International Journal of Pure and Applied Mathematics
Volume 57 No. 4 2009, 593-603

STATISTICAL PROCESS CONTROL ANALYSIS FOR MONITORING OF DANGEROUS HOSPITAL ACQUIRED INFECTIONS

S.K. Uma Maheswaran
Department of Mathematics
Sri Sai Ram Engineering College
West Tambaram, Chennai, 600044, INDIA
e-mail: s_mahesh4@yahoo.co.in

Abstract: The monitoring and detection of Hospital acquired infections (HAI) is a very important problem arising in hospitals. A hospital acquired or nosocomial infections is a disease that develops after admission into the hospital and it is the consequence of a treatment, not necessarily a surgical one, performed by the medical staff. This paper provides an overview of SPC and few practical examples of HAI monitoring control charts. The application of Shewhart, cumulative sum (CUSUM) and exponentially weighted moving average (EWMA) statistical process control charts are also discussed. This work can help both researchers and practitioners of quality improvement to determine weather the changes in process are making a real difference in outcome.

AMS Subject Classification: 92C60
Key Words: infection control surveillance, control charts, statistical process control

1. Introduction

A hospital-acquired infection, also called a nosocomial infection, is an infection that first appears between 48 hours and four days after a patient is admitted to a hospital or other health-care facility. About 5-10% of patients admitted to acute care hospitals and long-term care facilities in the United States develop a hospital-acquired, or nosocomial, infection, with an annual total of more than

Received: November 25, 2009 © 2009 Academic Publications

one million people [1]. Hospital acquired infections are usually related to a procedure or treatment used to diagnose or treat the patient's initial illness or injury.

The Centers for Disease Control (CDC) of the U.S. Department of Health and Human Services has shown that about 36% of these infections are preventable through the adherence to strict guidelines by health care workers when caring for patients [2]. Hospital-acquired infections can be caused by bacteria, viruses, fungi, or parasites. These microorganisms may already be present in the patient's body or may come from the environment, contaminated hospital equipment, health care workers, or other patients.

Hospital acquired infections may develop from the performance of surgical procedures; from the insertion of catheters (tubes) into the urinary tract, nose, mouth, or blood vessels; or from material from the nose or mouth that is aspirated (inhaled) into the lungs. The most common types of hospital acquired infections are urinary tract infections (UTIs), ventilator associated pneumonia, and surgical wound infections. A study in the journal *Infection Control and Hospital Epidemiology* shows that about 24% of patients with catheters will develop catheter related infections, of which 5.2% will become bloodstream infections. Death has been shown to occur in 4-20% of catheter-related infections.

Traditional methods of analysis often provide delayed identification of infection occurrence, however statistical process control (SPC) analysis is useful for detecting and monitoring infections. Statistical process control is a branch of statistics that combines rigorous time series analysis methods with graphical presentation of data, often yielding insights into the data more quickly and in a way more understandable to lay decision makers. SPC and its primary tool-the control chart-provide researchers and practitioners with a method of better understanding and communicating data from healthcare improvement efforts.

All improvement requires change, but not all change results in improvement. The key to identifying beneficial change is measurement. The major components of measurement include: (1) determining and defining key indicators; (2) collecting an appropriate amount of data; and (3) analysing and interpreting these data. This paper focuses on the third component – the analysis and interpretation of data using SPC.

SPC is an effective method of monitoring a process through the use of control charts. By collecting data from samples at various points within the process, variations in the process that may affect the quality of the end product or service can be detected and corrected, thus reducing waste and as well as the likelihood that problems will be passed on to the customer. With its emphasis

on early detection and prevention of problems, SPC has a distinct advantage over quality methods, such as inspection, that apply resources to detecting and correcting problems in the end product or service.

The basic theory of statistical process control was developed in the late 1920s by Dr Walter Shewhart, a statistician at the AT&T Bell Laboratories [3] in the USA, and was popularized worldwide by Dr W Edwards Deming. Both observed that repeated measurements from a process will exhibit variation. Shewhart originally worked with manufacturing processes but he and Deming quickly realized that their observation could be applied to any sort of process [4]. If a process is stable, its variation will be predictable and can be described by one of several statistical distributions.

SPC theory uses the phrase "common cause variation" to refer to the natural variation inherent in a process on a regular basis [5]. This is the variation that is expected to occur according to the underlying statistical distribution if its parameters remain constant over time. For example, the random variation between body temperatures within a population of healthy people is a result of basic human physiology, while the random variation in week to week wound infection rates is a result of factors such as training, sources of supplies, surgical and nursing care practices, and cleanliness procedures. Processes that exhibit only common cause variation are said to be stable, predictable, and in "statistical control", hence the major tool of SPC is called the "statistical control chart" [6].

The control chart therefore defines what the process is capable of producing given its current design and operation. If a different level of performance is wanted in the future, we must intervene and introduce a change in the process that is, a special cause. If we simply want to sustain the current level of performance, special causes of variation must be prevented or eliminated. Control charts can often help to detect special cause variation more easily and faster than traditional statistical methods [7], and therefore are valuable tools for evaluating the effectiveness of a process and ensuring the sustainability of improvements over time.

2. Overview of SPC

The control chart is the key tool of SPC. Shewhart developed a relatively simple statistical tool-the control chart-to aid in distinguishing between common and special cause variation. A control chart consists of two parts: (1) a series of

measurements plotted in time order, and (2) the control chart "template" which consists of three horizontal lines called the centre line (typically, the mean), the upper control limit (UCL), and the lower control limit (LCL). Examples are shown in Figure 1. The values of the UCL and LCL are usually calculated from the inherent variation in the data rather than set arbitrarily by the individual making the chart.

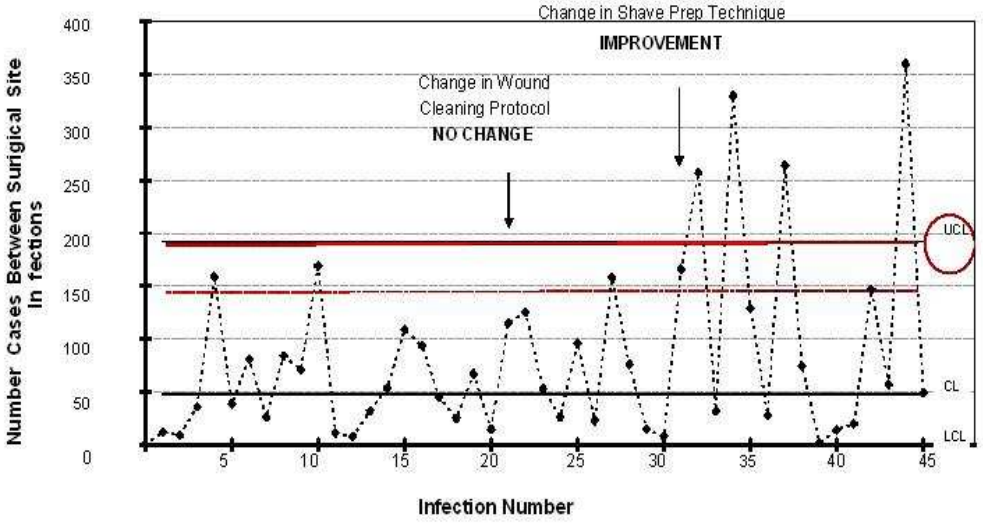

Figure 1: Control chart for SSI

A g type of control chart (based on the geometric distribution) for one type of surgery is shown in Figure 1. Instead of aggregating surgical site infections (SSI) in order to calculate an infection rate over a week or month, the g chart is based on a plot of the number of surgeries between occurrences of infection. This chart allows the statistical significance of each occurrence of an infection to be evaluated rather than having to wait to the end of a week or a month before the data can be analyzed. This ability to evaluate data immediately greatly enhances the potential timeliness of the analysis. The g chart is also particularly useful for verifying improvements (such as reduced SSIs) and for processes with low rates.

Many SPC techniques have been rediscovered by American firms in recent years, especially as a component of quality improvement initiatives like Six Sigma. The widespread use of control charting procedures has been greatly

assisted by statistical software packages and ever-more sophisticated data collection systems.

Over time, other process-monitoring tools have been developed, including:

Cumulative Sum (CUSUM) charts: the ordinate of each plotted point represents the algebraic sum of the previous ordinate and the most recent deviations from the target.

Exponentially Weighted Moving Average (EWMA) charts: each chart point represents the weighted average of current and all previous subgroup values, giving more weight to recent process history and decreasing weights for older data.

More recently, others have advocated integrating SPC with engineering process control (EPC) tools which regularly change process inputs to improve performance.

3. SPC Charts for Monitoring HAI

CUSUM Chart

Although designed for counts of data with a Poisson distribution, Lucas' counted data CUSUM chart is also applicable to data with a binomial distribution provided that the adverse event rate does not exceed 10%. It is thus particularly suitable for the assessment of SSI.

Small changes in infection rates can often be the result of random events. The CUSUM can be used to detect and separate a real change in the underlying rate from one caused by random fluctuation. We illustrate the use of the CUSUM with SSI data. Two charts are employed, a simple observational chart and a more complex statistical test chart. We find that hospital staff accepts these methods better when displayed in this way.

1. The CUSUM *observational chart* displays the accumulated number of adverse events plotted against time in a step-like line. The slope of the line illustrates the rate of infection; informally, the steeper the slope, the greater the rate.

2. The CUSUM *statistical test chart* provides a signal or alarm when the proportion of adverse events exceeds a predetermined level to an extent that is unlikely to be due to random variation. An acceptable adverse event rate after which assessment by infection control staff must be established. This is

an arbitrary level and can be set either by reference to published reports, or by analysis of past infection rates.

Basic Components of a CUSUM Chart

Blocks. Contiguous surgical procedures are grouped into 'blocks', in which one SSI may be expected on average. For an expected SSI rate of 3%, each block will contain 33 operations and for a 5% infection rate, each block will contain 20 operations. We employ the CUSUM to detect an increase to two SSI per block on average. When selecting surgical procedures for surveillance, it is preferable to choose those which are major, common and homogenous for risk. For example, for vascular surgery we select aorto-femoral and femoropopliteal bypass procedures. There should be at least 50 and preferably 100 or more procedures performed each year. With smaller numbers, changes are likely to take too long for action to be taken in a useful time frame.

Average Run Length (ARL). This concept refers to the number of blocks before the occurrence of a signal. When the observed rate equals the expected rate, the ARL should be of considerable duration before a signal occurs by chance; that is, false positive alarms must be minimised. However, when the SSI rate increases significantly above the expected level, for example to two infections per block, then the ARL is required to be as short as possible so as to provide an early warning of increased infection rate, thus avoiding false negative states. Therefore, the ARL is a balance of two opposing needs: the need to provide the earliest warning possible of a true increase in the infection rate and the need to minimise false positive signals.

Constants. Two constants are associated with the CUSUM statistical chart.

1. The first, denoted by h, can be set at 3-4. Our experience suggests that h is best set at 3. This has the effect of reducing the rate of false positive signals to approximately one in every 50 blocks of operations. For each block, the probability of a false positive signal is 1/ARL, so for 50 blocks this probability is 0.02. The ARL is approximately 5 blocks when the SSI rate just doubles. Setting h to 4 results in a false positive rate of approximately 1 in every 100 blocks, but when the SSI rate just doubles, the ARL rises to approximately 7.5 blocks so that there can be delay in its detection.

2. The second constant is denoted by k. It is mid-way between the expected number and the unsatisfactory number of SSI per block. For example, if the former is 1 per block and the latter is 2 per block, then $k = 1.5$.

Block	**No. infections**	**CUSUM value**	**CUSUM score**
1	2	2	0.5 (2.0-1.5)
2	0	0.5	0.0 (0.5-1.5)
3	3	3	1.5 (3.0-1.5)
4	3	4.5	0.0 reset
5	1	1	0.0 (1.0-1.5)
6	3	3	1.5 (3.0-1.5)
7	1	2.5	1.0 (2.5-1.5)
8	1	2	0.5 (2.0-1.5)
9	0	0.5	0.0 (0.5-1.5)
10	0	0	0.0 (0.0-1.5)

Table 1: Calculation of cumulative sum (CUSUM) value and CUSUM score

CUSUM Value and CUSUM Score. The CUSUM value is the number of SSI in a block plus the CUSUM Score brought forward from the previous block (Table 1). For the first block, the CUSUM Value is the number of SSI in that block. The CUSUM Score is the number carried forward from each block to the next. It is calculated by subtracting k from the CUSUM Value at the end of the block. If it is less than zero, it is set to zero.

Decision Level. The decision level, $d = h + k$ determines when the CUSUM Value reaches statistical significance. In the example shown in Table 1 the decision level is $d = 3 + 1.5 = 4.5$.

Signaling an Alarm and Resetting the CUSUM Value. When the CUSUM Value reaches the preset decision level d, a signal or alarm will be indicated on the CUSUM statistical chart. This indicates that the increase in adverse events is unlikely to be the result of random variation and suggests the need for further infection control assessment. After an alarm occurs, the CUSUM is reset to zero and a new block is commenced. These concepts are illustrated in block 4 of Table 1.

The CUSUM statistical chart is shown in Figure 2; there was an alarm in May. This indicates that by May the SSI rate had increased to 10% and that this change was not likely to be due to random variation. At that time assessment by infection control staff was indicated.

The CUSUM was reset to zero and a new block commenced after the alarm

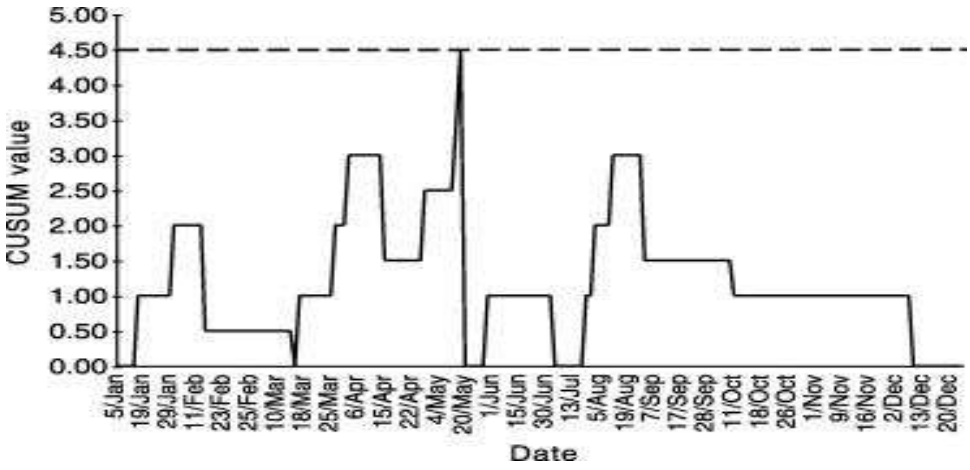

Figure 2: CUSUM chart

was recorded in May. For the remainder of the year, the CUSUM observational line was almost horizontal, indicating a rate that was not above the expected level. In addition, there was no further signal from the statistical chart.

Shewhart and EWMA Charts

Basic Components of a Shewhart Chart

Count. The number of events in each month plotted against time.

Mean Monthly Count of Infections. This should be calculated during a surveillance period that is free from unusual variation. Ideally, a series of at least 20 months' data should be obtained, from historical data if necessary, to estimate this value.

Upper Control Limit (U2S). In general, infection control surveillance is concentrated on detecting an increase in infection rates with most focus therefore on the upper control limit. This is set at the upper 2.5-th percentage point of the relevant distribution and is equivalent to two standard deviations from the mean (also called the 2 sigma warning limit) and is labeled U2S. When U2S is exceeded, it indicates a statistically significant increase in the infection rate. In addition, it suggests that causation of the increase is more likely to be related to so-called special cause variation. That is, the excess adverse events are more likely to be the result of a process that has not been implemented appropriately,

rather than the process itself being suboptimal.

When the infections are independent (e.g. BSI) and can be modeled by the Poisson distribution, the chi-square distribution can be used to calculate U2S. Counts of infections are often too low for the more familiar large sample normal approximation to be appropriate.

When infections are not independent the resulting correlation increases variation. This is frequently the case with MRO. In this situation, the negative binomial distribution is used and a formula based on the F distribution is employed.

The Poisson and negative binomial formulas for U2S are most easily calculated using a computer programme (Electronic Infection Control Assessment Technology [eICAT]; (http://www.eICAT.com).

Basic Components of the EWMA Chart

A Weight. A satisfactory general purpose weight is 0.2. Using this weight has the added advantage of simplifying the calculation of control limits.

EWMA Value. This is a weighted running estimate of the mean monthly infection count. The EWMA Value for the month is 0.2 times the count for the month added to 0.8 times the EWMA Value for the previous month. More generally, these multipliers are the weight and one minus the weight. For the first month, it is necessary to use historical data or some initial expected monthly count.

Upper EWMA Control Limits (U2E). The calculation of U2E for the first few monthly values is complicated by the fact that the initial expected value is considered not to vary. Thereafter, U2E levels out. When a weight of 0.2 is used, the expected value of U2E is one-third of the distance from the mean to U2S so that U2E = MEAN + (U2S - MEAN)/3. However, for the first 6 months, the divisor 3 must be replaced by 5, 3.9, 3.5, 3.3, 3.2, and 3.1, respectively. If the EWMA line exceeds U2E, it indicates a statistically significant shift in the mean value. This is often due to 'common cause variation' that is, the process itself may be suboptimal.

Figure 3 displays the data from June 2003 to November 2006 using a combined Shewhart EWMA control chart (note that we have omitted part of the series before 2003 as the chart becomes very cluttered if more than 4 years' data are included). In the epidemic period of 2004 the number of cases exceeded the Shewhart control limit. However, the increased counts in late 2005 did not

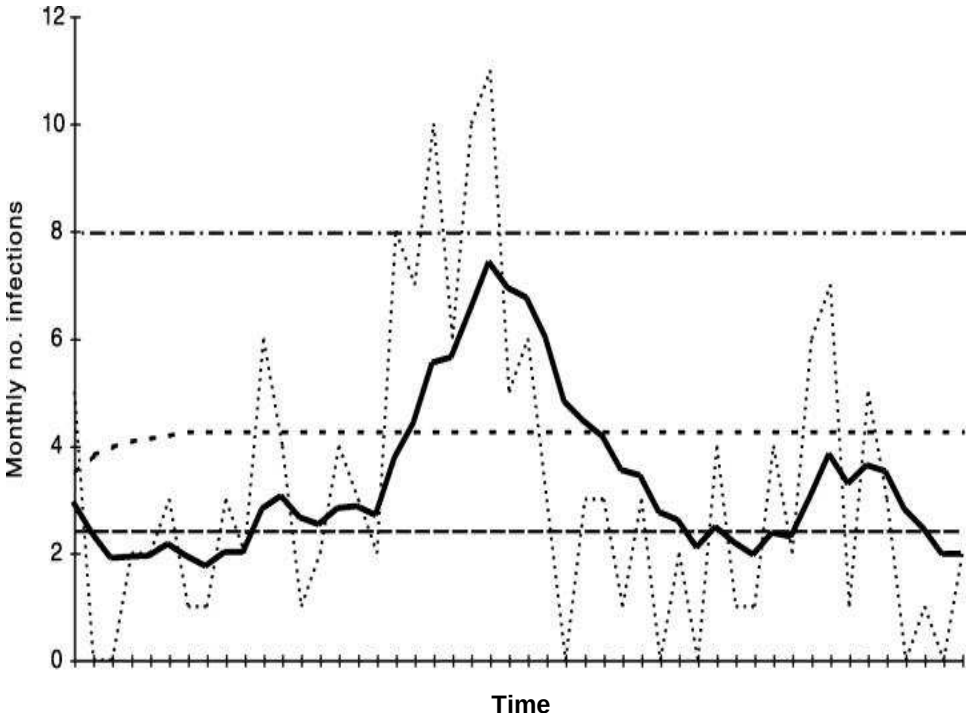

Figure 3: Shewhart and exponentially weighted moving average (EWMA) control chart for a kind of blood stream infections. (****) count; (- - -) mean; (– -) EWMA; (-*-*-) upper Shewhart control limit, U2S; (- - -) upper EWMA control limit, U2E

exceed the control limit, suggesting random variation.

The EWMA line and the upper control limit are also displayed in Figure 3. Again, it can be seen that the control limit U2E was exceeded by the EWMA value in the epidemic period of 2005, but not in late 2006. This is concordant with our view that the increased counts in late 2006 were due to random variation.

4. Conclusion

This study analyses the application of control charts to the monitoring of hospital- acquired infections. The nature of hospital-acquired infection is such that traditional monitoring methods may fail to detect unacceptable rate in-

creases rapidly. However, statistical process control methods such as the cumulative sum (CUSUM) and exponentially weighted moving average (EWMA) are particularly suitable for the detection of small sustained increases in uncommon events, while the Shewhart chart efficiently detects larger, more abrupt changes. Although statistical control charts have been used in a number of hospital management areas, application to infection control has been limited. These techniques provide a number of advantages to an infection control surveillance programme over traditional methods. Control charts are powerful, user friendly, and statistically rigorous process analysis tools that can be used by quality improvement researchers and practitioners alike. These tools can help managers, process improvement practitioners, and researchers to use objective data and statistical thinking to make appropriate decisions.

References

[1] J. Benneyan, Statistical quality control methods in infection control and hospital epidemiology, Part 1. Infect. Control, *Hospital Epidemiol.*, **19** (1998), 194-214.

[2] J.C. Benneyan, Statistical quality control methods in infection control and epidemiology. Part 2: Chart use, statistical properties, and research issues, *Infect Control Hosp Epidemiol*, **19** (1998), 265-83.

[3] W.E. Deming, *Out of the Crisis*, Cambridge, MA: Massachusetts Institute of Technology Center for Advanced Engineering Studies (1986).

[4] R.W. Haley, D.H. Culver, J.W. White, The nation wide nosocomial infection rate. A new need for vital statistics, *Am. J. Epidemiol.*, **121** (1985), 159-67.

[5] R. Kenett, S. Zack, *Modern Industrial Statistics*, Duxbury Press, Belmont (1998).

[6] W.A. Shewhart, *The Economic Control of Quality of Manufactured Product*, New York, Van Nostrand (1931).

[7] Center for Disease Control and Prevention, *Guidelines for Investigating Clusters of Health Events*, MMWR, **39** (1990), 1-22.