International Journal for Quality research
UDK- 614.253
Short Scientific Paper (1.03)

MONITORING TIME BETWEEN MEDICAL ERRORS TO IMPROVE HEALTH-CARE QUALITY

Eralp Doğu[1)]

[1)] *Muğla University*
Turkey,Email:
eralp.dogu@mu.edu.tr

Abstract: *Monitoring medical errors has a proven positive impact on improving health-care quality. This study is designed to discuss the statistical surveillance methods and propose useful procedures to medical practitioners for monitoring time between medical errors. Variable time between events (TBE) control charts are constructed in order to monitor time between dosing errors. Results indicate that the variable TBE control charts can easily be integrated to the medical error monitoring processes. Several methods are considered to analyze the dozing error data and discussion is provided for medical decision makers to apply a better medical error monitoring program.*
Keywords: *Health-care quality, time between events (TBE), control charts, statistical monitoring, medical errors*

1. INTRODUCTION

A medical error is defined as a preventable adverse medical effect of care whether or not it is obvious or give harm to the patient. This may include misdiagnosing a disease, giving the wrong drug or dose, wrong-site surgery or incorrect keeping of the records. The possible and current impact of medical errors may lead to serious problems such as preventable drug related injuries and preventable death. In fact, medical errors have been widely considered to be rare. However, the cost of a simple medical error such as a medication error may be too high to cope with. They may cause extra medical cost, severe injury or even loss of a patient. Recently, diligent attention has been given for preventing medical errors and adverse drug events by many organizations, medical authorities and practitioners. Several guidelines have been published to help medical professionals prevent and analyze medical errors. Root cause analysis and adverse medical event surveillance methods are proposed to reduce error rates and monitor the long time performance of the medical processes. The sensitive nature of medical processes requires sensitive surveillance methods to timely detect changes in order to prevent medical errors successfully. The medical practitioners should be aware of the medical error reporting regulations and requirements. They also need to apply statistical monitoring methods in order to decrease the occurrence rate of the medical errors.

Traditional statistical monitoring techniques have been widely applied in industry and successfully implemented for many industrial processes. Recently, medical practitioners have been attracted by these tools to monitor health related processes. Examples vary in a range from chronic and infectious disease monitoring to financial monitoring of health care processes and health care adverse event monitoring (for details see Thor et al. 2007; Tenant et al. 2007 and Xie et al. 2010).

Health care adverse event monitoring which is also used for medical error monitoring has been a major branch of statistical process control (SPC) applications. The adverse event monitoring efforts mostly focuses on the control of occurrence number between events. Benneyan (2001) g and h type control charts are proposed to monitor the number of cases between hospital acquired infections and other health care adverse events such as catheter related infections and contaminated needle sticks. Benneyan et al. (2003) monitored the postoperative surgical site infection rate using a control chart of the number of surgeries between occurrences of infection. Monitoring number of days between asthma attacks is proposed by Alemi and Neuhauser (2004).

The basic assumption in these studies is that the variable monitored follows a discrete probability distribution. For example, the number of days between preventable adverse drug errors follows a geometric distribution and requires a g type control chart. However, in real life some other distributional alternatives such as exponential distribution may be applicable. The monitoring tools class of variable TBE data has emerged to bridge the gap. Xie et al. (2010) noted that variable TBE charts can be applied successfully in the health care domain. The motivation behind monitoring variable TBE data is emphasized by several authors. It is noted by Radelli (1998) that the inter-arrival times between successive failures can be measured and monitored. Human congenital malformation surveillance example is also given in this study. The conditions of each newborn can be recorded and thus, the time elapsing between malformations can be monitored. Miller (2008) showed that these control charts can be used to monitor the time between omission errors occurred in a hospital. The variable TBE charts also solve some technical issues the practitioners face when using traditional SPC tools for rare event monitoring. In this paper, control charts for

monitoring variable time between medical errors are surveyed. Addition to the proposal in Miller (2008), alternative control charts are presented and discussed. In particular, powerful tools to detect small changes in time between medical errors are shown with an implementation.

The paper proceeds as follows. In section 2 the general framework for the variable TBE control charts are given. The discussion is supported by implementing the methods to a data set, which includes the time between omission errors in a U.S. hospital, obtained from Hovor and Walsh (2007). Following this application results are given in section 3 and recommendations on chart selection and implementations are provided.

2. MATERIALS AND METHODS

2.1 Description of the data

Data are obtained from a northeast acute care community hospital in the United States from Hovor and Walsh (2007). The data set consists of the dates of omission medication errors from January 1, 2005, till April 30, 2007. For the year 2005, 58 omission errors are obtained while the frequencies for 2006 and 2007 are 49 and 19, respectively. As the first 4 months of 2007 is considered, the number in 2007 is smaller than the others. The incidents for 2005 and 2006 are numbered consecutively from 1 to 108, whereas the 2007 incidents are labeled consecutively from 07-1 to 07-19 for a total of 127 incidents. The data set also includes the incident time in hours. Therefore, the time between medication errors can be considered to be a case of variable TBE. The data set include missing occurrence time values for the given set of observations: $\{3, 8, 9, 14, 20, 23, 48\}$. The observations which do not have the occurrence time are omitted. The contributing factors to the medication error are also provided by the practitioners. This information is very helpful for professionals to focus on the root causes of a potential change in the process. For each observation, time to next event is calculated and analyzed by Hovor and Walsh (2007) and Miller (2008).

The omission error data set is originally provided in Hovor and Walsh (2007). However, Miller (2008) provides a response to their applications and proposes using a *c* chart due to the fact that the number of dosing errors in a specified interval, say 10 days, follow a Poisson distribution. Another important conclusion can be made here that if the number of dosing errors follows an approximate Poisson process, the time between dosing errors will be approximately exponentially distributed. In this study, the stability of the time between dosing errors will be our concern instead of the errors themselves. Any interval will not be specified and just the time between dosing errors will be monitored. The approaches will be provided to monitor the time between dosing errors. These tools are promising to help practitioners control the stability of the time between these drug adverse events. If the time between dosing errors increases, the practitioner may conclude that the medical errors become rarer and error occurrence rate decreases. Thus, these control charts may be used as the medical error surveillance systems to reduce error occurrence rate. Another possible impact may be obtained when new adjustments or procedures are introduced to the system to reduce medical errors such as new recording methods or hospital accreditation. The medical professional may monitor the system with the control charts to obtain evidence of successful process adjustments.

2.2 A general framework for the variable TBE control charts

Variable TBE control charts provide an opportunity to solve some setbacks which practitioners may encounter when using p, np, c, u charts for high quality processes. The practical difficulties of using traditional control charts for attributes are summarized by Xie et al. (2002), Liu et. al (2004) and Liu et al. (2006), as meaningless control limits, high false alarm probability, difficulties in forming a rational subgroup and failure in detecting process improvement. In order to overcome these setbacks, the Cumulative Quantity Control (CQC) chart is first proposed to monitor variable TBE data (Chan et al. 2000). The CQC chart mentioned here is developed based on the assumption that the rate of occurrences can be modeled by homogeneous Poisson process and the time between events (X) can be regarded as independent and identically distributed exponential random variables with the given probability density function.

$$f(x,\beta) = \begin{cases} \beta^{-1}\exp(-x/\beta), & if\ x \geq 0 \\ 0 & , \ otherwise \ . \end{cases}$$

where β is the mean of the TBE data and $\lambda\,(>0)$ is the mean rate of occurrence of defects, which can be written as $\lambda = 1/\beta$. The chart plots the time produced before observing one event, say one nonconforming item of the process. The process is considered to be out-of-control when a point plotted is less than the lower control limit or greater than the upper control limit. The two-sided control limits are provided as $LCL = -\beta \ln(1-\alpha/2)$, $CL = -\beta \ln(1/2)$ and $UCL = -\beta \ln(\alpha/2)$ where α is the false alarm probability (Chan et al. 2000). The center line (CL) is defined as the median of the distribution. CQC-*r* chart as an extension of CQC chart is proposed (Xie et al. 2002). They showed that

the extension is able to improve the sensitivity of CQC chart by monitoring the time until a fixed number (r) of events observed based on Gamma distribution. The CQC-r chart provides more credibility to the decision regarding the statistical control of the process, since the decision is made on the basis of r events rather than a single event (Xie et al. 2002). Basically, the CQC-r chart is reduced to the CQC chart when $r = 1$ and the control limits can be calculated solving the given equations;

$$F(UCL_r, r, \beta) = 1 - \sum_{k=0}^{r-1} exp(-\frac{UCL_r}{\beta}) \frac{(UCL_r)^k}{(\beta)^k k!} = 1 - \frac{\alpha}{2}$$

$$F(CL_r, r, \beta) = 1 - \sum_{k=0}^{r-1} exp(-\frac{CL_r}{\beta}) \frac{(CL_r)^k}{(\beta)^k k!} = \frac{1}{2}$$

$$F(LCL_r, r, \beta) = 1 - \sum_{k=0}^{r-1} exp(-\frac{LCL_r}{\beta}) \frac{(\lambda.LCL_r)^k}{(\beta)^k k!} = \frac{\alpha}{2}$$

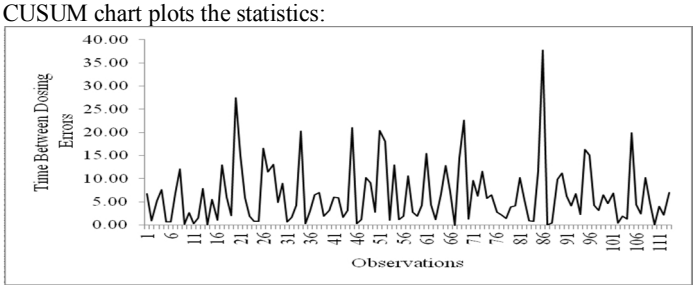
where β and r are the parameters of Gamma distribution. One can easily evaluate the state of the process with the location of the points plotted. If the point falls above the upper control limit (UCL), this indicates the mean TBE may have increased and a process improvement may have occurred. If the plotted point falls below the lower control limit (LCL), this indicates that the mean TBE may have decreased and process deterioration may have occurred. Thus, actions should be taken to identify the cause of improvement and sustain the improved process for the first case. On the other hand, actions should be taken to identify and remove the cause(s) of deterioration and make sure that it will not occur again in the future for the second case.

Alternatively accumulation control charts such as Exponentially Weighted Moving Average (EWMA) and Cumulative Sum (CUSUM) may be considered in variable TBE applications. According to Liu et al. (2006), a two-sided exponential EWMA can be obtained by plotting: $Z_t = (1-\lambda_z)Z_{t-1} + \lambda_z X_t$ against t for $t = 0, 1, \ldots$ where λ_z is a smoothing factor ($0 < \lambda_z < 1$) and $Z_0 = w$ ($h_l < w < h_u$). A signal is issued when $Z_t \le h_l$ or $Z_t \ge h_u$ where h_l and h_u are specific thresholds to achieve a predefined Average Time to Signal (ATS).

The exponential CUSUM chart plots the statistics: $S_t^+ = \max\{0, S_{t-1}^+ + (X_t - k_1)\}$ and $S_t^- = \min\{0, S_{t-1}^- + (X_t - k_2)\}$ where k_1 and k_2 are the reference values. If $S_t^- \le -h$ or $S_t^+ \ge h$, then the process is considered to be out-of-control (Liu et al. 2006). Usually $S_0^+ = S_0^- = 0$ and the calculation of k is summarized (Liu et al. 2006). The exponential EWMA and the exponential CUSUM control charts are generally considered to be effective when a small change in occurrence rate occurs. The performances of the exponential EWMA, the exponential CUSUM and the CQC-r charts are discussed in (Liu et al. 2006).

3 RESULTS

The control chart selection is a primary question for medical error monitoring. However, there may not be a unique control chart for all medical applications. The major aim of this study is to introduce various variable TBE control charts to the medical field and discuss the practical selection criteria for monitoring time between medical errors. The omission error data set is prepared and monitored with the CQC, CQC-r, the exponential EWMA and the exponential CUSUM control charts for this aim. To be consistent with the related literature, the standardized time between dosing errors is used to compute control chart statistics. The standardization is done by dividing each observation with the estimated mean time between dosing errors which is around 145 hours or 6 days. The targeted standardized mean occurrence rate is 1 for this process. The original and the standardized data are given in Figure 1, respectively. The limits of the control charts for various design parameters and type I error rate of 0.0027 are given in Table 1. The given control limits are valid for any standardized time between event data and can be used in medical error monitoring applications. The control charts are calibrated to achieve the specified in-control $ATS = 370.37$.



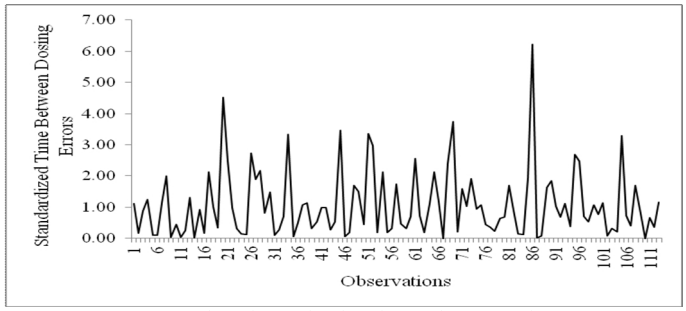


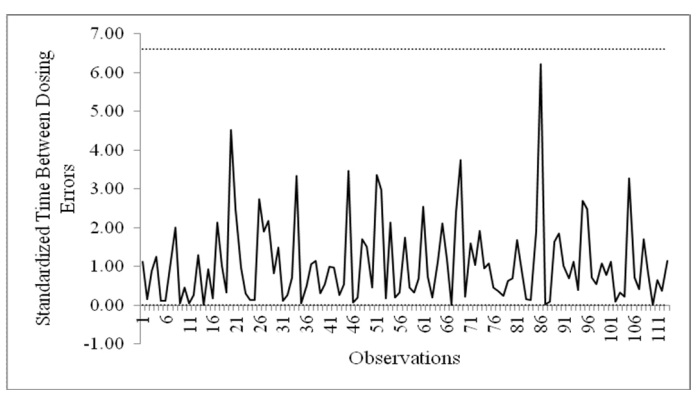
Figure 1. Original and standardized time between dosing errors.

Firstly the CQC and CQC-*4* control charts are constructed. These control charts are shown in Figure 2. CQC and CQC-*4* control charts use the original standardized data stream and do not require any further calculations. They are generally powerful when there is a large magnitude of shift in the process parameter. However, especially CQC chart is not effective in detecting small process shifts. As a competitive extension, CQC-*4* control chart is considered and the time to the forth medication error is monitored. The selection of r is arbitrary here to illustrate the chart, however, the practitioner should chose a proper r value based on the need and nature of the process.

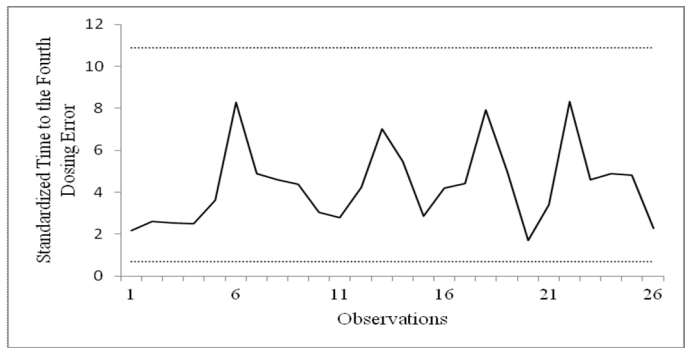
The CQC chart registers no out-of-control signals in Figure 2. However, the control chart provides two strong spikes around the observations 20 and 85. Thereafter, a CQC-*4* control chart is constructed and the standardized time to the 4th dosing error is monitored. Similarly to the CQC chart, this control chart does not provide any out-of-control signals. The dosing error process is statistically in-control when CQC and CQC-*4* charts are considered. As a small shift in the process may be suspected to happen, the exponential EWMA and the exponential CUSUM control charts are also constructed. Figure 3 displays the exponential EMWA control charts for different design parameters given in Table 1.

Table 1: The control limits for the variable TBE control charts when $ATS = 370.37$.

Control chart	**CQC**	**CQC-4**	**EWMA**		**CUSUM**	
Design parameters	$r = 1$	$r = 4$	$\lambda_z = 0.202$	$\lambda_z = 0.152$	$k_1 = 1.648$ $k_2 = 0.516$	$k_1 = 2.012$ $k_2 = 0.402$
UCL	6.608	10.875	2.350	2.050	2.200	1.330
LCL	0.001	0.687	0.360	0.430	6.500	5.366

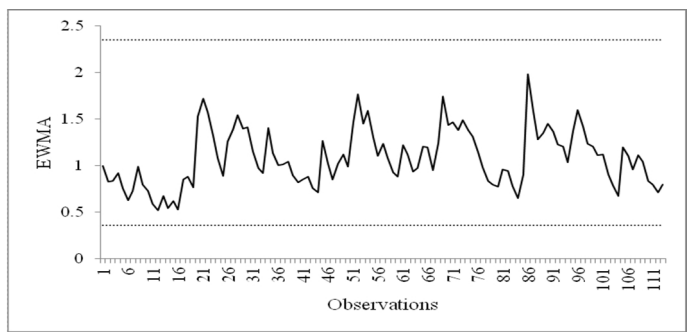


(a) CQC chart

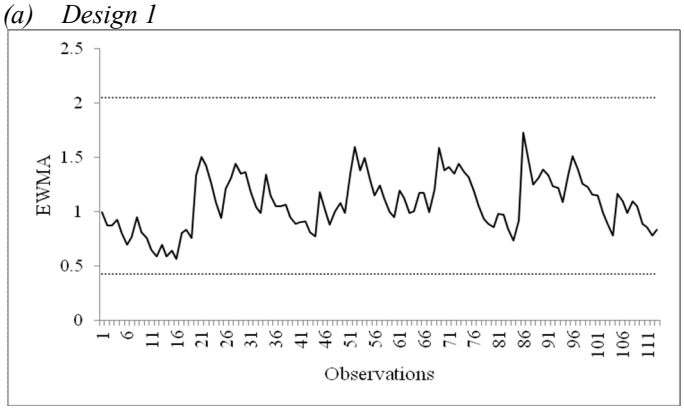


(b) CQC-4 chart

Figure 2. The CQC and CQC-4 charts for monitoring time between dosing errors.

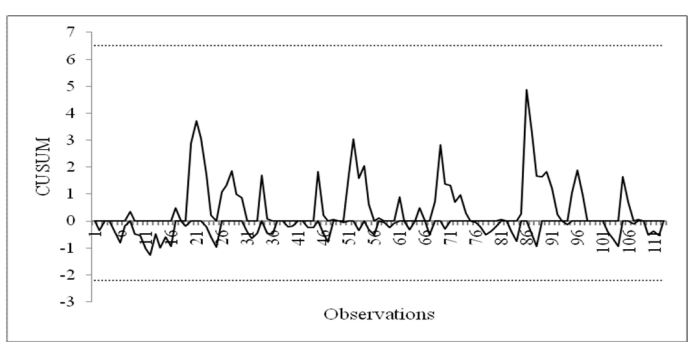


(a) Design 1

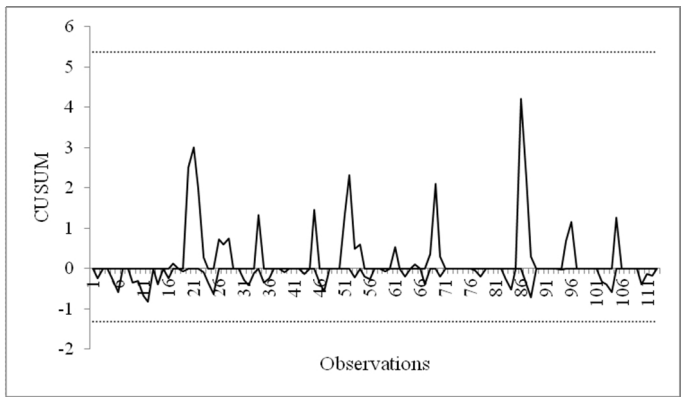


(b) Design 2

Figure 3. Two design alternatives of the exponential EWMA charts for monitoring time between dosing errors.



(a) Design 1



(b) Design 2

Figure 4. Two design alternatives of the exponential CUSUM charts for monitoring time between dosing errors.

Figure 3 shows us that the process is in-control and any out-of-control signals are not issued by the two design settings. Alternatively the exponential CUSUM control charts are constructed and shown in Figure 4. The design parameters are chosen as they are given in Table 1. The exponential CUSUM charts indicate any out-of-control signals and the process is considered to be in-control. The exponential CUSUM chart provides built-in positive and negative shift statistics. This property makes the exponential CUSUM visually attractive. It also enables the medical practitioner to keep track of an increase in occurrence rate with negative CUSUMs and a decrease in occurrence rate with positive CUSUMs. In other words, an increase in mean time between medical errors is reflected by positive CUSUMs and a decrease is reflected by negative CUSUMs. Here in these applications the design differences are insignificant; however the design difference stems from the optimality of the control chart statistics. As a criticism to those accumulation approaches, the design complexity makes the procedures to be hard to apply.

4 CONCLUSIONS

Statistical process control efforts are considered to ensure high-quality production and reduce costs in the competitive environment of business. High yield process monitoring is a special part of SPC and the medical practitioners are encouraged to apply these tools to health care domain (Benneyan 2001; Benneyan et al. 2003 and Xie et al. 2010).

In this study, presentation of several variable TBE control charts for monitoring medical errors is targeted. The CQC and CQC-*r* charts are presented firstly. After that, the exponential EMWA and CUSUM charts are introduced. The existing comparative studies show that the EWMA and CUSUM based control charts over-perform the CQC and CQC-*r* charts in terms of detection capability for most of the cases. However, in medical decision making there exist important features which may affect the control charts selection criteria.

From the viewpoint of medical applications, the CQC and CQC-*r* chart have some advantages when compared to the exponential EWMA and CUSUM charts. First of all, they are flexible and need less process information. The computations are much easier and simplicity in design parameters helps the process to be more stable when the requirements change. The medical staff may apply and interpret these tools without much expertise. Using the CQC and CQC-*r* charts is proposed when it is difficult to predict the process shift which is highly likely to be a case in health related processes (Liu et al. 2006). In many medical processes gathering data is quite difficult and it is likely not to be sure whether the process is improving or deteriorating. If the practitioner is not quite sure about the medical error process behavior, using the CQC and CQC-*r* charts can be a better choice due to their design simplicity. On the other hand, the target should be increasing the time between medical errors and decreasing the medical error occurrence rate. Therefore, if the medical decision maker focuses on the process deterioration and can obtain information about the process from historical data and other resources, the exponential EWMA and CUSUM control charts are considered to be more effective especially for small magnitudes of shift in occurrence rate. Their statistical background can be set to detect deterioration optimally and their design may be calibrated to this aim.

The omission error data is our focus for the illustration in this study and the applications indicate that the medication error process in this particular hospital for 2005 till 2007 is stable and statistically in-control. The quite obvious strikes obtained in the CQC chart and the exponential CUSUM charts are around the 20^{th} and 85^{th} observations. The plots display a potential

increase at those particular points. The medical practitioner is recommended to look back to the records for these dates. These increases in mean time between dosing errors indicate that the process work well and an improvement may happen. The practitioner can identify the root reasons causing these improvements and deploy them to the entire process. Thus reduce in medical error occurrence rate may be achieved.

In the omission error data set, a relatively long historical data stream is obtained. As the process in initially in-control, the mean time between medical errors estimation is done successfully. However, this is may not the case for many implementations. Since enough historical data may be unavailable for the medical error monitoring processes of hospitals, estimation of the occurrence rate may be ineffective. Estimation error may cause the approaches introduced here to be unsuccessful. In that case, attention should be given to proper data gathering and alternative advanced SPC methods may be considered in order to start right after a few observations are obtained. The medical practitioner should be warned for the early false alarms and their careful treatment.

REFERENCES

[1] Hovor, C., Walsh, C. (2007). Tutorial on monitoring time to next medication error. Quality Management in Health Care, 16(4), 321-327.

[2] Thor, J., Lundberg, J., Ask., J., Olsson., J., Carli, C., Härenstam, L.P., Brommels, M. (2007). Application of statistical process control in healthcare improvement. Quality and Safety in Health Care, 16, 387-399.

[3] Tenant, R., Mohammed, R.A., Coleman, J.J., Martin, U. (2007). Monitoring patients using control charts: a systematic review. International Journal of Quality in Health Care, 19(4), 187-194.

[4] Xie, Y.J., Tsui, K.L., Xie, M., Goh, T.N. (2010). Monitoring time between events for health management. Proceedings of the IEEE Conf on Prognostics & System Health Management Conference, Macau.

[5] Benneyan, J.C. (2001). Number between *g*-type statistical quality control charts for monitoring adverse events. Health Care Management Science, 4, 305-318.

[6] Benneyan, J.C., Lloyd, R.C., Plsek, P.E. (2003). Statistical process control as a tool for research and healthcare improvement. Quality and Safety in Health Care, 12, 358-364.

[7] Alemi, F., Neuhauser, D. (2004). Time between control charts for monitoring asthma attacks. Joint Commission Journal on Quality & Safety, 30(2), 95-102.

[8] Radelli, G. (1998). Planning time between event Shewhart control charts. Total Quality Management, 9(1), 13-140.

[9] Miller, J.G. (2008). Tutorial on monitoring time to next medication error: a response. Quality Management in Health Care, 17(4), 349-352.

[10] Xie, M., Goh, T.N., Kuralmani, V. (2002). Statistical models and control charts for high-quality processes. Boston: Kluwer Academic Publisher.

[11] Liu, J.Y., Xie, M., Goh, T.N., Ranjan, P. (2004). Time between events charts for on-line process monitoring. Proceedings of the IEEE Conf on International Engineering Management Conference, Singapore, 1061-1065.

[12] Liu, J.Y., Xie, M., Goh, T.N., Sharma, P.R. (2006). A comparative study of exponential time between events charts. Quality Technology and Quantitative Management, 3(3), 347-359.

[13] Chan, L.Y., Xie, M., Goh, T.N. (2000). Cumulative quantity control charts for monitoring production processes. International Journal of Production Research, 38(2), 397-408.

Received: 12.01.2012 Accepted: 01.04.2012 Open for discussion: 1 Year