MEDWELL PUBLISHING
Research Journal of Medical Sciences 3 (2): 87-90, 2009
ISSN: 1815-9346

On the Importance of Statistical Process Control in Health Care

Adeoti A. Olatunde
Department of Mathematics and Statistics, Bowen University, Iwo, Nigeria

Abstract: The mian aim of this study, is to provide an overview of Statistical Process Control (SPC) techniques, a sub-area of Statistical Quality Control (SQC), which has been widely used in the manufacturing industry for a long time and its primary tool the control chart, the challenges and the benefits in the non-manufacturing sector notably the health care.

Key words: Statistical Process Control (SPC), control chart, Variation, health care improvement, SQC

INTRODUCTION

We need control because we live in a non-stationary world, where, if left to themselves, machines do not stay in adjustment, operators forget or change jobs and things wear out. In short, our world is governed by the second law of thermodynamics, where the entropy (or disorganization) of any uncontrolled systems tends naturally to increase (Box *et al*., 1997).

We can never totally defeat this law, but can greatly reduce its influence in a way called process monitoring and control and continually striving to make the process better, which is known as process improvement. So, statistical methods play a vital role in this quality improvement process both in manufacturing and non-manufacturing process.

The term process means the transformation of a set of inputs, which can include materials, actions, methods and operations into desired outputs in the form of products, information, services or generally results. (Oakland, 1999). Process must be brought into statistical control before SPC is useful; the message that control limits are useless unless the process is in control is so fundamental and must not be easily forgotten. A process will be out of statistical control because of variation in values of a quality characteristic and understanding of the variation is of primary importance in SPC. The problem that variation poses in health care, theory of SPC, difficulty of using SPC in health care in the early stage of its introduction and an example of its application to common issues in health care improvement are given in subsequent sections.

VARIATION IN HEALTH CARE

In many production processes, regardless of how well or carefully maintained it is, a certain amount of inherent or natural variability will always exist. So, also in any process in health care; repeated measures of the same parameter often yield slightly different results. Most process exhibits some variability, all of which, can be classified into one of 2 categories namely natural (typical) or unnatural (atypical). The natural variability of process is the systemic variation inherent as a regular part of the process. This natural variability is the cumulative effect of many small, essentially unavoidable causes and referred to as common cause and a process operating in the presence of common causes is said to be in statistical control. Some examples of common causes of natural variability in health care include a department's waiting times, re-measurement of a patient's blood sugar level, appointment access satisfaction and time of day, hospital census, weight and physical condition of patients and varying behaviours of patients. However, there are others kinds of variability, which is generally large and it usually represent an unacceptable level of process performance in health care and are not part of the common cause and suggest that the process fundamentally has changed for better or worse due to a typical unnatural variability that should be traced to root assignable causes for quick intervention. These are called special causes and a process operating in the presence of this special cause is said to be out of statistical control. Examples of special causes of unnatural variability include Equipment failure, new health personnel, changes in clinical procedures, skill degradation, a patient's physiology and changes in population demographics. Like other statistical methods, SPC helps to tease out the inherent variability within any process and this is achieve through the SPC tools namely; check sheet/tally chart (how often it is done), Pareto diagram (prioritizing), cause-and-effect diagram (Ishikawa fish bone diagram) (what causes the problem), scatter diagram (exploring relationship), flowchart (what is done) and control chart (monitoring variation over time).

One advantage of SPC over that of classical methods is that SPC methods combine the rigour of classical statistical methods, which typically are based on “time static” statistical tests with the time sensitivity of pragmatic improvement (Benneyan *et al*., 2003). By integrating the power of statistical significance tests with chronological analysis of graphs of summary data as they are produced, SPC is able to detect changes and trends into relatively simple formulae and graphical displays that can easily be used by non-statisticians.

THEORY OF STATISTICAL PROCESS CONTROL

SPC is a powerful collection of problem-solving tools useful in achieving process stability and improving capability through the reduction of variability.

The basic theory of SPC was developed in the 1924 by Shewhart (1931), a statistician, who was charged with improving the quality of telephone at the AT and T Bell laboratories, U.S.A. His research there won him the accolade of the father of the modern quality control. His research was popularized worldwide by Deming (1986). Shewhart (1931) developed a theory of variation, which forms the basis of SPC. He originally worked with manufacturing processes but he and Deming (1986) soon realized that their observation could be applied to both manufacturing and non-manufacgturing process. The critical feature of Shewhart (1931) theory of variation is that it categorizes variation according to the action needed to reduce it. These variations are of two kinds: Common (random) cause variations and assignable (special) cause of variations and to help distinguish these 2 kinds of variation, Shewhart (1931) developed relatively simple statistical tool of SPC, which is the control chart.

CONTROL CHART- KEY TOOL OF SPC

Control chart is a statistical device used for the study and control of repetitive processes. It consists of 2 parts: a series of measurements plotted in time order and the template, which consists of three horizontal lines called the central line (typically, the mean or median), the upper line called the Upper Control Limit (UCL) and lower line called the Lower Control Limit (LCL).

The values of the UCL and LCL are not set arbitrarily by the individual making the chart but are usually calculated from the inherent variation in the data. For the appropriate application of control charts, a firm understanding of the standard distributions used for the common cause variation is essential.

Control chart is of univariate type and multivariate type. Univariate chart is used to monitor process with a single quality characteristic while, multivariate chart is used to monitor process with two or more quality characteristics that are usually correlated.

Data points outside the control limits (or unusual data patterns) are indications of special cause variation, which should be found and eliminated. Also, there should be no evidence of unusual behaviour between the limits such as cyclesor trends and other forms of non-randomvariation such as three consecutive subgroups beyond 2 standard deviations on a particular side of CL, six consecutive subgropus with either an increasing or decreasing tend. For as long as all values on the graph fall randomly between the upper and lower control limits, we assume that we are simply observing common cause variation. 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 and sometimes an outcome resulting from a special cause is mistakenly attributed to common cause variation. This situation is analogous to a false positive indication on a laboratory test and a false negative indication on a laboratory test. This is called the type I error and type II error, respectively. In the light of this, Shewhart *et al.* SPC experts recommend control limit set at $\pm 3\sigma$ (3SD) from the mean (or median). This choice was based on a combination of statistical theory, empirical evidence and pragmatism.

The simplicity of the control chart has inevitably led to its widespread and successful application in manufacturing and service industries and now standard control charts are often recommended for use in the monitoring and improvement of hospital performance. Particular advantages of quality control charts over other analysis methods are that they offer a simple graphical manner, by which to display process behaviour and outcomes, they examine these data chronologically as a time series and although, based in valid statistical theory, they are easy to construct and use Benneyan (1995). For example, one might monitor the infection rates, rates of patients’ falls, or waiting times of various sort e.t.c. Control charts can often help to detect special cause variation in health care more easily and faster than traditional statistical methods and therefore are valuable tools for evaluating the effectiveness of a process and ensuring the sustainability of improvements over time.

There are many types of control charts among, which proportion defective charts-p-chart, np chart and number defective charts-c-chart and u-chart all of which, are known as Shewhart (1931) Charts and Exponential Weighted Moving Average chart (EWMA), Cummulative Sum chart (CUSUM). Some general differences between the health related control chart applications and industrial applications are that the use of attribute data is much prevalent in healthcare applications than in industrial practice and there is much greater use of charts based on counts or time between failures with an assumed underlying geometric or exponential model, which are yet to be included in popular SQC textbooks, such as (Montgomery, 2005).

In summary, control charts are used in a manufacturing process for trouble shootings and used in health care for control and improvement. There are at least five reasons for the increasing use of the control chart in industries and other application areas:

- Control charts are a proven technique for improving productivity
- Control chart are effectiv in defect prevention, which is consistent with the do it right the first time slogan
- Control chart prevent unnecessary adjustment, which is consistent with the if it isn't broken, don't fix it philosophy
- Control chart provides diagnostic information
- Control charts provide information about process capability

An important point in the construction of control charts concerns the mechanics of calculating the σ (SD). As with traditional statistical methods, many different formulae can be used to calculate the σ depending on the type of control chart used and the particular statistical distribution associated with that chart. For example, if monitoring the proportion of surgery patients who acquire an infection, the appropriate formulae would use the σ of a binomial distribution; if monitoring a medication error rate the appropriate formulae would use the σ of a Poisson distribution and when using normally distributed data the appropriate formulae essentially block on the within sample.

STATISTICAL PROCESS CONTROL IN NIGERIAN HEALTH CARE

There is evidence that SPC is being increasingly applied in health care. But, one might question why SPC has been slow to transfer to health care especially, in Nigeria.

SPC was first used in manufacturing industry so there is reluctance, despite evidence to the contrary to accept that an approach for improving the quality of widgets can be legitimately applied to health care.

SPC feature in the most popular books in industrial statistics (a branch of statistics born incidentally from Shewhart (1931) research), but for historical reasons, application areas such as health care are rarely represented in traditional textbooks on statistical quality improvement owing to reluctance to accept the idea by the health care professionals. There are also, a number of statistical issues in using control chart in health care. In the first place, deciding what to measure or count is often a challenging problem. It is also, difficult to aggregate count data and determines appropriate measures of opportunity for rates and proportions in such a way that meaningful comparison can be made across groups. Finally, there is a natural tendency to use SPC-notably control charts as management or industry report cards rather than for genuine quality improvement. This is where past attempt to introduce SPC into health care have failed; -not on the statistical argument but on our reluctance to face the challenges that SPC makes to our overall management approach.

In Nigeria the unwillingness of health care institutions and agencies saddled with health matters to make available data to monitor and control health problems has made the use of SPC difficult if not impossible. Thus, the data of Mohammed (2004) provided an excellent scenario of the use of SPC in health care monitoring and control. Data, which shows surgeon specific mortality rates after colorectal cancer surgery was collected and control chart applied to explain whether the rate of mortality was as a result of assignable causes of variation.

The conclusion from the original study reveals that surgeons with hazard ratio above one are considered a danger to their patients and are said to be less competent technically than their colleagues since a hazard ratio of one is considered as neutral.

EXAMPLE OF APPLICATIONS OF SPC TO HEALTH CARE

The example of Mohammed (2004) illustrates the basic principles, application and versatility of SPC-in particular control chart in health care control and improvement. Data of surgeon specific mortality rates following cancer surgery extracted from Mohammed (2004) and the proportion of the number of death

Table 1: Surgeon specific mortality rates following colorectal cancer surgery

Surgeon	No. cases	No. death	Proportion of number of death
I	98	16	0.163
II	66	8	0.121
III	58	9	0.155
IV	52	7	0.135
V	52	15	0.288
VI	46	5	0.109
VII	38	3	0.079
VIII	37	11	0.297
IX	36	5	0.139
X	34	7	0.206
XI	32	4	0.125
XII	21	2	0.095
XIII	21	3	0.143

computed is given in Table 1. The number of defects attribute control chart- C chart for the data is shown in Table 1 revealing the sugeon whose case is out of control.

RESULTS AND DISCUSSION

Mohammed (2004) making use of control chart of surgeon specific hazard ratios concluded that all but one of the surgeons' results were consistent with common cause of variation and that surgeon VIII is consistent with special cause variation. However, with the aid of number of defects attribute control chart in Table 1, where number of death is taken as defects, all of the surgeons' results are consistent with common (random) cause of variation except Surgeon I patient mortality rate, which is susceptible to assignable (special) cause of variation, which is a sharp contrast to the result of Mohammed (2004). However, both the chart of Mohammed (2004) and that of Table 1 revealed an out-of-control situation. This should be investigated by the health institution concerned and the reasons for the high rate of mortality of surgeon I compared to other surgeons discovered. Thus, bringing out the importance of SPC in health care. Nonetheless, in recent time a number of publications have reported the use of SPC in high profile cases. This includes Carey (2003), Benneyan (1995), Hart and Hart (2002) and Morton *et al.* (2001) and Woodall (2006).

Finally, it should be noted that the usefulness of the control chart is enhanced when it is integrated with other SPC tools such as cause and effect analysis, Pareto chart and process flowcharting.

CONCLUSION

It is hoped that industrial practitioners and industrial SPC researchers will be encouraged to investigate further health care and public health applications of SPC. These have the opportunity to make some additional important contributions to the theory and applications of SPC to health care improvement rather leaving it to health care professionals only.

REFERENCES

Box, G.E.P., D.E. Coleman and R.V. Baxley, 1997. A comparison of Statistical Process Control and Engineering Process Control. J. Quality Technol., 29: 128-130.

Benneyan, J.C., 1995. Applications of Statistical Process Control to improve Health care. Conference presentation, Health care information and management systems society, http:/www.himss.org.

Benneyan, J.C., R.C. Lloyd and P.E. Plsek, 2003. Statistical Process Control as a tool for research and health care improvement. Quality and Safety in Health Care, 12: 458-464.

Carey, R.G., 2003. Improving Health care with Control Charts. Basic and advanced SPC methods and case studies. American Society for Quality, Milwaukee, Wisconsin.

Deming, E.W., 1986. Out of Crisis. Massachusetts Institute of Technology, Centre for Advanced Engineering Study, Cambridge, MA.

Hart, M.K. and R.F. Hart, 2002. Statistical Process Control for Health Care. Duxbury, Pacific Grove, CA.

Mohammed, M.A., 2004. Using Statistical Process Control to improve the quality of Health care. Quality and Safety in Health Care, 13: 243-245.

Montgomery, D.C., 2005. Introduction to Statistical Quality Control. 5th Edn. McGraw-Hill Book Company.

Morton, A.P., M. Whitby, M. Mclaws, A. Dobson, S. McElwain, D. Looke, J. Stackelroth and A. Sartor, 2001. The application of Statistical Process Control charts to the detection and monitoring of Hospital-Acquired Infections. J. Quality Clin. Practice, 21: 112-117.

Oakland, J.S., 1999. Statistical Process Control. Butterworth Heinemann Book Company.

Shewhart, W.A., 1931. Economic control of quality of manufactured product. Reprinted by American Society for quality Control, Milwaukee, Wisconsin.

Woodall, W.H., 2006. Use of Control charts in Health care Monitoring and public Health Surveillance. J. Quality Technol., 38: 89-104.