

A Comprehensive Study on Monitoring Treatment Outcomes Using Risk- adjusted CUSUM Control Charts

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ABSTRACT

Rapidly determining difficulties in the quality of care is critical to patient's well-being. Without proper inspection procedures, such issues can go unnoticed for years. Although cumulative sum (CUSUM) charts are effective for quality control, there is limited methodology for predicting survival results. They are powerful tools for detecting deviations from expected performance over time and are particularly suited for monitoring both continuous and binary outcomes in clinical settings. This study aims to an advanced statistical technique for evaluating treatment outcomes and monitoring quality in healthcare using CUSUM control charts. A Cox proportional hazards model was employed to estimate covariates and cumulative baseline hazard function, enabling risk-adjusted evaluations. Both CGR-CUSUM and BK-CUSUM charts were constructed. These charts were calibrated to detect changes in survival and treatment success during a predefined follow-up period. In parallel, a Bernoulli CUSUM chart was developed for binary outcomes, such as treatment success or failure, using logistic regression to adjust for covariates. By combining survival analysis and risk-adjusted quality control, the method ensures high sensitivity to performance changes while accounting for variability in patient characteristics. This integrative approach made by using success (survival control charts estimation software) package in R programming. The use of CUSUM charts for risk-adjusted monitoring gives a reliable solution to enhancing clinical outcomes and maintaining standards in healthcare environments.

Keywords: CUSUM Control Charts, Risk-Adjusted control charts, survival control charts, Bernoulli cusum

INTRODUCTION

Early detection of deterioration in the standard of care may protect patients from preventable health hazards. Monitoring the quality of a survival process is critical, particularly in the medical industry. Initially, the control charts are commonly used for monitoring industries; later they used for the survival outcomes. There are various inspection techniques available to measure care quality, including funnel plots (Spiegelhalter, 2005), Bernoulli Cumulative sum (Bernoulli CUSUM) charts (Steiner and others, 2000; Biswas and Kalbfleisch, 2008) and exponentially weighted moving average (EWMA) charts (Cook, Coory, and Webster 2011) work only with binary outcomes therefore, they may not always be effective. Usually, CUSUM charts can be used to monitor process quality over time, making them particularly useful. The inspection scheme should be matched to the desired objective. These charts involve dichotomizing continuous time outcomes, which might cause delays in detecting

quality of care issues. To overcome this situation, Biswas and Kalbfleisch (2008) developed the BK-CUSUM technique, which allows for real-time monitoring of survival outcomes. Gomon et al. (2022) introduced the Continuous Time Generalized Rapid Response CUSUM (CGR-CUSUM), which is a generalization of the BK-CUSUM. The CGR-CUSUM method estimates chart parameters, eliminating the requirement for users to correctly specify them as in the BK-CUSUM procedure. The CUSUM model's assumptions vary throughout charts, making them suitable to various contexts. At first, must specify a projected increase in the future rate of failure, which is a common feature across all studies. The charts may exhibit detection delays and generate misleading negative signals if this number is selected improperly. The aim of the research is to create a system that eliminates the need for researchers to declare multiple parameters in advance, resulting in speedier detection times in actual applications. Usually, Biswas and Kalbfleisch (2008) restricted their analysis to patient information provided up to a year following the operation. The CGR-CUSUM takes into consideration all available patient information at any given time. As a result of these modifications, our chart identifies underperforming hospitals more quickly, improving treatment quality. Steiner and Jones (2009) used the uEWMA chart for survival time data, while Grigg (2018) used the STRAND chart to continuously examine care quality. Grigg (2018) compares the BK-CUSUM, uEWMA, and STRAND charts and finds that the uEWMA and STRAND charts are most effective for detecting clustering failures. The BK-CUSUM and CGR-CUSUM identify increasing failure rates without a cluster-specific mechanism. This study derived an approximation for the average run length (average time to detection) of the BK-CUSUM and compared it to the CGR-CUSUM. This comparison shows that inaccurate prior knowledge can dramatically increase detection times for the BK-CUSUM process. The CGR-CUSUM chart is a valuable tool for practical applications when the projected rate of failure is uncertain and may change over time. Because the CGR-CUSUM chart is widely used in medical applications, it can help to improve healthcare efficiency by inspecting present practices. The chart can be used to analyse procedures having "survival" outcomes, such as manufacturing processes and client inspections. Currently, there are no publicly available software applications for these concepts. When creating control charts in continuous time, it is critical to incorporate both the time to failure and survival information up to the present moment. Many quality control systems cannot contain continuous time (survival) outcomes because the continuous time outcome must be categorized (for example, 30-day survival). Discrete time data refers to the resulting binary data.

This paper also provides an overview of the existing R utilities for generating control charts. The `qcc` (Scrucca 2004) package for discrete time data includes tools for constructing various charts, such as Shewhart, binary CUSUM, EWMA, and more. The software `qcr` (Flores 2021), `qicharts` (Anhoej 2021), and `ggQC` (Grey 2018) can generate discrete time control charts, although they have varied graphical capabilities and uses in healthcare, manufacturing, and economics. Using the `spc` (Knoth 2021) and `vlad` (Wittenberg and Knoth 2020) programs, discrete time-controlled charts can be evaluated in terms of their zero/steady state average run length. The `funnel` R package (Kumar 2018) generates funnel plots for proportion data, which are widely used in medical statistics to illustrate changes over time. The program `cusum` (Hubig 2019) monitors hospital performance using a Bernoulli CUSUM and provides control limits for continual inspections. The software requires input to be in binary format. There are few statistical software programs available for constructing quality control charts on survival data, and no R packages for continuous time examination of survival outcomes, as opposed to those for discrete time data. In addition, this paper will introduce the R package **success (SURvival Control Chart ESTimation Software)**, which is

a tool for creating quality control charts using survival data. This program requires to fill a need in open-source software for constructing control charts based on survival statistics. Success intends to make it easy for users to generate BK- and CGR-CUSUMs, as well as the discrete time funnel plot (Spiegelhalter 2005) and Bernoulli CUSUM chart (Steiner et al. 2000) for survival data, without the requirement for manual dichotomization. Using continuous time quality control methods can improve detection speed compared to traditional discrete time methods by ARL. The secondary mental health data used to determine the performance of survival after started the treatment. Even though this research aims for the medical data, the procedure can be helpful for any data with survival outcomes. The methods aim to quickly recognize hospitals with improvement rates by detecting deviations from a specific target performance indicator. This paper presents the complete introduction about the concept, develop the funnel plots, Bernoulli CUSUM, BK-CUSUM, and CGR-CUSUM, which are implemented in package success and compare ARL values of the control charts for the simulated data and real-life application. This article is organized as follows. In Section-2: Theory and Models, we provide a brief explanation of the theory behind the control charts in the program. Section-3: The R package success guides users through data preparation, functions, and parameters. The package's control charts are applied to data from a clinical study on mental healthcare in the application section, this paper concludes with a discussion of the addresses provided.

METHODS AND MATERIALS

Assume hospitals/units get a constant flow of patients/subjects requesting treatment (e.g., surgery). In survivor quality control, we want to determine if a hospital's treatment failure/death rates deviate significantly from a desired metric. An objective measure indicates an acceptable failure rate. The value can be approximated with historical data. Detecting an increase in hospital failure rates suggests poor performance and may require corrective efforts to enhance treatment quality. When failures occur at the goal level, the process is considered to be under control. Failures occurring at a higher rate than predicted indicate an out-of-control situation. Hospitals may have periods of control and then out-of-control. Early detection of out-of-control observations at a hospital allows for timely action. To ensure process quality, we created a control chart to monitor failure rates throughout the study. Patients enter the hospital via a Poisson process with a predetermined arrival rate ψ . Each i has a collection of factors that determine their survival time, which is determined from entry to failure or censoring.

$$T_i = A_i + X_i$$

where A_i is the patient's entry time, and X_i is their survival time from entry.

1.1 COX PROPORTIONAL HAZARDS MODEL: The Cox proportional hazards model depicts the subject-specific hazard function, which takes into account baseline hazard and patient variables. A patient is deemed at danger between admittance and failure or censorship. The number of failures seen up to any time point is counted, whereas cumulative failure intensity is a measure of overall failure risk across all patients.

$$h_i(x) = h_0(x)e^{Z_i\beta}$$

where $h_0(x)$ is the baseline hazard, and β represents the regression coefficients.

1.2 RISK AND FAILURE INDICATORS: To detect changes in failure rates, we modify the cumulative intensity and hazard function, scaling them by a hazard ratio. If this ratio is greater than one, the failure rate is considered out of control. Define the risk indicator as follows:

$$Y_i(t) = 1 \text{ if } A_i \leq t \leq \min(T_i, R_i)$$

where R_i is the proper censoring time for patient i . This indicator determines if a patient is at risk of failing at time t . The counting procedure $N(t)$ monitors if patient i fails at or before time t . The total number of failures observed in the hospital up to time t is provided as:

$$N(t) = \sum N_i(t) \text{ for } i \geq 1$$

1.3 CUMULATIVE INTENSITY FUNCTION:

Each patient's cumulative intensity function is

$$\Lambda_i(t) = \int_0^t Y_i(t) h_i(t)$$

The total cumulative intensity across all patients is $\Lambda(t) = \sum \Lambda_i(t)$. Since a patient is only at risk when $Y_i(t) = 1$, the individual intensity function is

$$\lambda_i(t) = Y_i(t) h_i(t)$$

When the patient is not at risk, the equation is equal to zero. To detect an increase in failure rates, we use a shifting cumulative intensity

$$\Lambda(t) = e^\theta \Lambda(t)$$

Similarly, the hazard function for this shift is $h_i(t) = e^\theta h_i(t)$ where e^θ represents the genuine hazard ratio. When $e^\theta = 1$ the failure rate is deemed under control. If $e^\theta > 1$, it suggests an out-of-control situation with rising failure rates.

1.4 MONITORING USING CONTROL CHARTS:

A control chart is used to track these changes, with a stop rule set as exceeding a predetermined threshold. The average run length is the predicted time until the chart shows an increase in failures limit has $E[\tau_h]$, where

$$\tau_h = \inf\{t > 0: K(t) \geq h\}$$

1.5 FUNNEL PLOT:

The risk-adjusted funnel plot (Spiegelhalter 2005) is a graphical method for comparing hospital performance across time. The data is structured as follows: there are k centres

/hospitals ($j=1 \dots k$) with n_j treated patients at hospital j . For each patient, we observe binary variable.

1 if the patient experienced an adverse event within C days ,

$$X_{ij} = \begin{cases} 1 & \text{if the patient experienced an adverse event within } C \text{ days,} \\ 0 & \text{otherwise} \end{cases}$$

0 otherwise

We model $X_{ij} \sim \text{Ber}(p_j)$, where p_j is the likelihood of failure at hospital j within C days. Consider the hypothesis: $H_0: p_j = p_0$. $H_1: p_j \neq p_0$ with p_0 some baseline(in-control) failure proportion. Let O_j be the observed number of failures at hospital j . The risk-adjusted proportion of failures at hospital j is provided by γ_j^{RA} , and $j = (O_j/E_j)$. p_0 uses the quantity γ_j^{RA} rather than γ_j . A funnel plot can be used to compare hospital performance over a certain time frame. The funnel plot is often used to assess

process quality by producing many charts at various time intervals. So, opposing such an inspection strategy since it raises the probability of type I errors due to multiple testing. So, I advise that you just utilize the funnel plot as a graphical tool for evaluating the fraction of failures across all hospitals over time. As a discrete time method, the funnel plot can only compare overall performance over a certain time period. One of the CUSUM charts should be used to determine whether a hospital was underperforming during the study period.

1.6 BERNOULLI CUMULATIVE SUM (CUSUM) CHART: The Bernoulli CUSUM

chart (Steiner et al. 2000) can be used to examine if the failure rate of patients at a specific hospital has changed over time, beginning with patient $v \geq 1$. Assume a hospital with patients $i = 1, \dots, v, \dots$ and a binary result.

$$X_i = \begin{cases} 1 & \text{if the patient had an undesirable outcome within } C \text{ days,} \\ 0 & \text{otherwise} \end{cases}$$

The model $X_i \sim \text{Ber}(p_i)$, where p_i represents the likelihood of failure within C days for patient i . The Bernoulli CUSUM can be used to test the hypothesis of an increased failure rate starting with a specific patient (v).

$$H_0: X_1, X_2, \dots \sim \text{Ber}(p_0). H_1: \{X_1, \dots, X_{v-1} \sim \text{Ber}(p_0)$$

$$X_v, X_{v+1}, \dots \sim \text{Ber}(p_1)$$

where $v \geq 1$ is not known in advance, $p_0 < p_1$, and patient outcomes are ordered according to the time of entry into the study A_i . The Bernoulli CUSUM statistic is given by

$$S_n = \max(0, S_{n-1} + W_n),$$

$$W_n = X_n \ln(p_1(1-p_0)/p_0(1-p_1)) + \ln(1-p_1/1-p_0)$$

Alternatively, the chart can be reformulated in terms of the Odds Ratio (OR), defined as

$$OR = p_0(1-p_1)/p_1(1-p_0) = e^\theta$$

Under this representation, the test statistic becomes and the null hypothesis is rejected when the chart exceeds a predefined control limit h

$$W_n = X_n \ln e^\theta + \ln(1/1-p_0 + e^\theta p_0)$$

A risk-adjusted technique uses a logistic regression model to estimate a patient's particular failure probability ($p_{0,i}$). The risk-adjusted Bernoulli CUSUM is suitable for sequential quality control on binary outcomes. The dichotomization of survival time can result in detection delays.

1.7 BISWAS AND KALBFLEISCH CUSUM (BK-CUSUM)

The BK-CUSUM chart monitors the hospital's patient rate of failure over the years. Assume a hospital with patients $i = 1, 2, \dots$ and the patient-specific hazard rate, $h_i(x) = h_0(x)e^{Z_i\beta}$. It can be used to test the hypothesis that the baseline hazard rate of all active patients increased from $h_0(x)$ to $h_0(x)e^{\theta_1}$ at time $s > 0$ following the study's

$$H_0 : X_i \sim \Lambda_i(t), i = 1, 2, \dots H_1 : X_i \sim \Lambda_i(t) | t < s, i = 1, 2, \dots X_i \sim \Lambda_{\theta_1 i}(t) | t \geq s, i = 1, 2, \dots$$

where $\theta_1 > 0$ is the user's estimate of the true hazard ratio θ and $s > 0$ is the unknown time of change in hazard rate. The likelihood ratio chart associated with the hypotheses is given by:

$$BK(t) = \max_{0 \leq s \leq t} \{ \theta_1 N(s, t) - e^{\theta_1} - 1 \Lambda(s, t) \}$$

to specify the estimated hazard ratio $e^{\theta_1} > 1$, use $N(s, t) = N(t) - N(s)$ and $\Lambda(s, t) = \Lambda(t) - \Lambda(s)$. The null hypothesis is rejected when the chart's value surpasses the control limit. Because hypotheses can be tested at any moment in time rather than only during the dichotomized outcome periods, the BK-CUSUM chart may identify faster than the Bernoulli CUSUM chart. Unfortunately, the chart requires users to specify θ_1 to estimate θ , which is rarely accessible beforehand in practical situations. Misspecification of this parameter can result in considerable detection delays (Gomon et al., 2022).

1.8 CONTINUOUS TIME GENERALIZED RAPID RESPONSE CUSUM (CGR-CUSUM)

The CGR-CUSUM chart can be used to test the following hypotheses:

$$H_0 : X_i \sim \Lambda_i, i = 1, 2, \dots, v-1 \quad H_1 : X_i \sim \Lambda_{\theta i}, i = 1, 2, \dots, v, v+1, \dots$$

where e^{θ} and v do not need to be prespecified. The CGR-CUSUM chart is then given by $CGR(t) = \max_{1 \leq v \leq n^{\theta} \geq v(t)} N_{\geq v}(t) - \exp^{\theta} \Lambda_{\geq v}(t)$

The CGR CUSUM uses the highest likelihood estimate e^{θ} to find the true hazard ratio e^{θ} from data, while the BK-CUSUM requires an estimate of e^{θ} beforehand. When e^{θ_1} is incorrectly set in the BK-CUSUM, the CGR-CUSUM offers faster discovery. The real hazard ratio (e^{θ}) is uncertain and can fluctuate over time. To overcome this issue, the CGR-CUSUM chart is generally preferred above alternative charts. The BK-CUSUM chart searches for a sudden change in the failure rate of all patients at risk of failing, whereas the CGR-CUSUM chart looks for a sudden change in the failure rate of all patients at risk of failing who arrived at the hospital after a certain time. The CGR-CUSUM has a limitation: calculating the MLE, θ , requires sufficient data (survival times/failures) to accurately represent the true value. The chart could be unstable at the start of the study, resulting in incorrect data for institutions with low numbers of patients.

$\tau_h = \inf\{t > 0: CGR(t) \geq h\}$ as the time it takes for a CGR-CUSUM to produce a signal. The average run length (ARL) is expressed as $E[\tau_h]$. The in-control average run length is the estimated time to detection when $\exp(\theta) = 1$, while the out-of-control average run length is when $\exp(\theta) > 1$.

1.9 AVERAGE RUN LENGTH:

This will give us a maximum limit on the CGR-CUSUM's average run length in the out-of-control condition. Approximating the ARL may be difficult due to the maximizing term in the equation. A bound on the ARL can be obtained by comparing it to a simple CGR chart. We examine at the Continuous time Generalized Initial Response (CGI) CUSUM chart. This graph can be used to test assumptions about an initial shift in the rate of failure:

$$H_0: X_i \sim \Lambda_i \text{ where } i = 1, 2, \dots \quad H_1: X_i \sim \Lambda_{\theta}, \text{ where } i = 1, 2, \dots$$

CGI-CUSUM is provided by:

$$CGI(t) = \theta^{\wedge}(t)N(t) - (\exp(\theta^{\wedge}(t)) - 1)t.$$

The CGI-CUSUM is a theoretical tool that, because of its simplified form, can be utilized for theoretical analysis rather than sequential change detection. The assumption that patient

arrivals follow a Poisson process with rate ψ allows us the following approximation: $n \approx \psi \cdot t$ If arrivals follow a Poisson process, then

$\theta > 0: t(CGI(t) - (\theta + \exp(-\theta) - 1)I(\theta, t)) \rightarrow dN(0, t\theta^2 I(\theta, t))$ For $\theta = 0$, use the shape k and scale b parametrization:

$CGI(t) \rightarrow d\text{Gamma}(k = 1, 2, b = t)$

where $I(\theta, t)$ represents the Fisher information from all observations at time t . The BK-CUSUM is described as:

$$BK(t) = s: \max_{0 \leq s \leq t} \{\theta_1 N(s, t) - (\exp(\theta_1) - 1) \Lambda(s, t)\}$$

where $\exp(\theta_1)$ is the predicted hazard ratio, which must be determined in advance.

1.9.1 APPROXIMATE ARL CALCULATION:

Estimate the ARL of CGI-CUSUM.

When $\exp(\theta) > 1$, we can solve the equation:

$$(\theta_1 + \exp(-\theta) - \frac{\exp(\theta_1)}{\exp(\theta)}) I(\theta, t) = h$$

Monte Carlo simulations are necessary to estimate ARL for $\exp(\theta) = 1$

The approximate ARL for BK-CUSUM, $ARL_{BK}(\theta, h)$, is found by solving:

$$(\theta_1 + \exp(-\theta) - \frac{\exp(\theta_1)}{\exp(\theta)}) I(\theta, t) = h \exp(\theta)$$

If θ_1 is incorrectly set, CGI-CUSUM (and CGR-CUSUM) will discover out-of-control conditions faster than BK-CUSUM.

The ARL comparison of CGR-CUSUM and BK-CUSUM is dependent on the restriction:

$$\frac{\exp(\theta_1)}{\exp(\theta)} < \theta_1 + \exp(-\theta) < \frac{\exp(\theta_1)}{1 + \exp(-\theta)}$$

If the criterion is met, CGR-CUSUM will have a shorter ARL than BK-CUSUM.

1.9.2 COMPARISON TO CGR-CUSUM

The CGR-CUSUM is a maximized version of CGI-CUSUM over the last $n-v$ patients. It follows that:

$$ARL \leq CGR(\theta, h) = CGI(\theta, h).$$

This upper bound enables CGI-CUSUM simulations to estimate CGR-CUSUM ARL effectively, hence lowering computing time. Both CGI-CUSUM and CGR-CUSUM update only at failure times, therefore values must be computed only at observed failure times, significantly decreasing computational requirements.

1.10 ADVANTAGES:

The Biswas & Kalbfleisch (2008) CUSUM requires a prior value $\theta_1 > 0$ for θ on the chart (t). BK-CUSUM (Biswas & Kalbfleisch, 2008) assumes patients active for just one year ($C = 1$) after the operation. This enables a closed-form ARL approximation. The CGR-CUSUM eliminates the need for

a predetermined hazard ratio, resulting in a more general test that relies less on past knowledge. CGR-CUSUM does not lose data after a year, resulting in more full information and perhaps faster detection times. This technique allows for shorter ARLs than the $C = 1$ limitation in BK-CUSUM. To achieve a fair comparison, this study exclusively considers the BK-CUSUM with the $C = 1$ constraint lifted. CGR-CUSUM automatically updates parameters with maximum likelihood estimation (MLE), responding to the most recent failure rates. However, MLE takes time to converge, which may result in detection delays as compared to a well-specified BK-CUSUM. CGR-CUSUM detects a change in hazard rate for all patients who enter after a specific time. BK-CUSUM detects a sudden shift in hazard rate for all patients at risk. BK-CUSUM requires a pre-specified hazard ratio (θ_1). CGR-CUSUM adapts dynamically. If the expected hazard ratio is mistakenly given, CGR-CUSUM performs better at identifying changes. CGR-CUSUM is more adaptable and responsive to variations in patient failure rates.

1.11 CHOOSING CONTROL LIMITS

For the funnel plot in Section Funnel plot, selecting a confidence level is sufficient to determine which hospitals perform worse/better than the baseline. For CUSUM charts, a control limit h must be chosen to ensure a signal occurs when the chart's value surpasses h . The most typical approaches to select this control limit are to restrict the chart's in-control ARL or to limit type I error over a specific time period. With the first strategy, one may opt to limit the in-control ARL to around 5 years, such that on average, we would expect a hospital that performs according to the aim to produce a false signal (detection) once every 5 years. Using the second method, choose a control limit that ensures no more than $\alpha\%$ of in-control hospitals make a false detection within 5 years. There are several numerical estimates for the risk-adjusted Bernoulli CUSUM and ARL, the majority of which are contained in the packages `spc` and `vlad`. In the `success` package, control limits are defined by constraining the type I error probability α to a fixed time frame, as continuous time control charts do not produce similar conclusions. We estimate limits on control using a simulation method.

1.12 FUNNEL PLOT:

A funnel plot is a type of scatter plot that is often used in statistics and healthcare monitoring to show performance variation across many institutions (for example, hospitals). It identifies outliers by comparing observed performance indicators to expected values within regulatory limits. If the points within the control limits, then the performance is as predicted. If the points over the upper limit indicate that hospitals are outperforming expectations (reduced mortality). If the points below the lower limit indicate underperforming hospitals (higher- than-expected mortality).

1.13 BASELINE HAZARD:

Determining the baseline is crucial in practical applications of BK- and CGR-CUSUM charts, since it impacts detection speed and false detection rates. The baseline is fixed in both circumstances using a null hazard rate and Cox regression coefficients. To ensure scientific accuracy, it's recommended to use an in-control data set with known failure rates. Obtaining a complete set can be challenging for various reasons. To obtain the null hazard rate and Cox coefficients, we use the entire data set as training data. The average national failure rate in hospitals meets the targeted criteria. Similarly, the funnel plot is generated as well. The baseline for the yearly funnel plot must be determined each year. To compare the funnel plot and CUSUM techniques, we calculate the baseline hazard rate, failure proportion, and risk-adjustment coefficients using the entire data set. The Cox proportional hazards function from Therneau's (2020) R package `survival` was used to do this. This ensures that all chart construction methods use the same information and adhere to the same "traditional of care".

1.14 DATA SOURCE:

The data used for the analysis is simulated accident data by using `success` package and for the real-life

application the secondary data of mental health patients' treatment details from data.gov.in (open government data (OGD) platform India). Success R package: This package success can be utilized by both beginners and professionals in the field of quality control charts, it provides an example data set to demonstrate the general data structure for creating control charts. The parameter-assist function, a function is described that may identify all required parameters for control chart generation for users who are not interested in technical specifics. Manual risk-adjustment- The CGR-CUSUM function, we give functions for computing control charts as indicated Theory and models. To input the data this package's features need a data.frame to generate control charts and estimate benchmark failure rates. This demonstrates how to utilize the success package with an enclosed data collection.

RESULTS AND DISCUSSION

For this study, the accident data is simulated using the success package in R. To generate the arrival times poisson distribution and for survival times based of exponential distribution. Fifteen hospitals with sampled from the normal distribution with mean and standard deviation. The data frame accident_data includes survival times, censoring times, and covariates (age, BMI, and sex) for patients from 15 hospitals, including small, medium, and large hospitals (0.5, 1, and 1.5 patients each day). Patients enter hospitals for a two-year period (2*365 days) once the trial begins. Survival times were calculated using a risk- adjusted Cox proportional hazards model with inverse transform sampling (Austin, 2012). The coefficient vector included age, gender, and BMI. The exponential baseline hazard rate $h_0(t, \lambda = 0.01) e^{\theta}$ was used. Hospitals are numbered 1-15, and the hazard ratio θ follows a normal distribution with a mean log (0.5) and a standard deviation of 0.25.

```
Install.packages(success) library(success) set.seed(1041996)
```

```
accident_data <- data.frame(matrix(ncol=9, nrow=0,
```

```
dimnames=list(NULL, c("entrytime", "survtime", "censorid", "unit",  
"exptheta", "psival", "age", "sex", "BMI"))))
```

```
# Save dataset in various formats save(accident_data, file = "accident_data.RData")
```

```
write.csv(accident_data, "accident_data", row.names = FALSE) data("accident_data", package =  
"success") head(accident_data, 5)
```

The data contains rows, each of which represents one patient. The first two columns (entry time and survtime) are crucial when developing control charts. These columns must be included in the dataset. Entry and survival times must correspond to the same time scale. Both must be filed in "numeric" format (dates are not permitted). The sample data is organized on a time scale of days, with entrytime reflecting the number of days since the study began and survtime representing the time since entry. The censorid column represents censorship, with 0 indicating right-censoring and 1 indicating that the event occurred. If the censorid is missing, a column of 1s will appear, indicating that no observations were right- censored. When this happens, all relevant functions in the package generate a warning. A funnel plot requires a column unit (which displays the hospital number), whereas CUSUM charts do not. CUSUM charts are generated separately for each unit, requiring users to manually subset data for each. The columns exptheta and psival show the parameters e^{θ} and ψ used to construct the simulated data. Each person's variables are age, gender, and BMI. User- supplied data.Frames can be given any name. Then, import the additional packages.

```
library(qcc) library(spcadjust) library(survival) library(ggplot2) library(gridExtra)
```

1.15 CONSTRUCTION OF PARAMETERS:

- Step 1: Give arguments to parameter_arrangements.
- Step 2: Apply one of the three control_limit functions to the output of Step 1 to determine the control

limit(s) for the appropriate control chart(s). Usually, the control limits are not required for funnel plots.

- Step 3, pass the result of Step 1 and the control limit from Step 2 into the function to create the required control chart.

The parameter arrangements

- `baseline_data(required)`: a `data.frame` organized as specified in Input data. Using the available data, calculate the desired performance metric for both discrete and continuous time charts. This data aids in estimating the "acceptable" failure rate as well as the effect of risk-adjustment variables on event probability. Preferably, this should be data from persons who have been known to fail at realistic rates, or historical data with which to compare. Typically, the target is determined using the average performance of all available data.
- `data (required)`: a `data.frame` prepared as specified in the Input data. It should offer the information required to generate a control chart. We want to see if this data matches the target provided in `baseline_data`. For example, statistics from a single hospital.
- A formula for creating risk-adjustment linear variables in generalized linear or Cox proportional hazards models. Only the right half of the formula will be used. If not completed, no risk adjustment will be offered.
- In discrete time charts, the following value should be in the exact same unit as the `entrytime` and `survtime`. It indicates the amount of time after `entrytime` we evaluate the patient's binary result (failure or not). Leave this option empty if you do not want to generate discrete time charts.
- `Theta` indicates an anticipated increase in the logarithms of failure/hazard rate. The default value is `log (2)`, which is designed to identify an increase in the failure rate.
- The time interval utilized to identify type I errors. The set value is the individuals' maximum input time in `baseline_data`.
- `Alpha (recommended)` requires type I error for control over a specified time frame. The default is 0.05.

```
for(k in 1:3) {  
  for(j in 1:3) {  
    for(i in 1:5) {  
      arrivtimes <- round(gen_arriv_times(psi = psivals[j], t = 2*365)) n <- length(arrivtimes)  
      age <- round(pmin(110, pmax(10, rnorm(n, mean = 60, sd = 20)))) BMI <- round(pmin(50, pmax(10,  
rnorm(n, mean = 25, sd = 5))), 2)  
      sex <- as.factor(sample(c("male", "female"), size = n, replace = TRUE, prob = c(0.45, 0.55)))  
      censorid <- sample(c(0, 1), size = n, replace = TRUE, prob = c(0.02, 0.98)) tdat <-  
data.frame(entrytime = arrivtimes, age = age, BMI = BMI, sex = sex)  
      coxmodt <- list(formula = formula("~ age + BMI + sex"), coefficients = c(age = 0.003, BMI = 0.02,  
sexmale = 0.2))  
      mu <- rnorm(1, mean = mumean[k], sd = 0.4)  
      survtime <- round(gen_surv_times(invchaz = function(t) inv_chaz_exp(t, lambda = 0.01), mu = mu,  
data = tdat, coxphmod = coxmodt))
```

```
tdata2 <- data.frame(entrytime = arrivtimes, survtime = survtime, censorid = censorid, unit = rep(s,
n),exptheta = rep(exp(mu), n), psival = rep(psivals[j], n), age = age, sex = sex, BMI = BMI)
```

```
accident_data <- rbind(accident_data, tdata2) s <- s + 1
```

```
}
```

```
}
```

```
}
```

The initial two arguments should always be supplied. Various package functions can be used based on the number of additional arguments provided. While most options have default values, they can sometimes not be appropriate for the specified inspection scheme. For developing risk-adjusted methods, a formula must be stated. A CGR-CUSUM can be constructed without risk-adjustment if just baseline data is supplied. There two models risk adjustment cox and general linear model (GLM).

```
#Determine Risk-adjustment Cox and GLM model on full data set: exprfit <-
as.formula("Surv(survtime, censorid) ~ age + sex + BMI") #150 day after surgery followup for
Bernoulli CUSUM
```

```
exprfitglm <- as.formula("(survtime <= 150) & (censorid == 1)~ age + sex + BMI") coxmod <-
coxph(exprfit, data= accident_data)
```

```
glmmod <- glm(exprfitglm, data = accident_data, family = binomial(link = "logit"))
```

The next step is simulation of parameters, then find the control limits for Ber, BK, CGR CUSUM restricting type-I error to 0.05 to 1 year.

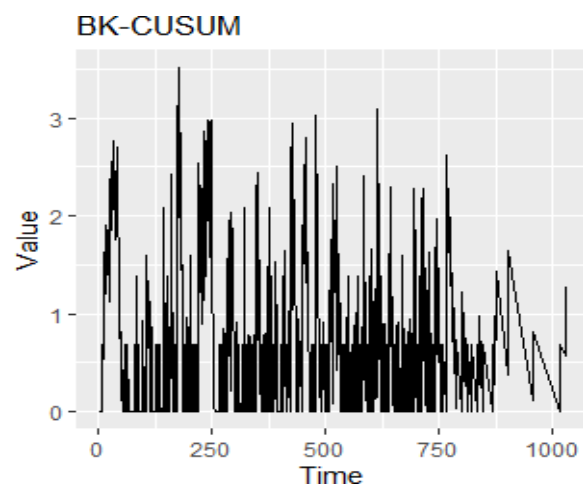
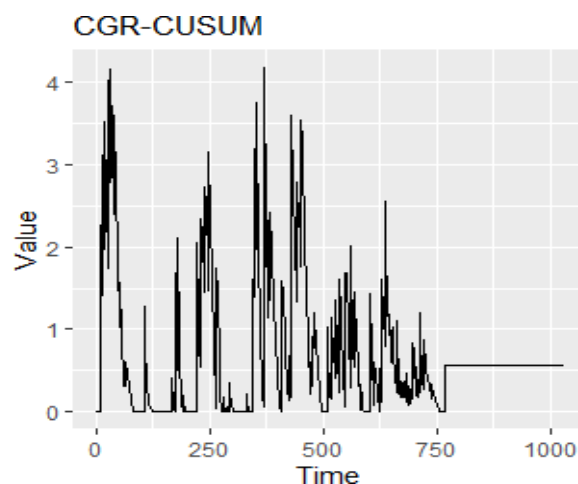
```
bk_control <- bk_control_limit(time = time, alpha = alpha, psi = psi, n_sim = n_sim_ic, theta =
theta, coxphmod = coxmod, baseline_data = accident_data, pb = TRUE)
```

```
cgr_control <- cgr_control_limit(time = time, alpha = alpha, psi = psi, n_sim = n_sim_ic, coxphmod
= coxmod, baseline_data = accident_data, pb = TRUE)
```

```
bernoulli_control <- bernoulli_control_limit(time = time, alpha = alpha,
```

```
psi = psi, n_sim = n_sim_ic, followup = followup, theta = theta, glmmod = glmmod,
```

```
baseline_data = accident_data, pb = TRUE)
```



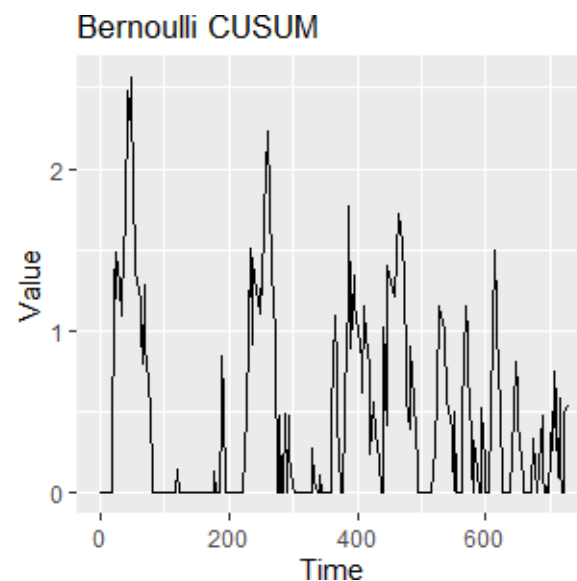


Figure.1 Bernoulli, BK- and CGR-CUSUM charts for hospital

Plot the control charts with the plot function (Figure 1). The Bernoulli CUSUM rises when a failure occurs after patient admission and falls when no failure occurs over that time span. When a failure is detected, the BK- and CGR-CUSUM show a sudden upward jump.

Otherwise, the slope is downward. The BK- and CGR-CUSUM exceeded their respective control limits (red lines) about the same time after the experiment began, suggesting a signal. The Bernoulli CUSUM transmits a delayed signal. The run length function can be used to calculate the time required to reach the control limit for the charts.

```
ARL_log2 <- c(mean(sapply(valid_oc_charts, function(x) if (!is.null(x$bk)) runlength(x$bk, h = h_bk) else NA), na.rm = TRUE))
```

The run length of the charts is based on the shortest time participants entered specified data. The trial begins with the first-person undergoing accident. Control limits are not required for the funnel plot, thus steps 2 and 3 can be avoided. To display the funnel plot, we use the plot function.

```
funnelplot <- plot(funnel_plot(data = accident_data, glmmod = glmmod, followup = 16, po = expected_failure_prob)) + ggtitle("Funnel plot")
```

Figure 2 displays the resulting plot. The blue rectangles show the 95% and 99% of the prediction ranges. A single dot suggests a hospital, and the colour shows the prediction limit at which it will be signalled. If a hospital goes outside of the predicted range, it will be reported at that level.

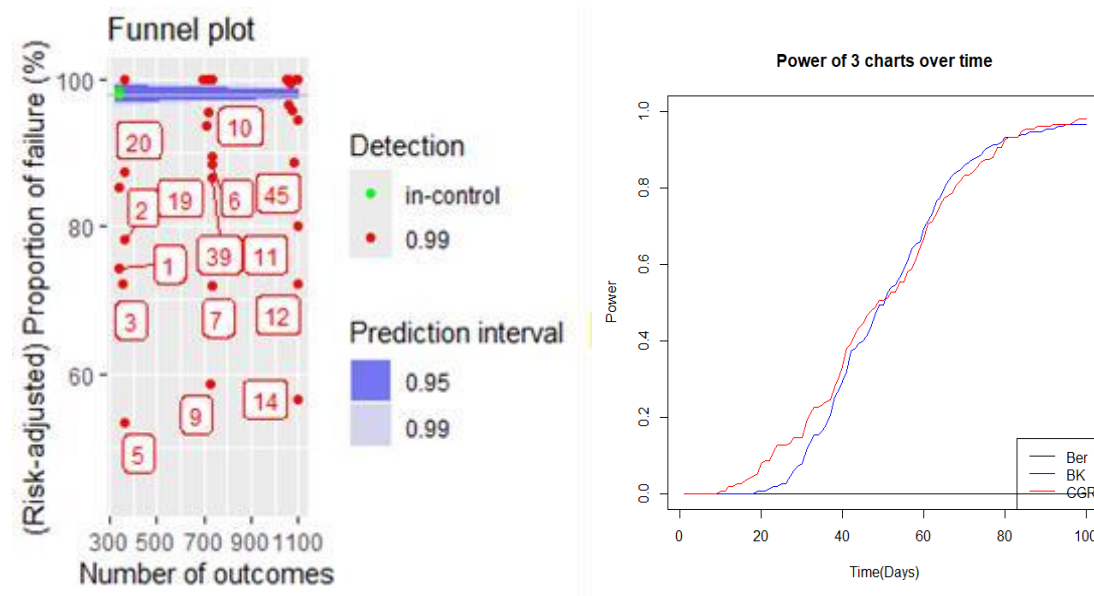


Figure 2 Funnel plot for hospitals and power chart

To increase or decrease chart values based on their corresponding control limits, specify scale

= TRUE. After scaling, all CUSUM charts will have a control limit at $h = 1$. By selecting highlight = TRUE, users can highlight CUSUM charts by hovering over them. Plotly offers a variety of interactive plotting options.

1.16 APPLICATIONS

The R Package Success utilized by the above simulated data set to show how to use the package. The data used for the study is simulated accident data produced by the success package. This application section shows how to use the real-world application, secondary data on mental health patients' treatment details is obtained from data.gov.in (India's open government data (OGD) platform). Covariates are available for 500 patients who underwent different treatments. Additionally, the time from the accident to the combined endpoint is known. To analyse the data with the success package, we must first organize it as mentioned in Section the R package success. The outcome of interest is event-free survival. Patients who did not experience an event during the study period had their observations censored based on their last known event-free status. The trial began with the first patient undergoing treatment. The data was saved as a data.frame named mental health data, which can be loaded using the data function. To develop risk-adjustment models, we employ a 50-unit post-surgery follow-up as an outcome. To alter risk in funnel plots and Bernoulli CUSUMs, we use a logistic model, whereas BK- and CGR-CUSUMs are modified using a Cox model.

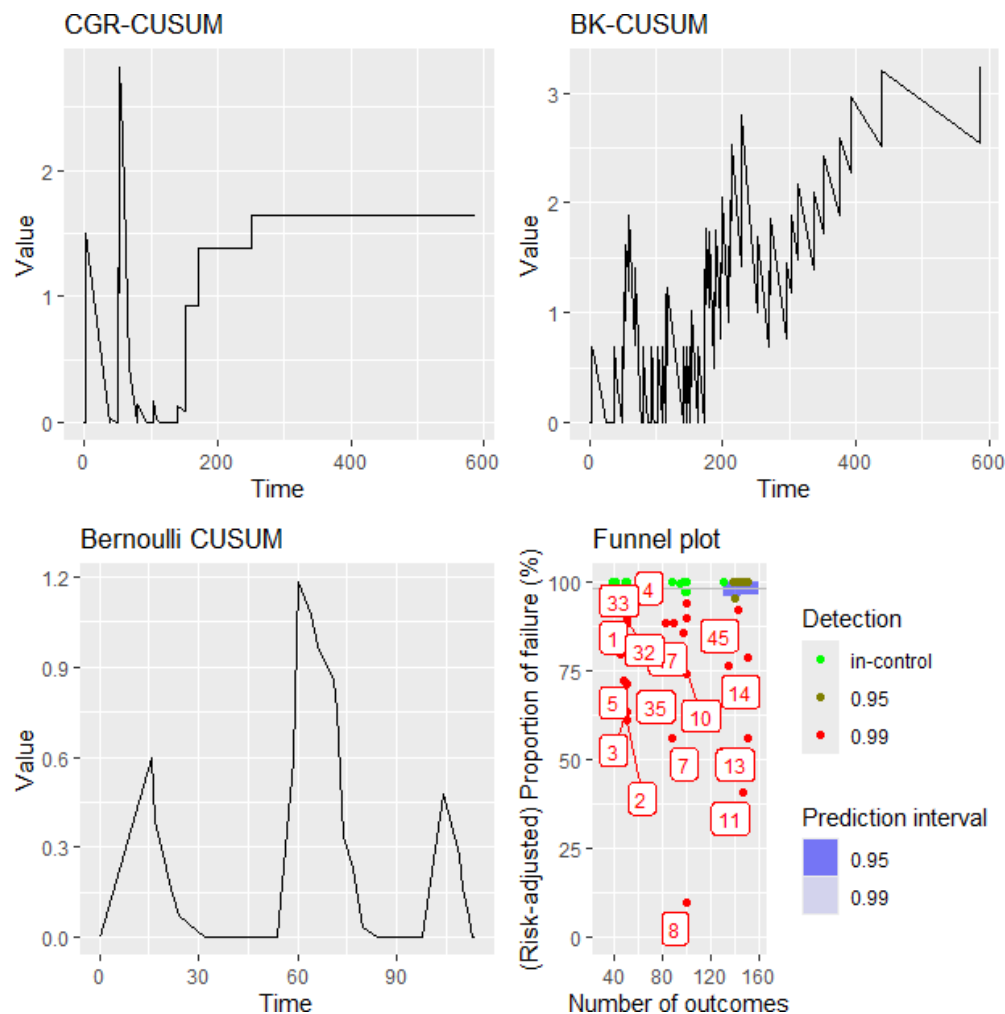


Figure. 3 Bernoulli, BK- and CGR-CUSUM charts for hospital

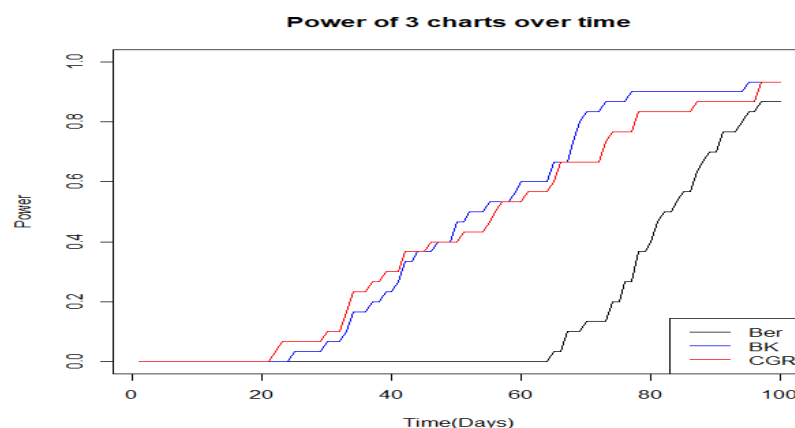


Figure.4 Power of 3 charts over time

For the most applications, the CGR-CUSUM provides faster detection times than the BK- CUSUM. This is due to the fact that the change in failure rate at a hospital is progressive and not instantaneous. As a result, the CGR-CUSUM will function well in practical circumstances. The expected true hazard

ratio $\exp(\theta)$ is unknown or varies over time. In reality, the CGR-CUSUM outperforms the BK-CUSUM in terms of detection time while retaining a similar number of "false" detections. It's worth noting that we don't know whether the hospitals identified by the funnel plot were truly hospitals. Instead of emphasizing "absolute" issues, van Schie and colleagues (2020) propose utilizing the funnel plot as an indicator. Overall, the CGR-CUSUM method is the most effective for quality inspection, especially with high arrival rates (ψ). Based on the simulation study, we discovered that the CGR-CUSUM can supply more power than the BK-CUSUM, although it may require some adjustments. Figure 3 shows the Bernoulli, BK- and CGR-CUSUM charts for mental health data. Figure 4 show the power of the charts. The ARL values of BK-CUSUM is 43.67 and CGR-CUSUM is 36.26. To the application data both BK-CUSUM and CGR-CUSUM have small differences only due to the sample size. But ARL values prove the CGR-CUSUM control charts performs better than the other two control charts.

1.17 CONCLUSION

The objective of this work is to develop an advanced statistical technique for evaluating treatment outcomes and monitoring healthcare quality using CUSUM control charts. By integrating survival analysis and risk-adjusted quality control, the approach ensures great sensitivity to performance changes while considering patient-specific variability. This integrative strategy was developed utilizing the success (survival control chart estimating software) package in R programming. For practical applications, we suggest applying the CGR-CUSUM to ensure quality control. However, it is critical to limit the highest likelihood estimate to an appropriate range. For small hospitals, the BK-CUSUM may be preferable if there is prior knowledge of the expected increase in failure. Prior knowledge can help to compensate for the limited information recalled by patients. A funnel plot is not advised because it is not a real-time method and may raise the risk of type I errors when performing multiple tests. To set control limits for CUSUM charts, either minimize the projected likelihood of a type I error over time or restrict the chart's average run length. The first technique may be preferred because of its low computational requirements. Ideally, the baseline hazard rate should be estimated using a dataset that is known to be under control. This is unlikely to be possible in many situations. It is often sufficient to take into account the average national rate of failure to maintain control. Control limits must be revised if the distribution of risk factors in the population shifts dramatically. Real-time gathering of patient failure data is possible, although consolidation across multiple institutions is improbable. If the risk distribution has changed over time, the CUSUM charts may need to be redrawn, which could result in new or different outcomes detections. The use of CUSUM charts for risk-adjusted monitoring provides a dependable approach for improving clinical outcomes and maintaining standards in healthcare settings.

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