Aligarh Journal of Statistics

Vol. 33 (2013), 11-31

THE USE OF SPC TOOLS IN HEALTH CARE MONITORING: BIBLIOGRAPHY & LITERATURE SURVEY

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ABSTRACT

Statistical Process Control (SPC) methods based on control charts have been used for more than 90 years, particularly in the area of Industrial Quality Control. However, transferring SPC tools to health care, it took a long time. During last two decades SPC tools are increasingly applied to monitor the health care section. There is also ample of research opportunities in the area of health care improvement for SPC tools. In this paper we shall try to highlight briefly, the works done by the scholars of QC and health care practitioners who used various SPC tools like magnificent seven tools, variable and attribute charts, advanced control charts like $CUSUM$, $EWMA$, $MCUSUM$, $MEWMA$, Sample Generalized Variance Charts, Six-Sigma methods in a systematic manner. The sensitivity of SPC tools are discussed with data dealing with health care statistics.

1. INTRODUCTION

Many techniques have been developed by the Mathematical Statisticians to analyze data to control the product quality. The expression *'quality control'* applies to a function much broader than the expression *'Stistical Quality Control'*. When the control of a product is made using statistical tools, then the adjective 'Statistical' is accurately applicable in the expression '*Statistical Quality Control'*: Some of the most commonly used working statistical tools in an industrial process are:

a. The Shewhart Control charts for measurable quality characteristics, popularly known as $X-$bar and R or $X-$bar and S chart.

b. The Shewhart Control Chart for fraction rejected, or known as p chart.

c. The Shewhart Control Chart for number of non-conformities or c-chart.

d. The acceptance sampling plans which deals with the quality protection.

The general model for a control chart as proposed by Dr. Walter A. Shewhart (1920) is given by:

$$\begin{aligned} UCL &= «_x + L±_x \\ CL &= «_x \\ LCL &= «_x - L±_x \end{aligned} \qquad (1.1)$$

where x is the sample statistic that measures some quality characteristic of interest, $«_x$ is the mean of x, $±_x$ is the standard deviation of x and 'L' is the distance of the control limits from the centerline expressed in standard deviation units.

All the control charts as mentioned in (a) to (c) above could be derived from equation (1.1) based on variable or attribute characteristics. Shewhart's control charts are widely used to display sample data from a process for the purpose of determining whether a process is in control, for bringing an out-of-control process into control and for monitoring a process to make sure that it stays in control. A control chart is maintained by taking samples from a process, a statistic is computed from these samples and the points are plotted in the chart. Control limits on the chart represent the limits within which the plotted points would fall with high probability if the process is operating in control. A point outside the control limits is taken as an indication that something has happen to the process; sometimes called an assignable cause (special cause) of variation, which changes the process. When the chart signals that an assignable cause is present, then rectifying action is taken to remove the assignable causes and bring the process back into control.

However, Shewhart Control Chart uses the information about the process in the last plotted point and it ignores any information given by the entire sequence of points. Further, they are relatively insensitive to small shifts in the process-say on the order of about $1.5±$ or less. These are majors disadvantages of Shewhart's Control Charts. To overcome these disadvantages, some advance control charts say Cumulative Sum ($CUSUM$) control chart, Exponentially Weighted Moving Average ($EWMA$) control charts, Sample Generalized Variance Charts etc. are developed. Apart from these advance charts, new concepts and modifications of existing control charts are made by wide range of scholars in last few decades. One of the new concepts developed in control chart techniques is economic design in which optimal sample size, cost of sampling and control limits are to be found out. Montgomery (1980) reviewed extensively in this topic. Similarly, Woodall (1997) gave a comprehensive bibliography of references on control charting by attributes.

It is relevant to mention that apart from using these statistical tools in manufacturing process, the management system should have direction to improve the quality of a product. The management must ensure to implement all the quality improvement philosophy to accomplish better quality of product. In fact no any company could exist in the competitive world market without producing better quality of product. Some new quality improvement philosophies emerged in last few decades are Total Quality Management (TQM), Companywide Quality Control $(CWQC)$. Total Quality Assurance (TQA), Six-Sigma, Process Capability Analysis (PCA) etc.

It is noteworthy to mention here that in production companies, the *SPC* tools have been used from 1920s, but it took long time to transfer the ideas of *SPC* to other non-productive areas like Healthcare Industry. Of late, *SPC* tools are used in healthcare section and it is gaining momentum from 1990s.

In the next four sections 2.1-2.5, we shall try to highlight briefly the bibliography and works done by the scholars of statistical quality control and health care practitioners in monitoring health care who used various types of SPC tools. As far as possible, we shall try to include most of the research works in the field in dealing with health care by using variable & attribute control chart, advance control charts like *CUSUM*, *EWMA*, *MCUSUM*, *MEWMA*, sample generalized variance charts, Six Sigma methods in a systematic manner.

2. REVIEW OF SOME WORKS USING SPC TOOLS IN HEALTH CARE

It is interesting to note that, though the use of *SPC* tools in health care sector gains momentum from 1990's yet, W.A. Deming advocated its application in disease surveillance and adverse health care events as early as in 1942. In recent times the "Joint Commission on Accreditation of Health Care Organizations", (JCAHO, (1997)) USA, stated their views on the use of *SPC* tools as follows:

"An understanding of statistical quality control, including SPC and variation is essential for a tool such as run charts, control charts and histograms are especially helpful in comparing performance with historical patterns and assessing variation and stability". On observing the importance of *SPC* application, the present authors studied some past works in the area.

2.1. Studies of health care data using variable & attribute control chart

Schnelle *et al.* (1990) described a statistical quality control system that allows nurse managers to monitor staff performance of a critical patient care function. The condition guaranteed was that the patients' protective garments were changed either in one hour or two-hour basis. The average and expected norms of patient wetness were calculated for a sample of patients in four different nursing homes and control charts were drawn for all the nursing home. This will help the nurse managers for Periodic monitoring of patient wetness in each sample and to determine if the nursing aides were changing patients on either a one- or a two-hour schedule. Vander (1992) described how the six step plan was implemented sequentially, starting with the crucial first step of obtaining administrative support of hospitals. He also observed that the Quality Improvement (*QI*) project succeeded in overcoming beginners' fear of statistics and in training both managers and staff to use inspection checklist, Pareto charts, cause-and-effect diagrams, and control charts. Pfadt & Wheeler (1995) considered how a different approach to the analysis of variability based on the writings of Quality Gurus Walter Shewhart and W E Deming in the area of Industrial Quality Control helps to achieve similar objective in health care. They also provided some examples to illustrate how SPC procedures can be used to analyze behavioral data and concluded that application of SPC problem solving tools like Cause & effect diagram, Scatter plot, Histogram analysis, Pareto diagram and Brainstorming etc could help for continuous improvement of health care services. Benneyan *et al* (1995) discusses the applicability of statistical process control (SPC) for analyzing, monitoring and improving clinical and non-clinical health care processes, the relation of quality engineering to hospital epidemiology, common misperceptions and some more advance issues pitfall to avoid, and the possible liability of failing to correctly use SPC. The strengths of control charting and other statistical process control (SPC) tools have been introduced newly by Shaha (1995) in acuity systems. He has mentioned that Intermountain Health Care, Salt Lake City, Utah, developed a new acuity system that relies heavily upon control charting for an array of purposes, including immediate feedback to caregivers regarding decisions, ongoing feedback to managers regarding decision patterns and longer-term feedback regarding trends and budget-relevant information. He found that the use of control charts has eliminated the need for auditing acuity-based staffing and has maintained the reliability of classifications at levels above 95 percent. Implications for other novel applications are also discussed by him. Thomas *et al* (1995) proposed using $X-$bar, $S-$chart & $p-$chart for laboratory blood glucose measurements of patients receiving enteral or parenteral nutrition. They used the charts to monitor glucose levels, reveal variations and illustrated the effects of new protocols designed to manage glucose levels. David *et al.* (1996) employed variable & attribute control charts to analyse perioperative morbidity and mortality and length of stay in 1131 nonemergent, isolated, primary coronary bypass operations conducted within a $17-$quater time period. Benneyan (1998a, 1998b, 1998c) dealt at length regarding the utility of variable and attribute control charts in improving health care. He also highlighted some common pitfalls to avoid and misunderstandings in using control charts tools in health care section. Latzko (2001) discussed the use of $X-$bar, R & u control chart in some health care data as a test instrument. He also presented some examples and background from the theory of control charts. Benneyan (2001a) and Benneyan *et al.* (2003) describe the problem that variation poses in analysis, provide an overview of statistical process control theory, explain control charts ($X-$bar, s, g), and provides examples of their application to common issues in health care improvement. Arantes *et al.* (2003) emphasized on the construction and use of $X-$bar control chart with warning limits for the endemic level of nosocomial infections per patient day rate. Callahan *et al.* (2003) observed that due to the increase of patient, the Emergency Departments is unable to serve the patient up to their satisfaction. He has cited various tools like *TQM* , bench marking and gave more emphasis on voice of the process (*VOC*) . By voice of the process we meant the ability to manage and control the process. Some case examples were given using variable control chart. Carey (2003) presented the informative study of how *SPC* methodology can help to improve the overall quality of health care in both short and long-term projections. He also gave emphasis on practical and real-life situation for improving health care with variable control charts. Fasting and Gisvold S.E. (2003) illustrated how the quality of the anesthesia process can be analysed using *SPC* methods basically using p-chart and also exemplified how this analysis can be used for quality improvement. Sonesson *et al.* (2003) reviewed the methods suggested in the literature for sequential detection of changes in public health surveillance data. They described the special aspects of prospective statistical surveillance and different ways of evaluating such methods. Attention is given to methods that include only the time domain as well as methods for detection where observations have a spatial structure. In the case of surveillance of a change in a Poisson process the likelihood ratio method and the Shiryaev-Roberts method are derived. Mohammed (2004) studied the adjusted hazard ratio and uses of *SPC* tools for continuous improvement of quality in health care. Yeung & MacLeod (2004) provide an introduction to the application of run charts and Shewhart control charts for identifying abnormal behaviour in healthcare processes. Anuradha and Waboso (2006) used quality control chart to plot the variability in the rate of endophthalmitis and they also said that their study is first one for demonstrating the use of control charts in ophthalmology. Woodall (2006) introduced many application of control chart in health care monitoring and in public health surveillance and he also considered the advantages and disadvantages of the charting methods proposed in the health care and public-health area. He suggested that Quality Scientists and researchers in industrial statistics have ample of opportunities to make further contributions to the theory and application of health related quality improvement activities. Coory *et al.* (2007) presented all hospital-specific comparative analyses, based on administrative data, using cross-sectional displays. They also compared cross-sectional analyses with sequential monitoring using control charts. Flowers (2007) looked at the uses of statistical process control (*SPC*) methods and associated visual display tools (control charts and funnel plots) in public health intelligence. Thor *et al.* (2007) reviewed the literature regarding how statistical process control with control charts as a core tool-has been applied to healthcare quality improvement and to examine the benefits, limitations, barriers and facilitating factors related to such application. Tennant *et al.* (2007) carried out a systematic review of uses of control charts to monitor clinical variables in individual patient. They also found that control chart appear to have a promising but largely under researched role in monitoring clinical variables in individual patients. Benneyan (2008) provided an overview of the use of *SPC* in healthcare process improvement and Six Sigma activities, including the process of selecting and using the appropriate type of control chart, their statistical performance and the guidelines for determining the appropriate sample sizes. In another paper, Mohammed *et al.* (2008) discussed control charts like $xmr-$chart, $p-$chart, $u-$chart, & $c-$chart using examples from healthcare. He has also discussed the various reasons for not transferring the SPC to health care section for a long time. One reason, he has point out that though Industrial companies used the SPC tools from 1920s, yet in Health Care section there is dearth of literature. More clearly in most of the medical books, SPC does not feature. Albers (2009) introduced Negative binomial chart in health care problems and described its behaviour in the homogeneous situation. He also derived the estimated version of the new chart. Chaim & Waboso (2009) applied control chart methodology to retrospectively analyse the variation in postcataract surgery for endophthalmitis data. He collected 10 years data and by using control chart he recommended that control chart can detect anomaly in the cases of postcataract surgery endophthalmitis. Olatunde (2009) provided 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. He observed that 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. Duclos & Voirin (2010) emphasised on the study of key elements to physicians, nurses, managers, students or researchers regarding the development and interpretation of control chart in clinical practices. Farahbakhsh (2010) conducted to design and utilize control charts in the primary health care (PHC) system. He also suggested that the Shewhart control chart for Attribute and Variable can be used in monitoring the public health care system.

2.2. Studies of health care data using Advanced Control Charts

Benneyan (2001b) developed the alternate Shewhart-type statistical control charts, called “ g ” and “ h ” charts and also evaluated for monitoring the number of cases between hospital-acquired infections and other adverse events, such as heart surgery complications, catheter-related infections, surgical site infections, contaminated needle sticks, and other iatrically induced outcomes. Lim *et al.* (2002) recommended the usefulness and acceptability of $CUSUM$ charting for assessing doctors’ performance. They also concluded that the $CUSUM$ chart may also be used to show proof of technical competence for the purpose of credentialing. Quesenberry (2002) demonstrated to the reader that recent research in statistics has developed modern statistical process control methods namely Geometric $Q-$chart method that can be used effectively with or without prior data. These methods make possible much more effective nosocomial infection surveillance programs that will give timely warnings of the onset of epidemics or evidence of the effectiveness of infection control initiatives. Tekkis *et al.* (2003) designed and validated a statistical method for evaluating the performance of surgical units that adjusts for case volume and case mix. Beiles and Morton (2004) proposed the *CUSUM* chart for analysing the data that detects changes in average outcome rates. Goris & Clercq (2005) compared the Shewhart and the exponentially weighted moving average (*EWMA*) control charts with respect to the day to day monitoring of internal quality control samples for the foot and mouth disease solid phase competition enzyme-linked immunosorbent assay. Jarrett and Pan (2007) suggested modern and multivariate applications of quality control techniques common in industrial applications to be utilized in the health care sector to both control and improve quality of these services. Biau *et al.* (2007) reviewed the use of the *CUSUM* across different interventional and surgical specialities and also clarified its use in the perspective of future studies. Yap *et al.* (2007) reviewed the history, statistical methods and potential applications for the *CUSUM* techniques in the field of surgery and they also illustrated the two common forms of charting (Cumulative failure and *CUSUM* charting) by using unadjusted outcome data from the cardiac surgery databases. Adeyemi (2008) carried out a retrospective analysis to provide diagnostic information about the process to be monitored. He also designed and implemented *CUSUM* scheme on hospital data. Madan *et al.* (2008) reported the empirical false-positive rates and power performance of the mean-σ $(X - S)$ control chart technique under various levels of autocorrelation. They also described a method for autocorrelation correction and finally compare the auto-correlation-corrected $X - S$ chart with the original $X - S$ technique. Salowi *et al.* (2009) gave emphasis on the application of *CUSUM* chart in monitoring performance of surgeons in cataract surgery and evaluates the response of performance to intervention. Chang *et al.* (2009) used the Cumulative Sum (*CUSUM*) method for monitoring of doctors' performance in skin biopsy. Fatahi *et al.* (2010) developed a new type of health-related attribute characteristic, named Zero inflation in binomial (*ZIB*) and also developed a proper control chart for monitoring such distributed observations values. Performance evaluation of the proposed control chart, based on average run length (*ARL*) was computed and illustrated. He also presented a motivating real health engineering case study, related to a hospital infection counts to show the applicability of the new method. Waterhouse *et al.* (2010) considered the implementation and performance of the T^2, multivariate exponentially weighted moving average (*MEWMA*) and multivariate cumulative sum (*MCUSUM*) charts in light of the challenges faced in clinical settings. They also discussed how to handle incomplete records and non-normality of data, and provided some recommendation on chart selection.

2.3. Studies of health care data using Risk Adjustment Control Charts

Poloniecki *et al.* (1998) used cumulative risk adjusted mortality chart to detect changes in mortality after surgery, with allowance being made for variations in case mix. They observed that Statistical quality control of a single series with adjustment for case mix is the only way to take into account recent performance when informing a patient of the risk of surgery at a particular hospital. Gustafson (2000) attempted to break the impasse by providing an empirical foundation and some preliminary guidelines for the use of control charts in infection control. Steiner *et al.* (2000), due to the limitation of standard (unadjusted) $CUSUM$ procedure, described a new risk-adjusted $CUSUM$ procedure that adjusts for each patient's pre-operative risk of surgical failure through the use of a likelihood-based scoring method. Grigg *et al.* (2003) discussed the use of charts derived from the sequential probability ratio test $(SPRT)$: the cumulative sum $(CUSUM)$ chart, $RSPRT$ (resetting $SPRT$), and FIR (fast initial response) $CUSUM$ The theoretical development of the methods is described and some considerations one might address when designing a chart, explored, including the approximation of average run lengths $(ARLs)$, the importance of detecting improvements in a process as well as detecting deterioration and estimation of the process parameter following a signal. They also used two examples to demonstrate the practical issues of quality control in the medical setting. Grigg and Farewell (2004a) presented a risk adjusted version of the refined Sets method and also gave an example to demonstrate its advantage over the unadjusted method. He also considered that the method was suitable for any risk distribution did not assume that changes in risk will be small. A graphical representation, referred to as the Grass plot, of the original and risk-adjusted methods was also given. Hart *et al.* (2004) discussed a risk adjusted control chart applicable for variables data that often skewed. The key features of these charts were their application of risk-adjusted data in addition to actual performance data. They also presented several control charts that vary in the data transformation and combination approaches. Data depicting hospital length of stay following coronary artery bypass graft procedures were used to illustrate the use of transformed and risk-adjusted control charts. Grigg and Farewell (2004b) provided an overview of risk-adjusted charts, with examples based on two data sets: the first consisting of outcomes following cardiac surgery and patient factors contributing to the Parsonnet score; the second being age-sex-adjusted death-rates per year under a single general practitioner. They also presented some charts including the cumulative sum $(CUSUM)$, resetting sequential probability ratio test, the set method and Shewhart chart and made comparisons between the charts. Estimation of the process parameter and two- sided charts were also discussed. Cockings *et al.* (2006) presented a cumulative expected minus observed $(E-O)$ plot and the risk-adjusted $p-$chart as methods of continuous process monitoring. They also described the construction and interpretation of these charts and showed how they can be used to detect planned or unplanned organizational process changes affecting mortality outcomes. Cook *et al.* (2008) described the methods for displaying risk adjusted mortality data for critical care units. Monitoring of risk adjusted performance over time was considered using $SMRs$, risk-adjusted p (RAP), observed minus expected outcome $(VLAD)$, risk-adjusted cumulative sum (*RACUSUM*), risk adjusted sequential probability ratio test (*RASPRT*), and risk adjusted exponentially weighted moving average (*RAEWMA*) charts. Baghurst *et al.* (2008) considered the applicability of risk-adjusted sequential control charts using the Paediatric Index of Mortality version 2 for monitoring of the quality of paediatric intensive care. They also conclude that the control chart technique is suitable for continuously screening for a change in outcome within a Paediatric Intensive Care Units (*PICU*) over time and complements other methods of monitoring the quality of pediatric intensive care. Trucco *et al.* (2009) described Error and Risk Antecedent Statistical Monitoring (*ERASMO*), a statistical process control method intended to monitor the antecedents of errors and to foster patient safety and quality improvement in healthcare.

2.4. Application of Six Sigma Methods in Healthcare Monitoring

Shaw (1999) highlighted some examples of lost due to medical errors along with the suggestion to use Six Sigma. Shah (2005) gave emphasis on the defects or errors in health care section and also highlighted the use of Six Sigma in health care. To minimize the delays, measurement and medical errors and variability in health care industry Taner *et al.* (2007) gave importance in applying Six Sigma methodology. They also discussed the root causes of healthcare problems and analysed them by flowcharts and fishbone diagrams and produced near-perfect healthcare services. Schweikhart and Dembe (2009) discussed the potential use of Lean and Six Sigma to improve the processes involved in clinical and translational research. Available literature involving applications of Lean and Six Sigma to health care, laboratory science, and clinical and translational research was also reviewed by them. Specific issues concerning the use of these techniques in different phases of translational research were identified. Chabukswar *et al.* (2011) gave accent on six sigma study of Ranitidine hydrochloride tablets to achieve perfection in tablet manufacturing by reviewing the present robust manufacturing process and to find out the ways to improve and modify the process which will yield tablets that are defect free and will give more customer satisfaction.

2.5. Process Capability Analysis use in Clinical Laboratory

Bais (2008) considered the use of the Capability Index (*Cps*) for detection of errors where the standard deviation is wide compared to clinical requirements. Capability of an analyte can be used to optimize the amount of quality control (*QC*) required and still maintain appropriate error detection. Lewis *et al.* (2009) discussed on how hospitals can apply Radio Frequency Identification (*RFID*) to transform work practices and address cost, safety and quality of care issues, most notably in inventory management. They also leveraged an interdisciplinary framework to explore adoption and use of *RFID* at multiple levels of analysis and adopt a multi-method approach to explore the research question guiding the study. Zhi-zhong *et al.* (2009) used the industrial process capability indices on medical quality and medical safety management to analyze and illustrate the quantitative significance of various data. They also proposed the protocol of improvement according to the data.

3. ANALYSIS OF HEALTH RELATED DATA USING SPC TOOLS

3.1. Normal Probability Plot

Many quality control experts argued that to use control chart the process data should be normally distributed. Montgomery opined that it is very important to check the normality assumption when using the control chart for individuals. A simple way to do this is with the normal probability plot. However, the caution that the normal probability plot is but a crude check of the normality assumption and the individual control chart is very sensitive to non-normality. Further, Montgomery and Runger (1999) also pointed out that a properly designed *EWMA* chart is very insensitive to the normality assumption.

We, however, wish to test the BP data (Source: T.T. Allen (2006) book, pp. 167) for normality by using Anderson-Darling method with the help of Minitab-14 version software. From the normal probability plot graph in fig.1 (a) & 1(b), the A-D normality test shows that both the BP data (Systolic & Diastolic) does not follow normal distribution.

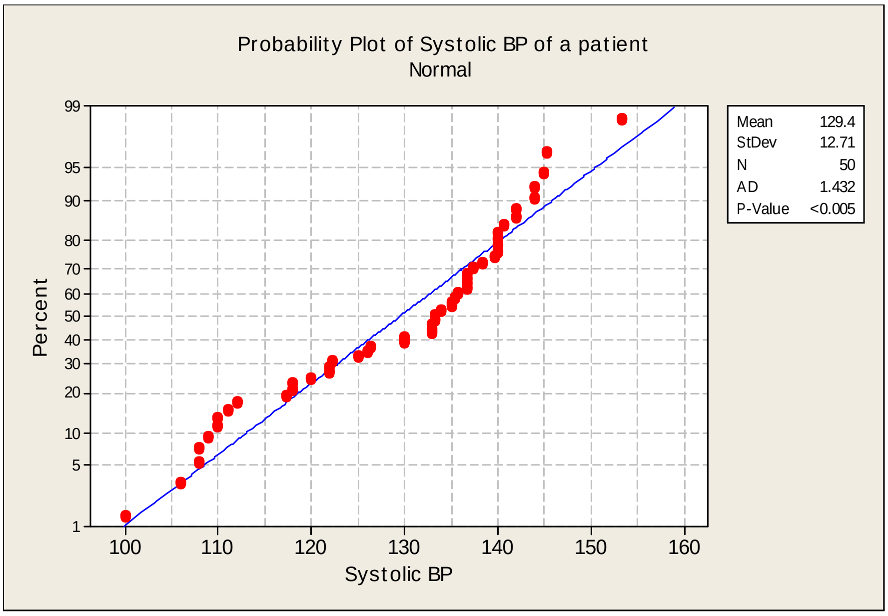

Figure1 (a). Normal probability plots for systolic blood pressure of a patient

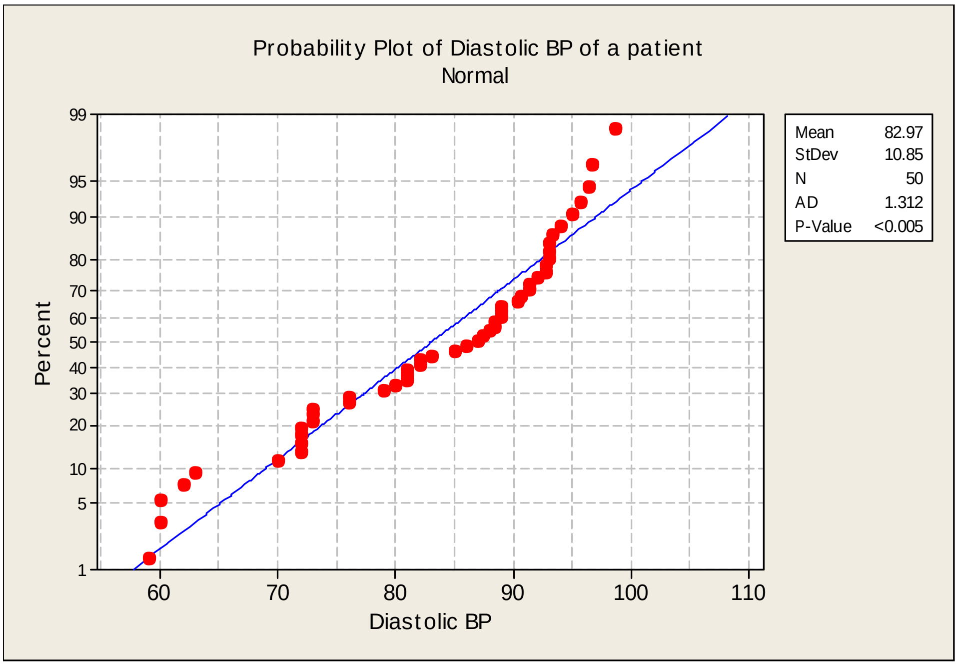

Figure1 (b). Normal probability plots for diastolic blood pressure of a patient

3.2. The *xmr* – chart (individuals chart)

In many applications of the individual control charts, one may used the moving range of two successive observations as the basis of estimating the process variability. The moving range is defined as

$$MR_i = |(X_i - X_{i-1}| \tag{3.2.1}$$

The control limits for individual measurements are given as,

$$\left.\begin{aligned} UCL &= \overline{X} + 3\frac{\overline{mr}}{d_2} \\ CL &= \overline{X} \\ LCL &= \overline{X} - 3\frac{\overline{mr}}{d_2} \end{aligned}\right\} \tag{3.2.2}$$

Where $\overline{mr}$ is the mean of the moving range.

The UCL and LCL for moving range chart is given by

$$\left.\begin{aligned} UCL &= D_4\overline{mr} \\ CL &= \overline{mr} \\ LCL &= D_3\overline{mr} \end{aligned}\right\} \qquad (3.2.3)$$

Where $D_3 = 0$ for $n = 2$ and $D_4 = 3.26$ for $n = 2$

[Table VI, Montgomery, 2004]

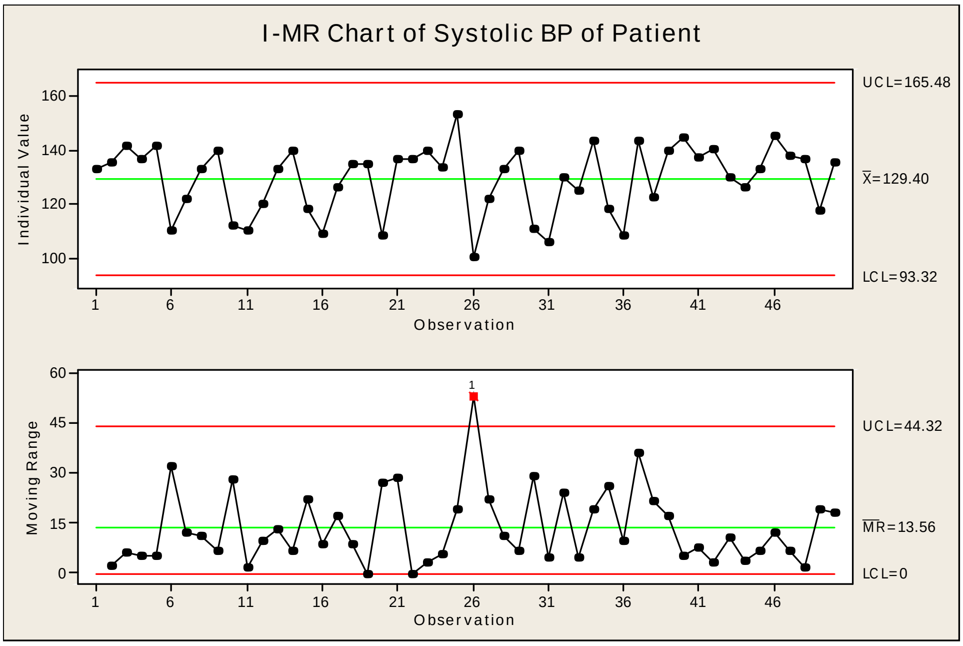

Figure 2: xmr – chart constructed by using systolic blood pressure readings of a patient. The top panel is the $\overline{x}$ – -chart (2(a)) & the lower panel is the mr – chart (2(b)).

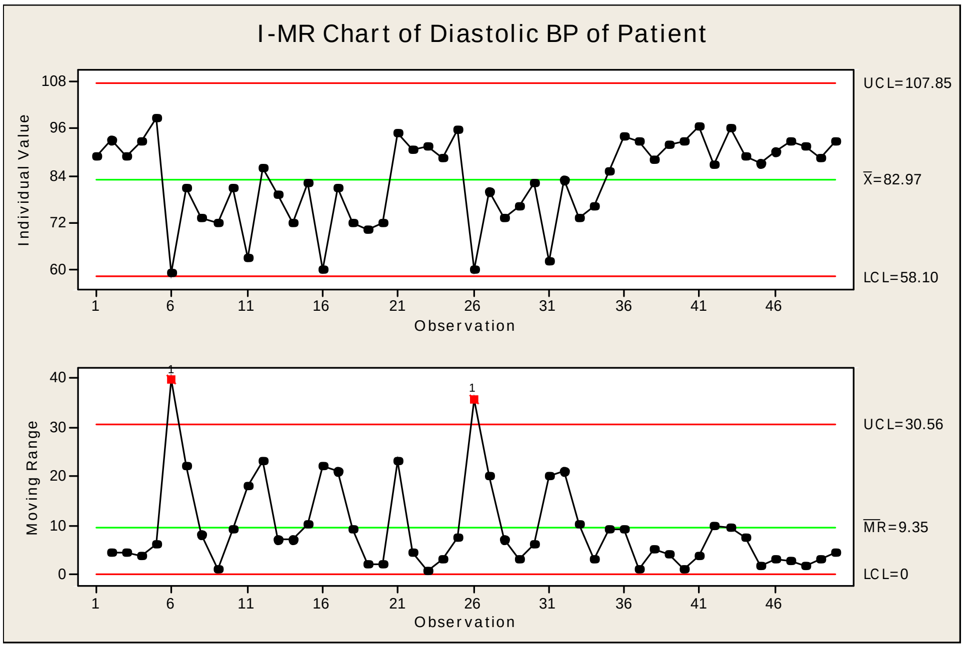

Figure 2: *xmr* – chart constructed by using diastolic blood pressure readings of a patient.

The top panel is the $\bar{x}$ – chart (2(c)) and the lower panel is the mr – chart (2(d)). Figure 2(a) shows that the patient's systolic blood pressure level is much higher than the normal range (120 – 140 mm Hg) for 37 days and it is less than 120 mm Hg for 13 days. Similarly from figure 2(c), we have seen that the diastolic blood pressure is higher than normal range (80 – 90 mmHg) for 34 days {Joint National Committee, Guideline VII (2003)) and it is less than 80 mmHg for 16 days. By using a control chart we found that the patient's blood pressure is almost abnormal in nature and one may conclude that the patient suffers from hypertension in majority of the days. Figure 2(b) shows that the 25 – th observation for systolic blood pressure is unusually high as compared to 26 – th observation. Similarly, figure 2(d) shows that the 6 – th and 25 – th observations for diastolic blood pressure is unusually low as compared to 5 – th and 26 – th observations respectively.

4. USE OF MULTIVARIATE QUALITY CONTROL CHART IN HEALTH CARE MONITORING

There are many manufacturing processes in which several quality characteristics have to be monitored at a time. Process Control problems involving several variables are known as Multivariate quality control. Hotelling (1947), first introduced multivariate quality control chart which is known as Hotelling T^2 control chart. New practical approaches for interpreting multivariate T^2 control chart signals were developed by Mason *et al.* (1997), Mason and Young (1999).

Other important developments of multivariate quality control statistics are Multivariate Cumulative Sum ($MCUSUM$), Multivariate Exponentially Weighted Moving Average ($MEWMA$) and Sample Generalised Variance Chart. Like manufacturing processes, there are also numerous problems in health care section, in which two or more quality characteristics have to be monitored simultaneously. In this section, we shall however confine ourselves to implement only the sample *generalized* variance $|S|$ chart in which we wish to see the joint variability of effects of a new heart drug on the heart rate, blood pressure, and weight of a patients for 10 10 weeks (Source: Minitab-14 worksheet of Heart.Drug. MTW). For Food and Drug Administration (FDA) approval of the drug, the variables must remain in control. Therefore, we want to create a generalized variance chart to see if the joint variability is constant.

4.1. Multivariate Control Chart Model

Alt (1985) presents a useful procedure for monitoring variability which is based on sample *generalized* variance, $|S|$. This statistics, which is the determinant of the sample covariance matrix, a widely used measure of multivariate dispersion. Montgomery and Wadsworth (1972) used the mean and variance of $|S|$ that is, $E(|S|)$ and $V(|S|)$ and the property that most of the probability distribution of |S| is contained in the interval

$$E(|S|) = \pm 3\sqrt{V(|S|)} \text{ .}$$

It can be shown that,

$$E(|S|) = b_1 |\Sigma| \text{ and } V(|S|) = b_2 |\Sigma|^2 \tag{4.1.1}$$

where

$$b_1 = \frac{1}{(n-1)^p} \prod_{i=1}^{p} (n-i)$$

and

$$b_2 = \frac{1}{(n-1)^p} \prod_{i=1}^{p} (n-i) \left[\prod_{i=1}^{p} (n-j+2) - \prod_{j=1}^{p} (n-j) \right]$$

Here, Σ is $p \times p$ covariance matrix,

b_1 and b_2 are constants, S is sample covariance matrix and n is the sample size

Therefore, the parameters of the control chart for $|S|$ would be

$$\left.\begin{aligned} UCL &= |\Sigma|(b_1 + 3b_2^{1/2} \\ CL &= b_1|\Sigma| \\ LCL &= |\Sigma|(b_1 - 3b_2^{1/2} \end{aligned}\right\} \qquad (4.12)$$

The lower control limits in equation (4.1.2) is replaced with zero if the calculated value is less than zero.

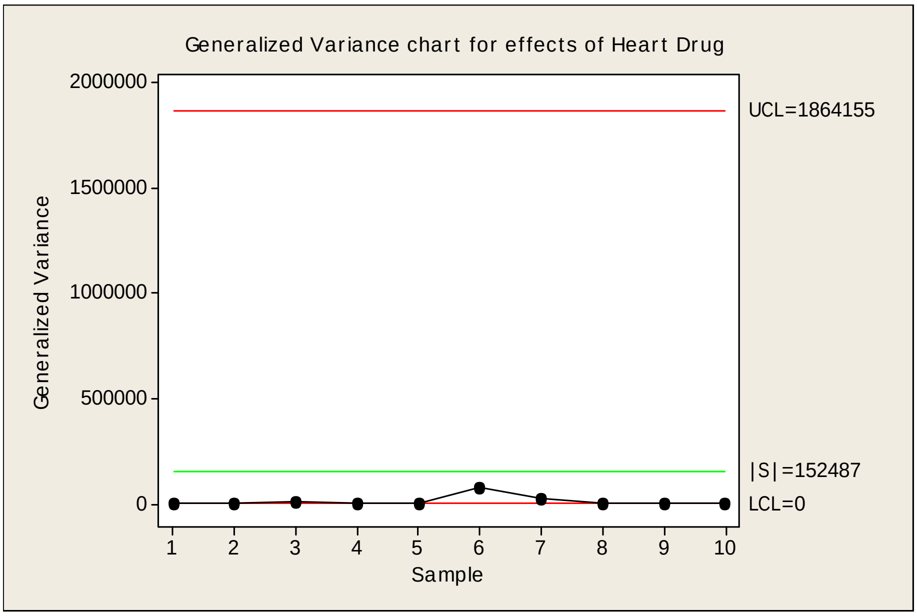

Figure 3. Generalized variance chart for effect of heart drug (Minitab-14)

From figure 3, it is evident that no out-of-control points appear, indicating that the joint variability of the patients' heart rates, blood pressure, and weight is constant.

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Received: 08.07.2011

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