]). The underlying assumption of SPC theory is that all processes, whether it be signing a signature or delivering complex patient care, will always show some variation.[10] Shewart described two sources of variation, later renamed by Edward Deming as common cause and special cause variation.[11] Common cause variation is systematic variation inherent to any process, and is the result of random factors (eg, time of day, patients' genetic and physical predisposition to treatment response) influencing the process being measured. A process that displays only common cause variation is said to be stable and in a state of "statistical control", and is predictable within limits defined by statistical theory.[1,12] Special cause variation, on the other hand, represents variation in the process that deviates from what is expected, and results from specific non-random events uncommon to the process. This type of variation signals a fundamental change in the process, which can be either an improvement or deterioration in performance. A process that displays any special cause variation is said to be unstable and "out of control", and no longer capable of performing as it has in the past.[1]

The key technique of SPC, the control chart, visually displays the time-ordered performance of a single process over time, and uses statistically derived interpretation rules to distinguish between the two types of variation contributing to the process. In line with SPC theory, when a quality improvement intervention changes the underlying process, this will flag as a special cause.[1,2] The ability of the control chart to place this change in performance (special cause variation) and the intervention in close temporal proximity allows clinicians and researchers to differentiate between variation in a process due to random fluctuations and improvements in a process due to process redesign. For this reason, control charts can be used to assess the impact of quality improvement interventions.

Control charts, and SPC methods in general, can also be utilised to track process performance over time, therefore acting as an ongoing system of performance control. SPC methods are the best available tool for this purpose because of the ability to highlight any variability in process performance; that is, whether the process is stable and in control, or unstable and out of control. Consistent and predictable processes that deliver quality care for every patient are important in health care. Any large variance (for example, service delay or process failure) may indicate that the system is lacking or can be improved. Detecting (and potentially reducing) process variability is therefore important.

Detecting the cause of variation in a process (common versus special) is of further value for process improvement purposes, as this guides decisions as to how improvements should be targeted in the first place, so as to prevent tampering with any natural variation.[13] A process in control, with only common causes of variation having influence, will continue to perform as it has in the past until a non-random event unusual to the process (that is, a special cause) changes it. For deliberate improvements to occur, a quality improvement intervention is needed to reduce common cause variation or to shift the entire process in the desired direction. In contrast, a process out of control is perform-

ing unpredictably, and needs to be stabilised first, through the removal of special cause variation. Sources of poor performance should be eliminated, while examples of good practice should be sustained so that they become common to the process.[12,14] This brings the process in control so that it is stable and predictable within expected limits; the process itself can then be improved.

It is necessary to note however, that an in-control process is not synonymous with a good process. Being in statistical control indicates that the process is stable, with minimal variation, and operating similar to how it has in the past.[3,15] This does not mean that the process is performing as it should; performance may still fall below accepted standards or patient expectations.[14,15] Alternatively, an out-of-control process is not synonymous with a bad process. Special causes may indicate sources of variation that result in better than usual care. Furthermore, control charts do not reveal *what* has gone wrong (or right), but rather *where* the process has changed. Those responsible for the process need to investigate each special cause using the pyramid model of investigation,[16] identify the source of the variation (data quality, patient casemix, structure or resource, process of care, or carers), and address any causes that are within their control.

Statistical process control in health care

SPC methods are increasingly being advocated in health care as a valuable quality improvement tool. For example, leading bodies such as the National Health Service Modernisation Agency in England and the Joint Commission (which governs health service accreditation) in the United States both promote the application of SPC principles when measuring for improvement.[10] Yet despite the evidence that SPC can be successfully applied in health care practice to improve the quality of patient care,[3,5-9] SPC is still not widely adopted. In a recent review,[2] only 57 studies published between 1990 and 2004 applied SPC methods for the improvement of clinical or patient care processes in a health care organisation; perhaps indicating a lack of knowledge or understanding as to the value of, or the inability to apply, SPC methods.[10]

If the full potential of SPC methods is to be realised, educating and training health care professionals in the theory and tools behind these methods, but also developing SPC skills and establishing the value of applying SPC in health care, is essential. An exemplar of this is Queensland Health's Clinical Education Development Service, which provides modules on SPC to expose clinicians to these methods and provide the opportunity to develop and apply SPC skills. As clinicians and health care professionals become experienced in applying SPC methods as part of their daily practice, widespread application of SPC in the health care sector, and the benefits of this, should result.

Conclusion

SPC methods, and control charts in particular, are a proven tool specifically designed for understanding the common and special causes of variation in a process, so as to optimise and evaluate quality improvement efforts. Still, the health care sector has not yet fully exploited the power of this set of techniques. For this to occur, health care professionals need to adopt both these tools and an improvement philosophy into their work, and by doing so, will begin to see both the value and the impact of SPC in achieving optimal improvements in the quality of patient care.

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Competing interests

The author declares that she has no competing interests.

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