

## The Effect of Estimation Error on Risk-adjusted Bernoulli GEWMA Control Chart in Multistage Healthcare Processes

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### Abstract

**Background and objectives:** Risk-adjusted Bernoulli control chart is one of the main tools for monitoring multistage healthcare processes to achieve higher performance and effectiveness in healthcare settings. Using parameter estimates can lead to significantly deteriorate chart performance. However, so far, the effect of estimation error on this chart in which healthcare services delivery is considered as Bernoulli response variable has not been surveyed.

**Methods:** We examined the effect of estimation error on the in- and out-control performance of Bernoulli Group Exponentially Weighted Moving Average (GEWMA) risk-adjusted chart for multistage healthcare processes. In this paper, the effect of estimation error is indicated by run length properties using repeated sampling of the data under different scenarios in both in- and out-of-control situations. In this regard, three methods of increasing sample size, adjusting control limit, and applying Dynamic Probability Control Limits (DPCL) are proposed to diminish the effect of estimation error on the proposed chart. Also, DPCL are applied in both zero- and steady-states.

**Results:** Simulation results showed that estimation error can have a substantial effect on Bernoulli GEWMA risk-adjusted chart performance. Also, results show that the effect of estimation error can be serious, especially if small samples are applied. Using our simulation, control limit can be adjusted in a given sample size to reduce the effect of parameter estimation for medical situations in which there is not enough sampling data.

**Conclusion:** Applying the DPCL has the superior performance than the other proposed methods to reduce the estimation error especially in steady state. Moreover, a comprehensive analysis on results allows us to provide suitable sample size recommendations in constructing these charts to reach a desired hospital performance.

**Keywords:** Monitoring healthcare performance, Average Run Length (ARL), Dynamic Probability Control Limits (DPCL), Sample size, Adjusting control limit.

### Background and objectives

Statistical process control (SPC) was firstly applied in laboratory and after then shifted to patient level in hospitals. As there is more involvement of human in healthcare, the chances of errors are also more. SPC i.e., control chart can help in determining the source of errors by identifying the special and common causes of variations. The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has developed a set of core measurements that focus on five key types of preventable deaths: acute myocardial infarction, heart failure, ventilator-assisted pneumonia, surgical infection prevention, and complications in pregnancy. The JCAHO measurements are just one example of clinical SPC data. There is some evidence that control charts are being increasingly used in hospital leadership and management.

In healthcare context, risk adjustments are needed so that hospital specialists can diagnose changes in medical processes due to the patient's prognosis at the start of the processes from changes that are due to a critical problem in medical processes. Hence, some risk-adjusted control charts are suggested to consider patient heterogeneity.

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Risk-adjusted control charts are widely used tools for monitoring healthcare processes and health policy improvement. Among these risk-adjusted charts, Steiner et al.<sup>1, 2</sup> first designed a risk-adjusted cumulative sum (CUSUM) chart using the logistic regression model which is fitted with the covariates and Bernoulli surgery outcome within thirty days for each patient. In healthcare-related studies, Tsui et al.<sup>3</sup> conducted a comprehensive review of applications of statistical processes control for monitoring of different subjects in healthcare, public health, and syndromic surveillance. Usually, healthcare processes comprise multiple stages in real-world applications. Health policy often comprises of dynamically interdependent processes. Medical systems contain some stages whose quality is affected by their risk levels, as well as the risk of the preceding stages. However, most works on healthcare performance monitoring study clinical outcomes in a single stage. As one of the first works, Sibanda<sup>4</sup> used the regression adjustment model for monitoring in healthcare multi-stage processes in Phase II. Recently, Sogandi et al.<sup>5</sup> designed a risk-adjusted Bernoulli chart for multi-stage healthcare processes with DPCL based on state-space models. They introduced a latent risk variable in their model to consider all of the risks that are unmeasurable, undetectable and invisible.

Usually, the risk-adjusted control charts concentrate on phase II monitoring in which the parameters of the risk-adjusted models are assumed known or can be precisely estimated. This assumption simplified the design and evaluation of control charts. However, in real applications, the parameters are unknown and must be estimated with limited historical data gathered from the phase I monitoring, which is known. The error due to parameter estimation inevitably affects the risk-

adjusted control chart performance in both in- and out-of-control situations. Then, the performance of every estimated chart has to be evaluated. The most commonly used metrics are the ARL and the Standard Deviation of the Run Length (SDRL).

So far, estimation error has been studied for various control charts in industrial settings. For example, Castagliola et al.<sup>6</sup> surveyed the effect of estimating the process variance on the properties of  $S^2$  control chart. Zhang and Castagliola<sup>7</sup> investigated the run length properties of the run rules X chart with estimated parameters. The effect of parameter estimation for Shewhart-type charts was surveyed by some authors such as Quesenberry<sup>8</sup> and Albers and Kallenberg<sup>9</sup>, while Jones et al.<sup>10,11</sup> worked on estimation error for the EWMA and CUSUM charts. Also, Zhang et al.<sup>12</sup> showed that parameter estimation substantially affects the properties of VSI X chart. Jensen et al.<sup>13</sup> evaluated the effect of estimation error on the ASSI X chart. They proved that the use of estimated parameters resulted in an important change in the chart's statistical properties. Jones<sup>14</sup> relaxed the assumption of known parameters and designed procedures for the developed EWMA chart. Moreover, Maravelakis and Castagliola<sup>15</sup> suggested a modified EWMA control chart for monitoring the standard deviation when the parameters are estimated. In addition, Ozson et al.<sup>16</sup> investigated the effects of parameter estimation on the performance measures of the exponential EWMA control chart. After that, Saleh et al.<sup>17</sup> assessed the in-control performance of the EWMA control chart in terms of the SDARL and percentiles of the ARL distribution when the process parameters are estimated. Also, Capizzi and Masarotto<sup>18</sup> studied the behavior of the combined Shewhart–EWMA with estimated parameters in both in- and out-of-control situations. For more information about estimation error

researches, Psarakis et al.<sup>19</sup> and Jensen et al.<sup>20</sup> gave the review papers.

In spite of considerable works on estimation error in industrial applications, a little work has done on healthcare applications. In this respect, Jones and Steiner<sup>21</sup> surveyed the effect of parameter estimation on risk-adjusted Bernoulli CUSUM performance using actual and simulated data on patients undergoing coronary artery bypass surgery. Afterward, Zhang and Woodall<sup>22</sup> reduce the impact of parameter estimation on in-control performance for risk-adjusted Bernoulli CUSUM Chart with DPCL. In this respect, Zhang and Woodall<sup>23</sup> extended a simulation-based method to determine DPCL for risk-adjusted CUSUM charts based on the method of Shen et al.<sup>24</sup>. Also, Zhang et al.<sup>25</sup> took into account the effect of parameter estimation error on the performance of the risk-adjusted survival time CUSUM control chart in continuous time with cardiac surgery data.

Usually, in the context of monitoring healthcare, researchers concentrate on the surgical quality characteristic. In this respect, process monitoring with Bernoulli data is a challenging issue. In these situations, logistic regression models are utilized for patient's risk adjustment. Woodall et al.<sup>26</sup> gave an extensive review paper on the monitoring of Bernoulli variables in the healthcare context. There are many studies in which risk-adjusted charts are designed using Bernoulli response. Spiegelhalter et al.<sup>27</sup> presented a control chart that included risk adjusted CUSUM chart as a resetting sequential probability ratio test chart. Besides, some risk-adjusted charts monitor the number of successful events between two unsuccessful events. For further details about these monitoring procedures, one can see the review papers by Grigg and Farewell<sup>28</sup> and Woodall<sup>29</sup>.

Driven by the need to appropriately monitor Bernoulli outcome for healthcare services

delivery, we focus on Bernoulli response variables in the healthcare setting. Also, we take into account monitoring the healthcare process with both inter-stage and intra-stage links by considering multistage processes. In this regard, we utilized proposed risk-adjusted Bernoulli GEWMA and modeling of multistage healthcare processes based on the state-space model given by Sogandi et al.<sup>5</sup>. On the other hand, the effect of parameter estimation will always exist since the model parameters are estimated using sampling which is subject to error due to random variation. Thus, the purpose of this research is assessing the effect of estimation error on risk-adjusted Bernoulli GEWMA control chart in multistage healthcare processes. Furthermore, we propose some methods to reduce this effect. The paper is organized as follows: In Section 2, the proposed methodology is given for assessing the effect of estimation error on risk-adjusted Bernoulli GEWMA control chart. Also, three approaches of increasing sample size, adjusting the control limit, and applying DPCL are provided to diminish the mentioned effect. In Section 3, the simulation studies about the effect of estimation error are done using repeated sampling of the data under different scenarios in both in- and out-of-control situations. Section 4 discusses the comparison of the proposed methods and gives some guidelines for choosing the situation and observations able to guarantee the desired performance of monitoring healthcare policy. Finally, in the last section, some concluding comments are given and some ideas for future research in this area are suggested.

## Method

In this section, the performance of the risk-adjusted Bernoulli GEWMA chart with estimated parameters are discussed in both in-control and out-of-control situations. This

allows us to find out how each of the parameter estimates individually affects the chart performance. The notations and model assumptions are consistent with the assumption made in the simulations of

Sogandi et al.<sup>5</sup>. Because the GEWMA chart is utilized to detect persistent changes in a healthcare multi-stage process. On this subject all of the used notations are given in Table 1.

**Table 1.** The used notations in our simulation runs.

Notation	Definition
$y_{ij}$	Response variable for $i$ th patient at the $j$ th stage.
$K_j$ ( $k_j=1,2, \dots, K_j$ )	Number of categorical covariates including $c_{k_j}$ levels for $k_j=1,2, \dots, K_j$ at the $j$ th stage.
$c_{k_j} - 1$	Number of dummy variables for each categorical variable to show its different levels.
$\pi_{ij}$	Failure rate of the $i$ th patient at the $j$ th stage.
$\theta_j$	Model parameter which is indirect effect of risks on the response variable at the $j$ th stage.
$\mathbf{x}_{ij} = (1, x_{ij1}, \dots, x_{ijp})$	Vector of $p$ risk factors for the $i$ th patient at the $j$ th stage.
$\boldsymbol{\beta}_j^T = (\beta_{j0}, \beta_{j1}, \dots, \beta_{jp})$	Coefficients vector of risk factors.
$\boldsymbol{\gamma}_{jk_j}$	Model vector which is the effect of covariate $k$ th on the response variable at the $j$ th stage.
$w_{ij} \square N(0, \sigma_{w_j}^2)$	Process noise with fixed variance for the $i$ th patient at the $j$ th stage.
$l_{i0} \square N(a_0, \sigma_0^2)$	Initial latent risk variable with known variance for the $i$ th patient.
$\mathbf{d}_{ijk_j} = (d_{ijk_j2}, \dots, d_{ijk_jl}, \dots, d_{ijk_jc_{k_j}})^T$	Vector of dummy variables in which $d_{ijk_jl}$ is equal to 1 when the $k$ th categorical variable is at $l$ th level and is equal to 0 otherwise for the $i$ th outcome at the $j$ th stage.
$\mathbf{d}_{ijk_jl} = 0$	Vector of dummy variable for $l=2, \dots, c_{k_j}$ when $k$ th categorical variable is at its first level.
$\boldsymbol{\gamma}_{jk_j}^T = (\gamma_{jk_j2}, \gamma_{jk_j3}, \dots, \gamma_{jk_jc_{k_j}})$	Coefficients vector of the $k$ th dummy variables with the $c_{k_j}$ levels in which $\gamma_{jk_jl}$ relates to $l$ th level of the $k$ th categorical covariate at the $j$ th stage.
$\sigma_{ij}^2$	Variance of $y_{ij}$ for the $i$ th patient at the $j$ th stage.
$N$	The number of Bernoulli random variables for design DPCLs.
$\zeta$	Stage in which a shift has occurred.
$z_{ij}$ and $\lambda$	Statistic for the $i$ th patient at the $j$ th stage and smoothing coefficient, respectively.
$\mathbf{Y}_{ij,t}$ ( $t = 1, 2, \dots, N$ )	$t$ th simulated Bernoulli random variable

The main advantage of this chart is that it can detect quickly small and moderate changes. It is worth mentioning that the charts which are more sensitive to smaller process shifts are more severely affected by parameter estimation.

To determine the effect of estimation error, the simulations are performed in the following steps:

1. Assume that the vectors  $\boldsymbol{\gamma}_{jk_j}$  and  $\boldsymbol{\beta}_j$  are known and, based on 7000 replications (true patient population), select the values of UCL such that

the  $ARL_0 = 200$ . The appropriate control limit can be determined by repeatedly using the Monte Carlo with different values of Upper control limit (UCL) until an appropriate threshold is achieved.

2. Sample Phase I data with sample size equal to  $n$ , from the assumed true patient population. Then, use the data to estimate the parameters of the risk-adjustment model.
3. Generate random variable Bernoulli  $y_{ij}$  based on the known parameters.
4. Calculate  $MZ_i$  statistics  

$$MZ_i = \max_{1 \leq j \leq J} \left( \sqrt{\frac{2-\lambda}{\lambda}} |z_{ij}| \right)$$
 for  $i=1, 2, \dots, n$  using the estimated parameters in step 2.
5. If the values of the computed statistics in Step 4 are equal to or

smaller than the UCL in step 1, then set  $RL = RL + 1$  and go to Step 3; Otherwise, go to Step 6 if the value of the statistic is larger than the control limit.

6. Record RL and go to step 2.

Now, we need 10000 replications for steps 2 to 6 to calculate  $ARL_0$ ,  $SDRL_0$ , and  $CVRL_0$ . According to the mentioned steps, we generate 7000 simulated data using the assumed parameters in Sogandi et al.<sup>5</sup>. Afterward, the vectors  $\gamma_{jk_j}$  and  $\beta_j$  are estimated based on historical data by means of the maximum likelihood approach which is in Appendix. On the other hand,  $\theta_j$  are estimated by fitting the regression model of  $l_{ij}$  and  $l_{i(j-1)}$ . The estimated parameters in Bernoulli state-space model are as follow:

**Table 2.** The estimated parameters in Bernoulli state-space model.

Parameter	$\gamma$	$\theta$	$\beta$
Stage 1	1.153	2.104	(0.897,1.053)
Stage 2	0.792	1.208	(1.104,2.121)
Stage 3	1.098	1.976	(1.21,0.899)

In practice, it is never known whether the parameters are under or overestimated. Thus, it is also important to perform a general study of the overall estimation effect on the risk-adjusted Bernoulli GEWMA chart performance. To appraise this performance criteria  $ARL$ ,  $SDRL$ , and  $CVRL = \frac{SDRL}{ARL}$  are used. Using replacing the estimated parameters, the accurate Bernoulli state-space model is achieved. The UCL is simulated by the accurate Bernoulli state-space model and  $MZ_i$  statistics such that

$ARL_0 = 200$  is given. Afterward, we use different samples size 100, 200, 300, 400, 500, 600, 750, 1500, and 3000 to show the effect of the estimation error of the Phase I monitoring on Phase II monitoring.

Note that these samples are chosen randomly by 5000 patients. Then, the parameters are estimated again using these samples and the  $MZ_i$  statistics are recalculated using them in designing the control chart. Afterward, the criteria  $ARL_0$ ,  $SDRL_0$ , and  $CVRL_0$  are reported in Table 3.



**Table 3.** The criteria  $ARL_0$ ,  $SDRL_0$ , and  $CVRL_0$  in different samples size.

Criterion			$N$
CVRL	SDRL	ARL	
2.2804	853.2569	374.0165	100
1.8009	456.8127	253.6510	200
1.6071	369.3214	229.7956	300
1.3613	289.1872	212.4192	400
1.3076	274.7190	210.0925	500
1.2275	254.6495	207.4474	600
1.1380	231.9241	203.7893	750
1.0449	210.9958	201.9274	1500
1.0051	201.8460	8059.200	3000
1.0011	200.3752	200.1056	5000

Now, three methods of increasing sample size, adjusting the control limit, and applying DPCLs are proposed to diminish the effect of estimation error on the proposed control chart.

#### \*Increasing the sample size

In light of the deterioration of the risk-adjusted Bernoulli GEWMA chart that results from parameter estimation, one may wish to collect a sample of data large enough to ensure that the estimates of  $\gamma_{jk_j}$  and  $\beta_j$  are sufficiently close to their true values. The determination of the minimum sample size required to properly estimate the parameters if they are unknown is an important consideration when setting up a chart for monitoring. This minimum sample size requirement indicates how much data should be accumulated before implementing phase II monitoring, in which reliable control limits are designed to enable us to monitor correctly. Gradual increasing the sample size determines the sample size required for the proposed chart with estimated parameters to perform like one with known parameters. On this subject, minimum sample sizes are estimated in Phase I to achieve minimum  $ARL_0$  under different percentages of the achievement.

Thus,  $\Delta$  is a percentage of achievement from  $ARL_0$  with known parameters and is as follows:

$$\Delta = 100 \times \left( 1 - \frac{|ARL_0 - ARL_m|}{ARL_0} \right) \quad (1)$$

Now, minimum of sample sizes in Phase I is estimated to achieve minimum of  $ARL_0$  under different percentage of achievement according to Eq. (1) using simulation approach. In this regard, the minimum values of  $N$  and corresponding criteria are reported in Table 4 to achieve  $\Delta \in \{80\%, 85\%, 90\%, 95\%\}$ .

#### \*Adjusting control limit

Apley and Lee<sup>30</sup> presented a method for widening the control limits of the residual-based EWMA charts by using the upper boundary of the confidence interval of the true EWMA standard deviation. Although widening control limits can achieve a desired false-alarm rate, it decreases the detection power of the control chart. To lessen the severity of the trade-off from widening control limits, the best solution (when possible) would be to collect a large sample size to reduce parameter uncertainty. Since this number of samples is considered to be too large to be used in most practical applications, they proposed the use of adjusting the control limit. Adjusting the

control limit approach leads to the construction of control charts with estimated limits that achieve the desired  $ARL_0$ . On this subject, the adjusted UCLs of the proposed control are calculated to obtain  $ARL_0 = 200$  chart using simulation studies. These adjusted UCLs are given in Table 5 for different  $N$ .

### \*Applying dynamic probability control limits

Applying fixed control limit ignores the risk distribution of patients. Therefore, Sogandi et al.<sup>5</sup> propose a DPCLs to remove the effect of different populations of patients on the  $ARL_0$  for risk-adjusted Bernoulli GEWMA chart. A simulation-based method first proposed by Shen et al.<sup>24</sup> is developed. Their idea is related to the concept discussed by Margavio et al.<sup>31</sup> in which the probability of a type I error is fixed from sample to sample conditional on no false alarms for the previous samples. For the proposed control chart based on Bernoulli state-space model, DPCLs  $\mathbf{h}(\alpha) = (h_1(\alpha), h_2(\alpha), \dots, h_k(\alpha), \dots)$  are considered to satisfy Eq. (2) to the extent possible.

$$\begin{cases} \Pr(Mz_1 > h_1(\alpha) | x_1, d_1, l_1) = \alpha, \\ \Pr(Mz_i > h_i(\alpha) | Mz_k < h_k(\alpha), 1 \leq k < i, x_i, d_i, l_i) = \alpha, \text{ for } i=2,3,\dots, \end{cases} \quad (2)$$

where  $\alpha$  is the predetermined conditional type I error rate. Furthermore,  $x_i, d_i$  and  $l_i$  are the sequence of risks which are explained in Sogandi et al.<sup>5</sup>. Based on Eq. (2), the in-control run length roughly follows a Geometric distribution with parameter  $\alpha$ . For each patient,  $Mz_i$  is calculated according to (3) based on the response variables and all of the given risks. In applying DPCL method, it should be performed a sample with size  $N$ . Then, the parameters of the Bernoulli state-space

model are estimated based on the considered sample. Afterward, a lot of random variables (for instance  $N=500$ ) are generated using the estimated parameters and risk variables. Also, GEWMA statistics are calculated according to Sogandi et al.<sup>5</sup>. After that these values are sorted increasingly and quartiles  $\alpha$  are considered as the UCL. Then, the parameters of Bernoulli state-space model (vectors of  $\gamma_{jk_j}$  and  $\beta_j$ ) are estimated for all of the observation. Now, the statistic for observation which is monitored should be calculated using these estimations. If the value of the computed statistic is equal to or smaller than the considered UCL, then  $RL = RL + 1$  is set. If the value of the statistic is larger than the control limit, RL value is record. It is worth mentioning that value  $Z_{ij}$  is chosen randomly from in-control values in previous replication. Here, we can investigate the effect of the parameter estimation by adjusting  $N$  at the start of the algorithm in terms of the criteria. The algorithm of the simulation-based procedure is implemented to apply DPCL to diminish estimation error according to the following flowchart:

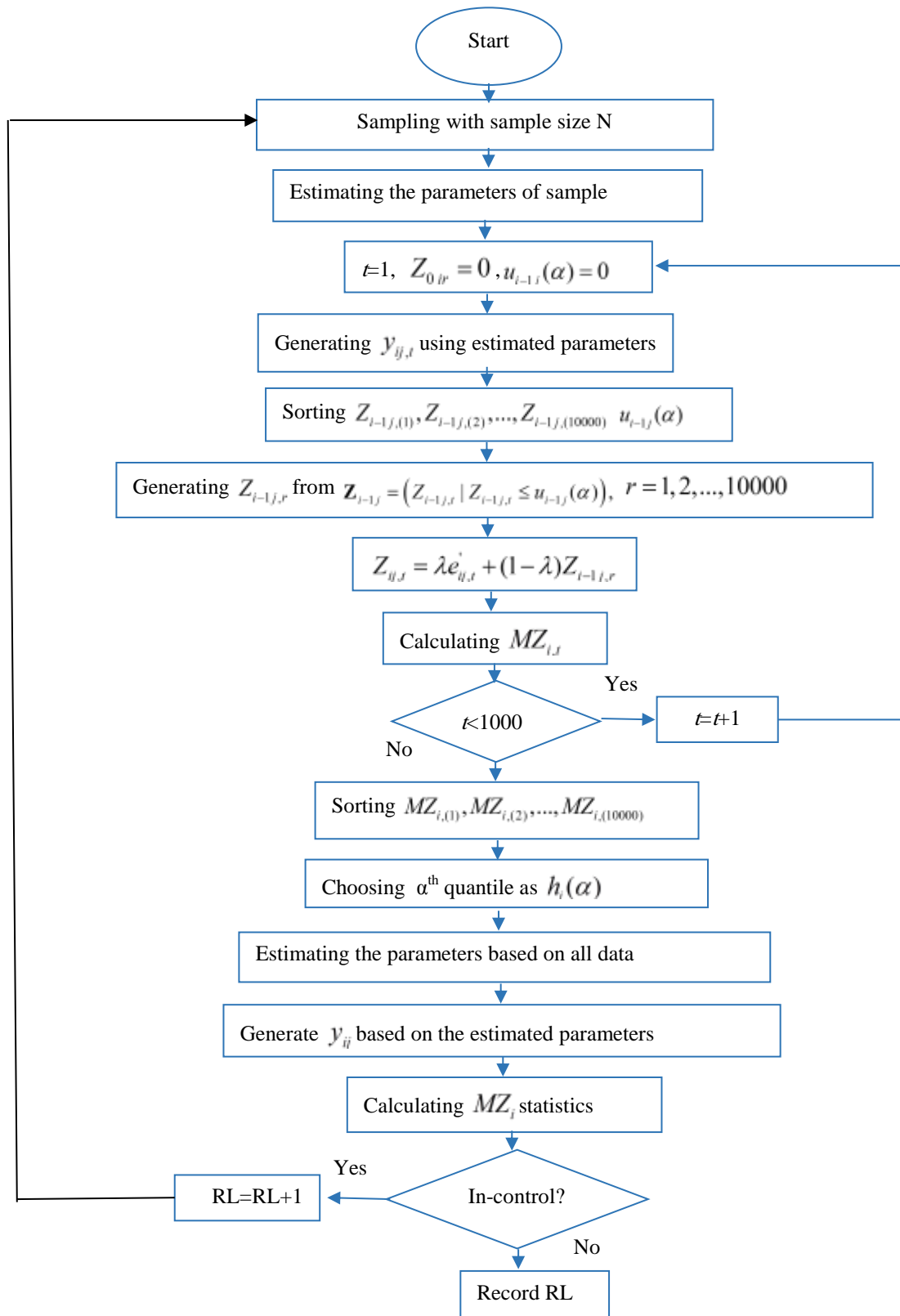


Figure1. Flowchart of the applying DPCL in the proposed control chart to survey the estimation error.



Now, the performance of risk-adjusted Bernoulli GEWMA control chart with DPCL is appraised in terms of the criteria and using simulation. According to the aforementioned method in applying DPCL, these criteria are reported under different  $N$  in Table 6.

#### \*Performance of the proposed control chart with estimated parameters in out-of-control state

In this section, regarding to the effect of the estimation error on the Phase II monitoring of the healthcare processes, performance of the proposed control chart with estimated parameters is evaluated in out-of-control state. In this regard, the assumption of the model and the imposed shifts are according to Sogandi et al.<sup>5</sup>. We use the applying DPCL method to reduce the effect of the parameter estimation in monitoring healthcare multi-stage processes. Thus, the criteria  $ARL_1$ ,  $SDRL_1$ , and  $CVRL_1$  are given in Table 7 under single stage and multiple stage with  $N \in \{100, 500, 1000, 1500, 3000, 10000\}$ . It worth mentioning that using  $N=10000$  indicates all of the parameters are known.

Similarly, these simulation results are performed under steady state in Table 8. Since Sogandi et al.<sup>5</sup> showed that the risk-adjusted Bernoulli GEWMA control chart in steady-state ( $\tau=150$ ) perform better than the same chart under zero-state ( $\tau=1$ ).

## Results

As shown in Table 4, when parameter estimates are used instead of known parameters,  $ARL_0$  values are different. In this regard, increasing the sample size with estimated parameters leads to close  $ARL_0$  values to  $ARL_0$  values with known parameters  $ARL_0=200$ . Also,  $SDRL_0$  values are decrease by increasing sample size to close  $SDRL_0$  values with known parameters. The criterion  $CVRL_0$  which represents a measure of variation per unit mean, is reduced by increasing sample size to achieve known parameters as far as possible. As seen in Figure 2, the performance of the control chart with estimated parameters is similar to the same chart with known parameters for sample size equal to 5000.

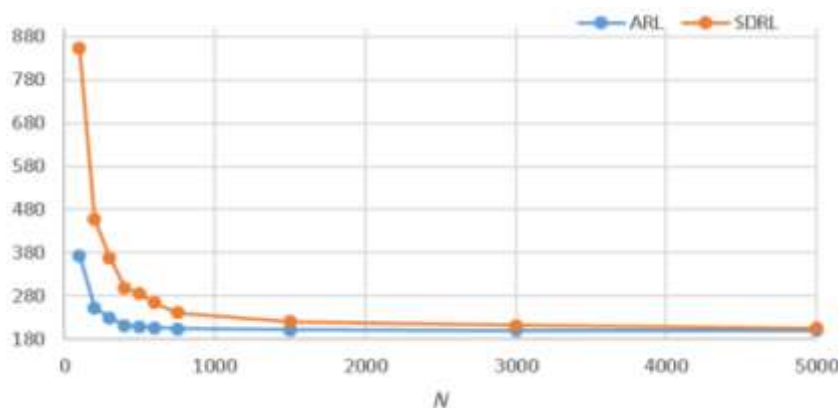


Figure 2.  $ARL_0$  and  $SDRL_0$  values with estimated parameters for different sample size and fixed limit.

The sample size 5000 required to obtain a chart performance similar to that of the

known parameter case. The properties of the run-length are quite different than those corresponding to the case of the known parameters. The difference decreases as the

number of phase I samples increases and becomes negligible. Note that for small values of the smoothing constant,  $\lambda$ , the false alarm rate for the estimated parameters chart is higher than that of the known parameters chart. Because, the estimation error in the parameters introduces additional shifts in the residuals, which means that the

risk-adjusted Bernoulli GEWMA chart shows more false alarms than when  $\gamma_{jk_j}$  and  $\beta_j$  are known. Here, Table 4 show a minimum sample size for the different achievement of  $ARL_0$  using Eq. (1) based on simulation results.

Table 4. The appropriate sample size for the different  $\Delta$ .

$\Delta$				Criterion
%95	%90	%85	%80	
510	383	295	240	$N$
209.8727	217.8796	230.1215	241.0011	$ARL$
265.7194	316.6243	376.2075	405.2857	$SDRL$
1.5086	1.4399	1.6348	1.6816	$CVRL$

Table 4 shows the results for investigating the effect of different sample sizes on the performance of the control chart. Moreover, a well-understood result of the effect of different sample size indicates increasing the

sample sizes improves the criteria. For example, the results showed that 295 sample size is required to reach  $\Delta=85\%$  for risk-adjusted Bernoulli GEWMA charts with smoothing constants of 0.2.

Table 5. UCL values to achieve  $ARL_0 \approx 200$

Criterion				$N$
$CVRL$	$SDRL$	$ARL$	$UCL$	
2.9128	582.6985	200.0447	2.8401	100
1.9125	382.7602	200.1258	2.9147	200
1.888	377.2221	199.7204	2.9366	300
1.4210	285.5384	200.9337	2.9529	400
1.2738	254.8834	200.8684	2.9624	500
1.2331	245.7639	199.2949	2.9635	600
1.2178	243.7353	200.1294	2.9641	750
1.0681	214.4785	200.8035	2.9711	1500
1.0125	203.2219	200.7110	2.9730	3000
1.0011	200.3752	200.1056	2.9736	5000

As seen in Table 5, decreasing  $N$  value lead to close the control limit. For example, it is necessary to UCL is closed around one percent to obtain  $ARL_0=200$  under  $N=200$ . While for  $N=150$ , it should be closed less

than 0.5 percent and the control limit is widened. Note that if the control limits will be too tight, the risk-adjusted Bernoulli GEWMA control chart will signal more frequently.

Table 6. The  $ARL_0$ ,  $SDRL_0$ , and  $CVRL_0$  for different  $N$  in DPCL method.

Criterion			$N$
$CVRL$	$SDRL$	$ARL$	
1.0085	213.5295	211.7258	100
1.0047	210.8102	209.8242	200
0.9975	208.5425	209.0558	300
0.9975	206.5996	207.1102	400
0.9974	209.6904	210.1652	500
0.9946	207.3782	208.5031	600
0.9885	205.2641	207.6437	750
1.0085	205.6712	203.9271	1500
1.005	204.0137	202.8298	3000

As shown in Table 6, risk-adjusted Bernoulli GEWMA control chart with the estimated parameters has a satisfactory performance. Because, the  $ARL_0$  values are close to the real  $ARL_0$  (200). The signal probability of the risk-adjusted Bernoulli GEWMA chart with estimated parameters under the shift is smaller than when  $\gamma_{jk_j}$  and  $\beta_j$  are known.

Comparing the results of the Tables 6 with 2 indicates that the proposed control chart with DPCL outperforms this chart with fixed control limit. In this regard, Figure 3 demonstrates the  $ARL_0$  and  $SDRL_0$  values for different  $N$  for the proposed control chart with applying DPCL.

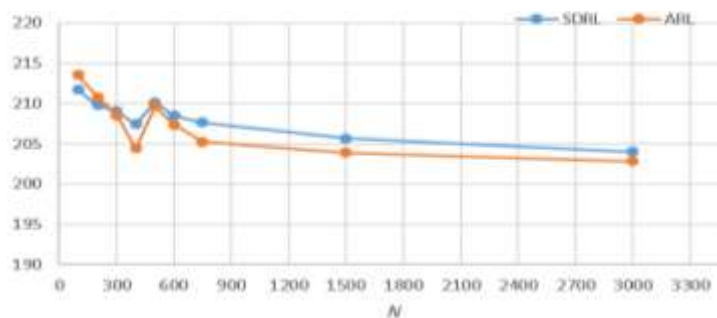


Figure 3.  $ARL_0$  and  $SDRL_0$  for different  $N$  in DPCL method.

As seen in analysis of Tables 7 and 8, it is clear that the detection power also depends on the different  $N$ . Furthermore, the performance of the mentioned control chart

does not depend on stages in which the shifts are imposed. So, we analyze the simulation results for only  $j=2$  for the sake of simplification. Also, results show

increasing sample size leads to partially decrease  $ARL_1$ . Because parameters are estimated based on the more data in determination of DPCL and then accuracy of the estimations increases. Hence, the performance of the proposed control chart improves. As we expected, when statistics are designed based on known parameters have better criteria than statistics and DPCLs are designed based on estimated parameters. Also, it can be concluded that smaller values are obtained with increasing  $N$ . For example, under magnitude of shifts

$(\cdot, \cdot, \cdot, \delta, \cdot, \cdot, \cdot, \cdot)$ , increasing  $N$  (1500 to 3000) leads to decreasing  $SDRL_1$  (116.3354 to 86.8951). Considering  $CVRL_1$ , it can be seen that increasing sample size in Phase I reduces variation of the run length. Analysis of the performance summaries in Table 8 is similar to Table 7. Similarly, these results show increasing sample size leads to partially decrease  $ARL_1$ . Note that risk-adjusted Bernoulli GEWMA chart with DPCL in  $\tau=150$  outperform this chart in  $\tau=1$ .

Table 7.  $ARL_1$ ,  $SDRL_1$ , and  $CVRL_1$  under the different shifts and  $N$  values,  $\tau=1, j=2$ .

$N$	$(\delta_1, \delta_2, \delta_3, \delta_4)$	$ARL_1$	$SDRL_1$	$CVRL_1$
100	(0.5,0,0,0)	44.7303	178.7856	3.9970
	(0,0.5,0,0)	42.7165	169.9954	3.9796
	(0,0,0.5,0)	42.521	167.1052	3.9299
	(0,0,0,0.5)	45.28	181.2354	4.0025
	(0,0.1,0,0.5)	38.6277	149.2951	3.8650
	(0,0,0.5,0.1)	35.97	139.0021	3.8644
500	(0.5,0,0,0)	44.6999	138.6652	3.1021
	(0,0.5,0,0)	42.6861	132.0053	3.0925
	(0,0,0.5,0)	41.6026	128.2256	3.0822
	(0,0,0,0.5)	47.249	147.3457	3.1185
	(0,0.1,0,0.5)	38.5973	118.655	3.0742
	(0,0,0.5,0.1)	33.9425	98.9651	2.9157
1500	(0.5,0,0,0)	44.656	122.0752	2.7337
	(0,0.5,0,0)	42.6422	116.3354	2.7282
	(0,0,0.5,0)	41.5587	112.9158	2.7170
	(0,0,0,0.5)	47.2051	129.5056	2.7435
	(0,0.1,0,0.5)	38.5534	104.1055	2.7003
	(0,0,0.5,0.1)	33.8986	90.9754	2.6838
3000	(0.5,0,0,0)	44.5928	92.1253	2.0659
	(0,0.5,0,0)	42.579	86.8951	2.0408
	(0,0,0.5,0)	41.4955	83.0954	2.0025
	(0,0,0,0.5)	47.1419	98.4653	2.0887
	(0,0.1,0,0.5)	38.4902	76.9955	2.0004
	(0,0,0.5,0.1)	33.8354	67.0652	1.9821
10000	(0.5,0,0,0)	44.2402	45.6471	1.0318
	(0,0.5,0,0)	42.2264	43.5063	1.0303
	(0,0,0.5,0)	41.1429	42.0512	1.0221

$N$	$(\delta_1, \delta_2, \delta_3, \delta_4)$	$ARL_1$	$SDRL_1$	$CVRL_1$
	(0,0,0,0.5)	46.7893	49.0198	1.0477
	(0,0.1,0,0.5)	38.1376	38.835	1.0183
	(0,0,0.5,0.1)	33.4828	33.8105	1.0098

Table 8.  $ARL_1$ ,  $SDRL_1$ , and  $CVRL_1$  under the different shifts and  $N$  values,  $\tau = 150, j=2$ .

$N$	$(\delta_1, \delta_2, \delta_3, \delta_4)$	$ARL_1$	$SDRL_1$	$CVRL_1$
100	(0.5,0,0,0)	39.7303	151.7856	3.820399
	(0,0.5,0,0)	37.7165	142.9954	3.791322
	(0,0,0.5,0)	37.521	140.1052	3.734048
	(0,0,0,0.5)	40.28	154.2354	3.829081
	(0,0.1,0,0.5)	33.6277	122.2951	3.636737
	(0,0,0.5,0.1)	30.97	112.0021	3.616471
500	(0.5,0,0,0)	39.6999	111.6652	2.812733
	(0,0.5,0,0)	37.6861	105.0053	2.786314
	(0,0,0.5,0)	36.6026	101.2256	2.76553
	(0,0,0,0.5)	42.249	120.3457	2.848486
	(0,0.1,0,0.5)	33.5973	91.655	2.728047
	(0,0,0.5,0.1)	28.9425	71.9651	2.486485
1500	(0.5,0,0,0)	39.656	95.0752	2.397498
	(0,0.5,0,0)	37.6422	89.3354	2.373278
	(0,0,0.5,0)	36.5587	85.9158	2.350078
	(0,0,0,0.5)	42.2051	102.5056	2.428749
	(0,0.1,0,0.5)	33.5534	77.1055	2.297994
	(0,0,0.5,0.1)	28.8986	63.9754	2.213789
3000	(0.5,0,0,0)	39.5928	65.1253	1.644877
	(0,0.5,0,0)	37.579	59.8951	1.593845
	(0,0,0.5,0)	36.4955	56.0954	1.53705
	(0,0,0,0.5)	42.1419	71.4653	1.695825
	(0,0.1,0,0.5)	33.4902	49.9955	1.49284
	(0,0,0.5,0.1)	28.8354	40.0652	1.389445
10000	(0.5,0,0,0)	39.2402	40.6471	1.035854
	(0,0.5,0,0)	37.2264	38.5063	1.034382
	(0,0,0.5,0)	36.1429	36.497	1.009797
	(0,0,0,0.5)	41.7893	44.0198	1.053375
	(0,0.1,0,0.5)	33.1376	32.897	0.992739
	(0,0,0.5,0.1)	28.4828	28.0153	0.983587

## Discussion

In this section, we understand that the effect of parameter estimation on out-of-control performance is more severe for smaller shifts in the process than for larger shifts. The effect of the use of estimated is not serious when the values of out-of- control

ARL and SDRL are closer to the values of the known parameters case. This is clear evidence of degradation in the performance of the risk-adjusted Bernoulli GEWMA chart when the parameters are estimated. Note that the in-control average of ARL of risk-adjusted Bernoulli GEWMA chart is larger than desired. The marginal RL distribution of GEWMA chart is utilized to

make sample size recommendations for chart performance based on estimates similar to one based on known parameters. An important recommendation is to make the smoothing constant small for GEWMA chart to make it more sensitive to small shifts. But, the smaller  $\lambda$ , the larger sample size needs to be to ensure performance similar to that of a chart based on known parameters.

The results showed that the impact of the parameter estimation is severe but can be eliminated by the use of more than 5000 phase I samples for estimating the control limits. The suggested sample sizes give practitioners some guidelines on how much data should be collected for the parameters to be considered to be known, which further indicates when a phase II control chart can be used. Note that the required sample sizes are considerably larger than one might expect. It is worthwhile pointing out, necessary sample sizes increase as the prescribed in-control ARL becomes larger.

Since, collecting so large a sample may sometimes be infeasible, the researchers proposed the use of new chart constants for the estimated parameters case that allows obtaining a fixed in-control ARL irrespective of the number of samples. In fact, it is recommended that the practitioners choose a moderate number of samples and update the control limits as more in-control samples become available. But they also result in a negative effect on out-of-control performance. Healthcare practitioners should consider these analyses when designing the risk-adjusted GEWMA chart. Using the new control chart constants results in  $ARL_1$  values that are always slightly larger than control chart with known parameters.

Note that  $ARL_0$  is larger than out-of-control under any different shifts. Generally, we can understand applying DPCL on risk-adjusted Bernoulli GEWMA chart more diminish the

estimation error than the other methods. It is worthwhile outlining that, the effect of estimation errors vanishes as the imposed shifts decreases. Moreover, the results indicate the proposed control chart has a bias ARL. Because  $ARL_1$  values are less than  $ARL_0$  under different shifts. Moreover, the performance of the control chart with the estimated  $\gamma_{jk_j}$  and  $\beta_j$  will increase as the shift in increases. The capability of the proposed control cart with estimated error is reduced to detect shifts.

The proposed control chart helps health systems measure healthcare processes and determine a strategy for an improvement initiative. Also, control chart method provides a formal way to decide whether observed variation in a measure of quality is due to implemented changes or to other causes of variation in the system. But using parameter estimates can lead to significantly deteriorate chart performance. Finally, our simulation results show that estimation error can have a substantial effect on Bernoulli GEWMA risk-adjusted chart performance. Also, results show that the effect of estimation error can be serious, especially if small samples are applied. Using our simulation, control limit can be adjusted in a given sample size to reduce the effect of parameter estimation for medical situations in which there is not enough sampling data.

## Conclusion

Many healthcare organizations are seeing tremendous benefits from using control charts and SPC methods to improve performance and monitor key healthcare processes. SPC can monitor the “health” of patient care using two key clinical indicators: the patient’s length of stay and errors such as infection rates. It can also be used for operational indicators such as denied insurance claims. Risk-adjusted Bernoulli GEWMA chart identify potential



changes that will result in improvement in multi-stage healthcare processes. In this study, we have investigated and discussed the performance of the risk-adjusted Bernoulli GEWMA control chart with estimated parameters. The performance metrics in our study include the ARL, SDRL and CVRL. We have also given practical recommendations on choosing the minimum reference sample size for achieving desired in-control chart performances. Results show that in-control and out-of-control ARL and SDRL are higher when estimated parameters are used than when parameters are known. Moreover, the effect of estimation error becomes very small for large shift magnitudes. Also, one should be wary of their determination of the needed Phase I sample size is based on an approximation of the ARL. It is not clear if the approximation is accurate unless the sample size is large enough.

The proposed method is used in hospital process improvement projects, by accrediting bodies and governmental agencies, and for public health surveillance. The aim of this paper is to provide the guidance in the direction of implementing risk-adjusted Bernoulli GEWMA chart with a sample size in healthcare processes.

The values of the out-of-control ARL and SDRL are closer to the values of the known parameters case, though for small process shifts, the values for the known and estimated parameters are different unless a large number of samples are used for the estimation of the process parameters. Applying multiple responses is a potential topic for further study. It would be advantageous to investigate the effect of smoothing parameter,  $\lambda$ , on these results. Also, another challenging topic would be evaluating the effect of parameter estimation in the other control charts in healthcare context.

### Abbreviations:

UCL: Upper Control Limit  
GEWMA: Group Exponentially Weighted Moving Average  
DPCL: Dynamic Probability Control Limits  
ARL: Average Run Length  
CUSUM: Cumulative Sum  
SDRL: Standard Deviation of the Run Length  
ASSI: Adaptive Sample Size and Interval  
VSI: Variable Sampling Interval

### Authors' Contributions:

F. Sogandi contributed to study design, data simulation and analysis, and manuscript drafting. Also, M. Aminnayeri took part in the interpretation of the results and drafting the manuscript. Both authors read and approved the final manuscript.

### Competing Interests:

The author declares no competing interests of inputs

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