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USES OF CONTROL CHARTS FOR HEALTHCARE PRACTITIONERS USING COUNT DATA

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Abstract

Statistical process control (SPC) tools such as control charts have been widely used in the manufacturing industry for a long time. Though SPC is relatively new to the healthcare practitioners, yet in recent times, it is increasingly being used in healthcare to aid in process understanding, assess process stability and identify changes that indicate either improvement or deterioration in quality. Those working in healthcare today are challenged more than ever before to quickly and efficiently learn from data to improve their services and delivery of care. In this paper, an attempt has been made to provide an overview of control charts applications for common healthcare data and also to illustrate a new type of statistical process control charts called '*g*' type and '*h*' type charts for monitoring the number of cases between hospital acquired infections or other healthcare adverse events such as heart surgery complications, catheter-related infection,

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contaminated needle sticks, medication errors, surgical site infections, etc. These types of charts are simple to use and exhibit significantly greater detection power over conventional Binomial or Poisson approaches specifically for infrequent events and very low defect rates.

Introduction

Statistical process control (SPC) tools are widely used in manufacturing industries to understand process performance, set up standard for operational parameters, maintaining the standard and continual monitoring for improvement. However, the application of SPC tools in healthcare section is relatively new and has not been featured earlier even in most popular text books of medical statistics or no such course has been taught in medical institutes. However, from 1990s, the application of SPC tools in healthcare sector is increasing and there is now a growing demand to apply the concept of quality measurement and management that has been successfully used in industrial process for last nine decades. Though the traditional SPC tools are excellent for using in manufacturing sectors, yet it has some limitations to use in non-manufacturing sectors like healthcare control. Therefore, SPC tools have to be understood properly by the management involved in healthcare sectors and some modification of Shewhart Control chart may be necessary to apply properly in healthcare data. Within healthcare field, experts from quality scientist and medical professional have to develop methodology to deal with realistic case studies in healthcare section. Different types of data may be useful for application of SPC tools which included-reduction rate of adverse drug events, surgical site infections, patients' falls, central line infections, surgical complications, skin biopsy, cataract surgery, etc.

Following a brief overview of SPC in healthcare, in this paper, an attempt has been made to focus on approaches to apply SPC tools to common healthcare data with particular emphasis on the design and use of *g*-type and *h*-type control chart for infrequent events and very low defect rates.

Control Chart Viewpoint

The main principles of statistical process control are:

1. Measured quality of manufactured product is always subject to a certain amount of variation as the result of chance.

2. Some "constant system of chance causes" is inherent in any particular scheme of production and inspection.

3. Variation within this stable pattern is inevitable.

4. The reasons for variation outside this stable pattern may be discovered and corrected.

These simple principles provide the foundation of statistical process control.

The constant system of chance causes referred to by Shewhart also has been called a *stable system* or defined as *statistical stability*. Deming [4] referred to these constant or stable systems as *common causes* of variation, constantly operating within a system. Variation outside this stable system, called *assignable* cause variation by Shewhart and *special cause* variation by Deming, may be detected using control charts and its cause or causes eliminated through analysis and corrective action. Often these actions result in substantial improvement in the quality of products and services and reductions in spoilage, rework, and error rates. Moreover, by identifying certain quality variations as inevitable chance variation, the control chart tells when to leave a process alone and thus prevents unnecessarily frequent adjustments that tend to increase variability rather than decrease it.

General Model of Control Chart

The general model for a Shewhart control chart could be designed as follows:

Let ω be a sample statistic that measures some quality characteristic of interest and suppose that the mean of ω is μ_ω and the standard deviation of ω is σ_ω. Then the center line, the upper control limit, and the lower control

limit become

$$UCL = \mu_\omega + L\sigma_\omega,$$

$$CL = \mu_\omega,$$

$$LCL = \mu_\omega - L\sigma_\omega, \quad (1)$$

where L is the "distance" of the control limits from the center line, expressed in standard deviation units. This general theory of control charts was first proposed by Shewhart [14] and control charts developed according to these principles are often called Shewhart control charts.

The most important use of a control chart is to improve the process. We have found that, generally,

1. Most processes do not operate in a state of statistical control.

2. Consequently, the routine and alternative use of control chart will identify assignable causes. If these causes can be eliminated from the process, then variability will reduce and the process will be improved.

3. The control chart will only detect assignable causes. Management, operator, and engineering action will usually be necessary to eliminate the assignable causes.

Uses of Control Charts in Healthcare

Control charts have been used in industrial production process for a long time. However, in recent times, it is increasingly being used in healthcare to aid in process understanding, assess process stability and identify changes that indicate either improvement or deterioration in quality. There are different types of control chart, e.g., Mean and Range Chart (X-bar and R), Mean and Standard Deviation Chart (X-bar and S), *p*, *u* and *c* charts. Their use is mostly determined by the types of data to be plotted on the chart. Two important types of data are continuous (measurement) data and discrete (attribute or count) data.

Continuous data involved measurement, e.g., weight, height, blood pressure, length of stay and time from referral to surgery. Discrete data involved counts, e.g., number of errors, number of prescription, etc.

In analyzing continuous data, a sizeable research worker has published papers dealing with problems of healthcare in recent times. Similarly, by using *p*-chart or *u*-chart in healthcare count data, several works have also been published. In our next section, we will, however, confine our study in reviewing some past works in healthcare with discrete data only. The consideration of continuous data in healthcare will be reported in our future study on the subject.

Review of past works on control chart in healthcare with count data

It is interesting to note that, though the use of SPC tools in healthcare sector gains momentum from 1990's yet, Deming advocated its application in disease surveillance and adverse healthcare events as early as in 1942. On observing the importance of SPC application, the present authors studied some past works in this area with special reference to attribute (count) data.

Oniki et al. [12] focused the application of Statistical Quality Control (SQC) chart to monitor the management of patients' glucoses. Shahian et al. [15] employed SQC chart, basically attribute charts like *p* and *u* charts to analyze perioperative morbidity and mortality and length of stay in 1131 nonemergent, isolated, primary coronary bypass operations conducted within a 17-quarter time period. Benneyan [2] provided an overview of quality engineering and SPC, illustrates common types of control charts both variable and attribute and provides references for further informations or statistical formulae. He (Benneyan [3]), provided a brief introduction to the use of SQC charts for analyzing, monitoring, and improving healthcare processes. He also gave some examples of uses of control charts use, its interpretation and highlighted some common pitfalls to avoid further exploration. Amin [1] gave an overview of control chart applications for common healthcare data and also developed the appropriate type of charts (both variable as well as attribute) for the healthcare users. Fasting and Gisvold [6] applied statistical process control methods specifically for '*p*'

chart to analyze the adverse events. Limaye et al. [9] demonstrated the count control chart, basically '*u*' chart which can be applied to infection control surveillance data from children's hospital and makes recommendations for a control chart which is most suitable for monitoring hospital-associated infections. Mohammed et al. [11] illustrated the selection and construction of four commonly used control charts (*xmr*-chart, *p*-chart, *u*-chart and *c*-chart) using examples from healthcare. Duclos and Voirin [5] provided key elements to physicians, nurses, managers, students or researchers regarding the interpretation of attribute chart like *p*-chart dealing with count data. There may be more works in this area, which the authors might have been not aware till date. However, the works are going on and in future more research works in this area are offing.

Development of control chart for monitoring rare events

The earlier authors of healthcare quality control uses the attribute chart specially *p*, *c* and *u* charts for monitoring the discrete data in production process or in administrative processes. These charts are based upon the assumption that either Binomial or Poisson distribution is an appropriate model for the outcome data but in practice these models are often constructed without examining the underlying distribution. It is also revealed that in many occasions, assumption of Poisson or Binomial is not valid and the practitioner should seek some alternative control chart for monitoring the random process, especially for data dealing with adverse events, such as heart surgery complication, surgical site infection, and contaminated needle sticks, etc. In this section, we shall discuss the theory of *g*-type control chart and *h*-type (companion) control chart for data dealing with infrequent adverse events, as these charts are appropriate to deal with adverse events in lieu of traditional *p*, *c* or *u*-chart.

The theory of *g*-type and *h*-type control charts

Kaminsky et al. [8] developed *g*-type and *h*-type control chart which is given as follows:

Here, we consider the *g*-control charts for "Standard given" case first.

Let us assume that a process is generating events according to a geometric distribution. If X is the number of events per process unit, then its probability function is

$$\Pr[X = x] = p(1-p)^{x-a} \text{ for } x = a, a+1, a+2, ..., \quad (2)$$

where the parameter a is the known minimum possible number of events. Let the subgroup $X_1, X_2, ..., X_n$ be a random sample of size n from the process. The X_i for $i = 1, 2, ..., n$ are, therefore, independent and identically distributed random variables from a geometric distribution. The two statistics of interest are the total number of events $T = X_1 + X_2 + \cdots + X_n$ and the average number of events $\overline{X} = T/n$ in the subgroup. The sum of independent and identically distributed geometric random variable is a negative binomial random variable which can be expressed as

$$\Pr[T = na + j] = \binom{n + j - 1}{n - 1} p^n (1-p)^j \text{ for } j = 0, 1, 2, ... \quad (3)$$

Since the event $\{\overline{X} = (na + j)/n\}$ is identical to the event $\{T = na + j\}$, the distribution of $\overline{X}$ is negative binomial. This knowledge is useful in evaluating the probabilities of the Type I and Type II errors that can be ascribed to a single subgroup.

The expected values and variances of these statistics are

$$E[T] = n\left(\frac{1-p}{p} + a\right),$$

$$Var[T] = \frac{n(1-p)}{p^2},$$

$$E[\overline{X}] = \frac{1-p}{p} + a,$$

$$Var[\overline{X}] = \frac{1-p}{np^2}. \quad (4)$$

Using these expectations and variances, the centerline and $k\sigma$ control limits are computed in the usual way. For ease of identification, the *total* number of events chart is called a *g-type chart* and the *average* number of events chart is called an *h-type chart*. The centerline (CL), the upper control limit (UCL), and the lower control limit (LCL) for each chart are presented below:

For *g*-type chart,

$$UCL = n\left(\frac{1-p}{p} + a\right) + k\sqrt{\frac{n(1-p)}{p^2}},$$

$$CL = n\left(\frac{1-p}{p} + a\right),$$

$$LCL = n\left(\frac{1-p}{p} + a\right) - k\sqrt{\frac{n(1-p)}{p^2}}. \tag{5}$$

For *h*-type chart,

$$CL = \frac{1-p}{p} + a,$$

$$UCL = \frac{1-p}{p} + a + \frac{k}{\sqrt{n}}\sqrt{\frac{1-p}{p^2}},$$

$$LCL = \frac{1-p}{p} + a - \frac{k}{\sqrt{n}}\sqrt{\frac{1-p}{p^2}}. \tag{6}$$

If the assumption of subgroups of equal size is dropped, then the centerline and control limits can easily be obtained. The smallest possible value of the total number events is $T = na$, and the smallest possible value of the total number of events is $\overline{X} = a$. These minimum values are, therefore, the minimum possible values of the lower control limits of the *g*-type chart and *h*-type chart, respectively.

Now let us consider trial control charts for *g*-type chart (when standard is not given). It is seen that in most of the circumstances, the location parameter *a* is known and, therefore, not subject to estimation. Development of a trial control chart therefore depends on estimating only the parameter *p*. Both the method of moments and the method of maximum likelihood estimation yield the same estimator for *p*, namely

$$\hat{p} = \frac{1}{\bar{\bar{X}} - a + 1},$$

where $\bar{\bar{X}}$ is the average of all the count data. The trial control chart is assumed to be based on *r* subgroups, each of size *n*. The total number of events occurring in each subgroup can be represented as $t_1, t_2, ..., t_r$ and the average total number of events per subgroup is

$$\bar{t} = \frac{t_1 + t_2 + \cdots + t_r}{r}.$$

Thus,

$$\bar{\bar{X}} = \frac{\bar{t}}{n} = \frac{1 - \hat{p}}{\hat{p}} + a$$

and $\frac{1 - \hat{p}}{(\hat{p})^2} = \left(\frac{\bar{t}}{n} - a\right)\left(\frac{\bar{t}}{n} - a + 1\right).$

The estimated centerline, upper control limit and lower control limit for the *g*-type chart and the *h*-type chart are presented as follows:

For trial *g*-type chart,

$$CL = \bar{t},$$

$$UCL = \bar{t} + k\sqrt{n\left(\frac{\bar{t}}{n} - a\right)\left(\frac{\bar{t}}{n} - a + 1\right)},$$

$$LCL = \bar{t} - k\sqrt{n\left(\frac{\bar{t}}{n} - a\right)\left(\frac{\bar{t}}{n} - a + 1\right)}. \quad (7)$$

For trial *h*-type chart,

$$CL = \frac{\bar{t}}{n},$$

$$UCL = \frac{\bar{t}}{n} + \frac{k}{\sqrt{n}}\sqrt{\left(\frac{\bar{t}}{n} - a\right)\left(\frac{\bar{t}}{n} - a + 1\right)},$$

$$LCL = \frac{\bar{t}}{n} - \frac{k}{\sqrt{n}}\sqrt{\left(\frac{\bar{t}}{n} - a\right)\left(\frac{\bar{t}}{n} - a + 1\right)}. \quad (8)$$

Monitoring rare events with *g*-chart

Rare events inherently occur in all kinds of processes. In hospitals, there are medication errors, infections, patient falls, ventilator-associated pneumonias and other rare or adverse events that cause prolonged hospital stays and increase healthcare costs.

For rare and adverse events, the *g*-type chart, based on geometric distribution is a control chart, i.e., designed especially for monitoring rare events. *g*-type chart can also be used to plot the number of opportunities between rare events. For example, suppose we want to monitor heart surgery complications, then we can use a *g*-type chart to graph the number of successful surgeries that were performed in between the ones that occurred with unfortunate complications.

The *g*-type chart is simple to create and use. The only data required to produce a *g*-type chart is either the dates on which the rare events occurred or the number of opportunities between occurrence. In addition to its simplicity, this control chart also offers greater statistical sensitivity for monitoring rare events than the traditional '*c*' chart or '*u*' charts.

Numerical Example

In some circumstances, such as with low nonconforming rates, it may be desirable (e.g., more powerful) to consider Bernoulli processes with respect

to geometric rather than traditional binomial probability distributions. For example, a very costly healthcare process defect is called *nosocomial infections*, which are any infections that are acquired or spread as a result of hospitalization. Due to low rates of infection and immediate availability of each observation, the *number of days between occurrences of nosocomial infection* were proposed (Spencer et al. [13]) as a good measure for monitoring and studying infections. By description, this random variable satisfies the classic geometric distribution. The *g*-type chart plots count between events and it is appropriate to use when number of cases or amount of time between occurrences are considered. It is to be noted that *g*-type chart is particularly useful for rare events or when rate is low, e.g., rate < 0.1. Thus, some other examples of empirical geometric random variables in healthcare sector are such as the number of surgeries between infections, number of patients between complications, number of days between adverse drugs events, etc.

Following Montgomery [10, p. 212]/Grant and Leavenworth [7, p. 44], we first generate 30 subgroups of data by computer programming. Now we illustrate the use of *g*-type and *h*-type charts with this set of geometric data. Each subgroup consists of five observations, where the number of events for each observation was generated from a geometric distribution with $a = 1$ and $q = 0.80$ with the probability function

$$\Pr[X = x] = p(1 - p)^{x-a} \quad \text{for } x = a, a + 1, a + 2, \ldots.$$

These data are shown in Table 1 as follows.

Now, let us compute the control limits of the trial *g*-type chart and trial *h*-type chart for the dataset given in Table 1. Using the formulas as mentioned above, the control limits for both the trial *g*-type chart and trial *h*-type chart are computed and accordingly presented in Tables 2 and 3.

The lower control limit for the *g*-type chart is set at 5 because the location constant $a = 1$ and the subgroup size $n = 5$.

Table 1. Simulated geometric data

Sl. no.	X_1	X_2	X_3	X_4	X_5	Total	Mean
1	6	4	5	3	3	21	4.2
2	8	1	7	9	7	32	6.4
3	1	3	10	8	3	25	5.0
4	16	10	1	14	3	44	8.8
5	4	8	1	5	4	22	4.4
6	3	5	6	2	2	18	3.6
7	9	9	5	20	12	55	11.0
8	2	6	19	2	4	33	6.6
9	2	34	6	1	5	48	9.6
10	1	1	8	3	1	14	2.8
11	3	3	3	14	18	41	8.2
12	3	2	2	2	6	15	3.0
13	3	3	7	3	5	21	4.2
14	2	2	5	1	4	14	2.8
15	12	2	8	3	3	28	5.6
16	12	5	5	4	1	27	5.4
17	5	6	12	9	1	33	6.6
18	5	12	4	6	4	31	6.2
19	4	4	3	3	2	16	3.2
20	1	2	18	1	3	25	5.0
21	3	4	2	4	2	15	3.0
22	5	5	2	14	6	32	6.4
23	4	3	2	8	4	21	4.2
24	7	5	9	1	2	24	4.8
25	1	1	3	2	1	8	1.6
26	4	6	5	9	1	25	5.0
27	2	6	4	3	2	17	3.4
28	6	13	4	1	7	31	6.2
29	3	4	4	2	3	16	3.2
30	1	5	2	13	1	22	4.4

Table 2. Control limits for trial *g*-charts and *h*-charts with "standards not given" case for the data set given in Table 1

	Total number of events chart average (*g*-chart)	Average number of events chart (*h*-chart)
Centerline	25.80	5.16
Upper control limit	56.94	11.38
Lower control limit	5.00	0

Now let us plot both the *g*-type and *h*-type charts for the simulated geometric data which is depicted in Figures 1 and 2:

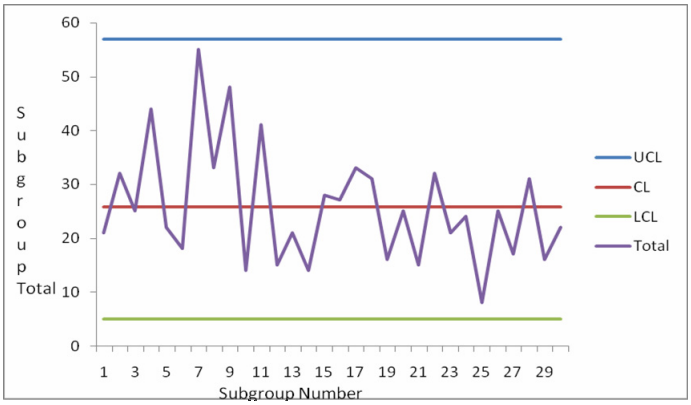

Figure 1. Trial *g*-type chart for simulated geometric data.

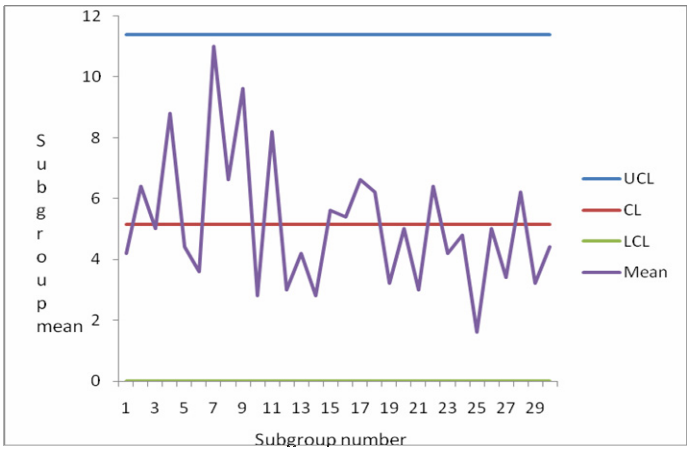

Figure 2. Trial *h*-type chart for simulated geometric data.

Similarly, one can generate separate sets of data [atleast 20-25 samples of size n (typically n is between 3 and 5, Montgomery [10])] and evaluate the trial control limits of g-type and h-type charts by fixing the parameters as discussed in our example.

Conclusion

From the above two charts, we have seen that the data are under control. It is obvious because the data which we have generated from same geometric distribution with same location parameter, i.e., no any observation differs from the other observations too much, which means observations are identical.

It is hoped that industrial practitioners and SPC researchers will be encouraged to investigate further healthcare and public health applications of SPC. These would be an opportunity to make some additional important contributions to the theory and applications of SPC tools in service industry like healthcare and its improvement.

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