

or a whole clinical team. The future probably lies in a judicious application of both forms of techniques, using systems analyses of incidents to generate both enthusiasm and hypotheses as a basis for more resource intensive analyses of whole processes and systems.

A major concern with all the techniques discussed is the lack of formal testing and evaluation. The process of analysing incidents could be considered simply as a method of engaging teams in reflecting on safety; in that case, formal evaluation may not be critical. However, if we believe it could function as a more formal diagnostic technique exposing flaws in healthcare systems, then questions of inter-rater reliability and the validity of the conclusions become important. With vast funds being sunk into the research and development of reporting and tracking of incidents, it is perhaps time to pay more

attention to the ultimately more important—but greatly neglected—issue of incident analysis.

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REFERENCES

- 1 National Patient Safety Agency. www.npsa.nhs.uk (accessed 8 June 2004).
- 2 Agency for Healthcare Research and Quality. www.ahrq.gov, 2004.
- 3 Runciman B, Merry A, McCall Smith A. Improving patients' safety by gathering information. *BMJ* 2001;**323**:298.
- 4 Cook RI, Woods DD, Miller CA. A tale of two stories: contrasting views of patient safety, US National Patient Safety Foundation, 1998.
- 5 Vincent C. Understanding and responding to adverse events. *N Engl J Med* 2003;**348**:1051–6.
- 6 Spath P, ed. *Error reduction in health care: a systems approach to improving patient safety*. Washington: AHA Press, 1999.
- 7 Stalhandske E, Bagian JP, Gosbee J. Department of Veterans Affairs patient safety program. *AJIC: Am J Infection Control* 2002;**30**:296–302.
- 8 Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. *BMJ* 1998;**316**:1154–7.
- 9 Vincent C, Taylor-Adams S, Chapman EJ, et al. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. *BMJ* 2000;**320**:777–81.
- 10 Clinical Safety Research Unit. www.csr.u.org.uk (accessed 8 June 2004).
- 11 Institute for Healthcare Improvement. www.ihp.org (accessed 25 June 2004).
- 12 DeRosier J, Stalhandske E, Bagian JP, et al. Using health care failure mode and effect analysis: the VA National Center for Patient Safety's prospective risk analysis system. *Jt Comm J Qual Improv* 2002;**28**:248–67.
- 13 McNally KM, Page MA, Sunderland B. Failure-mode and effects analysis in improving a drug distribution system. *Am J Health System Pharmacy* 1997;**54**:171–7.
- 14 Frankel A, Graydon-Baker E, Neppel C, et al. Patient safety leadership walk rounds. *Jt Comm J Qual Improv* 2003;**29**:16–26.

Statistical process control

Using statistical process control to improve the quality of health care

M A Mohammed

To achieve continuous quality improvement "it is not enough to do your best ..."

Continuous improvement in health care and elsewhere is not a contentious issue—but the means by which this may be achieved is the subject of much debate. A key aspect of continuous improvement is the measurement, analysis, and interpretation of variation. Consider, for example, the data in table 1 which shows surgeon specific mortality rates after colorectal cancer surgery.¹ Ranking the mortality rates or the adjusted hazard ratios, with or without statistical tests, invites the interpretation that some surgeons are better than others. Furthermore, since a hazard ratio of 1 is defined as neutral, surgeons with a hazard ratio above 1 are considered a hazard to their patients. So, by categorising the hazard ratio as either acceptable or unacceptable, the study concludes that "some surgeons perform less than optimal surgery; some are less competent technically than their colleagues..." To improve outcomes the next logical step is to stop the less competent surgeons from operating and transfer their patients to the more competent surgeons. Surprisingly, per-

haps, there is another way of analysing these data using statistical process control (SPC) which leads to very different conclusions.

BACKGROUND TO STATISTICAL PROCESS CONTROL (SPC)

In the 1920s Walter A Shewhart, a physicist, was charged with improving

the quality of telephones in Bell Laboratories, USA. His work there won him the accolade of the "father of modern quality control".² Shewhart developed a theory of variation³ which forms the basis of SPC. His theory is easily illustrated. Consider the first five "QSHC" signatures in fig 1. Two important observations can be made: (1) despite being produced by the same process, they show variation; and (2) the variation is controlled—it lies within certain limits. If nothing is known about the underlying process one would be justified in suggesting that the process appears to be stable. What would traditional approaches to understanding variation tell us about these signatures? The five signatures could be compared to a standard, and some would fall below the standard. A league table could be created, ranking the signatures from best to worst. A statistical test might identify one signature as significantly different from the others. These

Table 1 Surgeon specific mortality rates following colorectal cancer surgery

Surgeon	No of cases	No (%) died	Case mix adjusted HR
A	98	16 (16)	1.10
B	66	8 (12)	1.03
C	58	9 (16)	0.87
D	52	7 (13)	1.09
E	52	15 (29)	1.09
F	46	5 (11)	0.86
G	38	3 (8)	0.86
H	37	11 (30)	1.61
I	36	5 (14)	0.91
J	34	7 (21)	1.05
K	32	4 (13)	0.59
L	21	2 (10)	0.97
M	21	3 (14)	0.79

HR, hazard ratio.

approaches invite punishment of the writer of the worst signature and reward for the writer of the best signature. Yet, from the point of view of the underlying process, the five signatures are similar. No signature is better or worse than the others. For improvement, the process which produced these signatures must be fundamentally changed.

Now consider the sixth signature. It is clearly different from the others. A casual look suggests that this variation must have a special cause which needs to be found and eliminated to prevent it from interacting with an otherwise stable process. In this case the sixth signature was produced with the writer using his left hand. By finding this out, a simple lesson is learned—one hand is better than the other at writing signatures.

The critical feature of Shewhart's theory of variation is that it categorises variation according to the action needed to reduce it. To reduce common cause variation one must act on the process. To reduce special cause variation one must find and act on the special cause(s). To help distinguish between these two kinds of variation Shewhart devised the premier tool of SPC—the control chart (fig 2). Control charts have three important lines. The central line is the mean or median, and the upper and lower lines are termed control limits. Data points outside the control limits (or unusual data patterns) indicate a special cause which should be found and eliminated. However, like any diagnostic tool, the guidance from the control chart is not infallible. Sometimes an outcome resulting from common cause variation is mistakenly taken to indicate a special cause. Sometimes an outcome resulting from a special cause is mistakenly attributed to common cause variation. It is impossible to reduce the frequency of both errors to zero. In the light of this, Shewhart chose to set the control limits at three sigma from the mean (or median), a level that minimised the economic consequences of both kinds of mistakes. This choice was based on a combination of statistical theory, empirical evidence, and pragmatism.³

Now, if the data in table 1 are reconsidered with the aid of a control chart, profoundly different conclusions are reached from those of the original study. All but one of the surgeons' results are consistent with common cause variation. The appropriate action to improve their results is to change

Figure 1 Signatures.

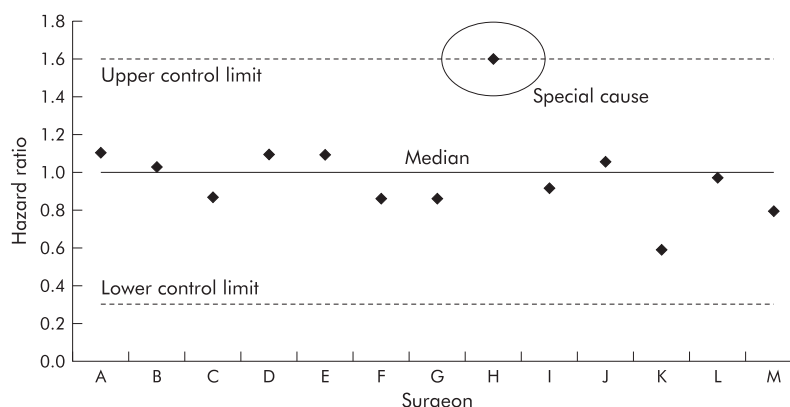


Figure 2 Control chart of surgeon specific hazard ratios.

fundamentally the underlying process of colorectal cancer care—for example, introduce colorectal cancer screening. In contrast, surgeon H's mortality rate is consistent with special cause variation. This should be investigated, the special causes identified according to a predefined search strategy (such as the pyramid model of investigation^{4 5}) and, if possible, eliminated.

FEATURES OF A CONTROL CHART

The simplicity of the control chart has inevitably led to its widespread and successful application in manufacturing and service industries.⁶ However, behind this apparent simplicity underlies some important concepts. For instance, the control chart retains the information in the data by plotting (with respect to order, where appropriate) on a graph and so enjoys the ease of communication associated with (good) graphs⁷ while incorporating statistical thinking. The control chart is a guide to continual action—for common and special cause variation. The control limits continually remind us that the major improvement gains lie in reducing common cause variation (fig 2). Furthermore, by allowing for the play of chance and not ranking the data, control charts overcome the fundamental limitations and negative consequences of league tables and comparison with standards. Perhaps its most fundamental advantage is that "... the control chart process takes us through the complete cycle of the scientific method where we develop theories based on data prior to testing them ... it is one of very few statistical methods that complete the hypothesis generation-hypothesis testing cycle of the scientific method, which is one reason for its popularity with practitioners. Practitioners have found that they learn new information from the charts, rather than just making a 'yes/no' decision."⁸

It thus generates the knowledge which is the key to improvement. Finally, the usefulness of the control chart is

enhanced when it is integrated with other SPC tools/concepts such as cause-effect diagrams, Pareto charts, flow charts, and operational definitions.^{6 9}

TRANSFER OF SPC TO HEALTH CARE

Why then has SPC not been widely adopted in health care? Firstly, there is evidence that SPC is being increasingly applied in health care—for instance, a keyword literature search (using the term "statistical process control") of the Medline database found zero hits for 1951–88, two for 1989–91, 26 for 1992–5, and 71 for 1996–2004. In addition, a number of recent publications^{10–13} have reported the use of SPC in high profile cases such as the Bristol Inquiry and that of Dr Shipman,^{4 14} several health care specific SPC books have been published,^{15 16} and organisations such as the Joint Commission on Accreditation of Healthcare Organisations in the USA¹⁵ and the National Health Service Modernisation Agency in the UK have advocated its use.¹⁷ However, these are notable exceptions and not the rule.

In my view the reasons why SPC has been slow to transfer to health care include:

(1) SPC was first used in manufacturing industry so there is a reluctance,¹⁸ despite evidence to the contrary,^{4 19} to accept that an approach for improving the quality of "widgets" can be legitimately applied to health care.

(2) Industry has a branch of statistics called industrial statistics (born, incidentally, from Shewhart's work²⁰); in health care we have medical statistics. Unfortunately, SPC does not feature in the most popular books on medical statistics.

(3) Ultimately, perhaps, the key constraint is that SPC is above all a way of thinking which challenges many of our fundamental assumptions about how to

deliver improvement documented by Deming²¹—for example, management by objectives, futility of performance related pay, increased quality means increased costs and less production, local optimisation results in global optimisation. This is where past attempts to introduce SPC into health care have failed—not on the statistical arguments but on our reluctance to face the challenges that SPC makes to our overall management approach. For example: “*In Australia in the early 1980s, hospital ‘reform’ was in full swing under the influence of a managerialist management system obsessed with very short term financial objectives and individual performance. The system was one of reducing costs in the short term and judging individuals, not of providing a quality service. SPC was bound to fail.*”²²

CONCLUSION

If we are to be more successful at continuous improvement in health care we must recognise that it embodies a science²³ encompassing a range of disciplines from SPC to human psychology. Given that the majority of our health-care leaders and professionals have not been exposed to this science, we must address this deficiency through widespread education and training. One exemplar model of this is the Veterans Administration (VA) National Quality Scholars Fellowship Program (VAQS) in the USA.²⁴ This is a two year postgraduate fellowship programme (primarily aimed at physicians) which seeks to develop leaders who will apply and develop the science of improvement. Incidentally, the core curriculum draws

on the work of Shewhart and Deming. Perhaps the VA has been foremost in realising that, for health care continually to improve: “*it is not enough to do your best; you must know what to do and then do your best.*”²⁵

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REFERENCES

- McArdle CS, Hole D. Impact of variability among surgeons on postoperative morbidity and mortality and ultimate survival. *BMJ* 1991;**302**:1501–5.
- American Society for Quality. <http://www.asq.org/about/history/shewhart.html>. 2000 (accessed June 2004).
- Shewhart WA. *Economic control of quality of manufactured product*. New York: D Van Nostrand Company, 1931 (reprinted by American Society for Quality Control, Milwaukee, Wisconsin, 1980).
- Mohammed MA, Cheng KK, Rouse A, et al. Bristol, Shipman, and clinical governance: Shewhart's forgotten lessons. *Lancet* 2001;**357**:463–7.
- Mohammed MA, Rathbone A, Myers P, et al. An investigation into general practitioners associated with high patient mortality flagged up by through the Shipman inquiry: retrospective analysis of routine data. *BMJ* 2004;**328**:1474–7.
- Ryan TP. *Statistical methods for quality improvement*. 2nd ed. New York: John Wiley and Sons, 2000.
- Cleveland WS. *Visualizing data*. Summit, NJ: Hobart Press, 1993.
- Hoerl RW. Discussion. *J Qual Technol* 2000;**32**:351–5.
- Wheeler DJ, Chambers DS. *Understanding statistical process control*, 2nd ed. Knoxville, TN: SPC Press, 1992.
- Tekkis PP, McCulloch P, Steger AC, et al. Mortality control charts for comparing performance of surgical units: validation study using hospital mortality data. *BMJ* 2003;**326**:786.
- Benneyan JC, Lloyd RC, Plsek PE. Statistical process control as a tool for research and healthcare improvement. *Qual Saf Health Care* 2003;**12**:458–464.
- Adab P, Rouse AM, Mohammed MA, et al. Performance league tables: the NHS deserves better. *BMJ* 2002;**324**:95–8.
- Spiegelhalter D, Grigg O, Kinsman R, et al. Risk-adjusted sequential probability ratio tests (SPRTs): applications to Bristol, Shipman and adult cardiac surgery. *Int J Qual Health Care* 2003;**15**:7–13.
- Aylin P, Best N, Bottle A, et al. Following Shipman: a pilot system for monitoring mortality rates in primary care. *Lancet* 2003;**362**:485–91.
- Kelly DL. *How to use control charts for healthcare*. American Society for Quality. Wisconsin, USA: Quality Press, 1999.
- Carey RG. *Improving healthcare with control charts. Basic and advanced SPC methods and case studies*. American Society for Quality. Wisconsin, USA: Quality Press, 2003.
- NHS Modernisation Agency. *Real measurement for real improvement using statistical process control*. Innovation and Knowledge Group, <http://www.modern.nhs.uk/search/> (accessed June 2004).
- Wilson T, Holt T, Greenhalgh T. Use of Shewhart's technique (letter). *Lancet* 2001;**357**:1528–9.
- Laffel G, Blumenthal D. The case for using industrial quality management in health care organizations. *JAMA* 1989;**262**:2869–73.
- Pearson ES. A survey of the uses of statistical method in the control and standardization of the quality of manufactured products. *J R Stat Soc* 1933;**96**:21–75.
- Deming WE. *Out of the crisis*. Massachusetts: Massachusetts Institute of Technology, 1986.
- Morton AP. The use of statistical process control methods in monitoring clinical performance. *Int J Qual Health Care* 2003;**15**:361–2.
- Langley GJ, Nolan KM, Nolan TW, et al. *The improvement guide, A practical approach to enhancing organisational performance*. New York: Jossey-Bass, 1996.
- Splaine ME, Aron DC, Dittus RS, et al. A curriculum for training quality scholars to improve the health care of Veterans and the community at large. *Qual Manage Health Care* 2002;**10**:10–18.
- Deming WE. http://www.brainyquote.com/quotes/authors/w/w_edwards_deming.html (accessed June 2004).