

Bayesian Estimation of the Time of a Linear Trend in Risk-Adjusted Control Charts

Hassan Assareh, Ian Smith, Kerrie Mengersen

Abstract—Change point detection is recognized as an essential tool of root cause analyses within quality control programs as it enables clinical experts to search for potential causes of disturbance in hospital outcomes more effectively. In this paper, we consider estimation of the time when a linear trend disturbance has occurred in an in-control clinical dichotomous process in the presence of variable patient mix. To model the process and change point, a linear trend in the odds ratio of a Bernoulli process is formulated using hierarchical models in a Bayesian framework. We use Markov Chain Monte Carlo to obtain posterior distributions of the change point parameters including location and magnitude of changes and also corresponding probabilistic intervals and inferences. The performance of the Bayesian estimator is investigated through simulations and the result shows that precise estimates can be obtained when they are used in conjunction with the risk-adjusted CUSUM and EWMA control charts for different magnitude and direction of change scenarios. In comparison with alternative EWMA and CUSUM estimators, reasonably accurate and precise estimates are obtained by the Bayesian estimator. These superiorities are enhanced when probability quantification, flexibility and generalizability of the Bayesian change point detection model are also considered.

Index Terms—Bayesian Hierarchical Model, Change Point, Hospital Outcomes, Markov Chain Monte Carlo, Risk-Adjusted Control Charts.

I. INTRODUCTION

Control charts monitor behavior of processes over time by taking into account their stability and dispersion. The chart signals when a significant change has occurred. This signal can then be investigated to identify potential causes of the change and corrective or preventive actions can then be implemented. Following this cycle leads to variation reduction and process stabilization [1]. The achievements obtained by industrial and business sectors through the implementation of a quality improvement cycle including quality control charts and root causes analysis have motivated other sectors such as healthcare to consider these tools and apply them as an essential part of the monitoring process in order to improve the quality of healthcare delivery.

One of the earliest comprehensive research studies was undertaken by Benneyan [2], [3] who utilized SPC methods and control charts in epidemiology and control infection and discussed a wide range of control charts in the health context. Woodall [4] comprehensively reviewed the increasing stream

of adaptations of control charts and their implementation in healthcare surveillance. He acknowledged the need for modification of the tools according to health sector characteristics such as emphasis on monitoring individuals, particularly dichotomous data, and patient mix. Risk adjustment has been considered in the development of control charts due to the impact of the human element in process outcomes. Steiner *et al.* [5] developed a Risk-adjusted type of Cumulative Sum control chart (CUSUM) to monitor surgical outcomes, death, which are influenced by the state of a patient's health, age and other factors. This approach has been extended to Exponential Moving Average control charts (EWMA) [6], [7]. Both modified procedures have been intensively reviewed and are now well established for monitoring clinical outcomes where the observations are recorded as binary data [8], [9], [10].

Consideration of identified needs and how they are being satisfied in industrial and business sectors can accelerate other sectors in their own research and development of effective quality improvement tools. The need to know the time at which a process began to vary, the so-called change point, has recently been raised and discussed in the industrial context of quality control. Precise identification of the time when a change in a hospital outcome has occurred enables clinical experts to search for potential special causes more effectively since a tighter range of time and observations are investigated. Assareh *et al.* [11] discussed the benefits of change point investigation in monitoring cardiac surgery outcomes and post-signal root causes analysis by providing precise estimates of the time of the change in the rates of use of blood products during surgery and adverse events in the follow-up period.

A built-in change point estimator in CUSUM charts suggested by Page [12], [13] and also an equivalent estimator in EWMA charts proposed by Nishina [14] are two early change point estimators which can be applied for all discrete and continuous distribution underlying the charts. However they do not provide any statistical inferences on the obtained estimates.

Samuel and Pignatiello [15] developed and applied a maximum likelihood estimator (MLE) for the change point in a process fraction nonconformity monitored by a p-chart, assuming that the change type is a step change. They showed how closely this new estimator detects the change point in comparison with the usual p-chart signal. Subsequently, Perry *et al.* [16] compared the performance of the derived MLE estimator with EWMA and CUSUM charts. These authors also constructed a confidence set based on the estimated change point which covers the true process change point with a given level of certainty using a likelihood function based on the method proposed by Box and Cox [17]. It is not rare to experience other types of change in the process parameters.

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Bissell [18] and Gan [19], [20] investigated the performance of CUSUM and EWMA control charts over linear trends in the process mean. Such drifts can be caused by tools wearing, spread of infections, learning curve and skill improvement or motivation reduction that may lead to shifts the process parameter over time in an industrial or clinical contexts. MLE estimators of the time when such drifts has occurred were developed for normal [21] and Poisson processes [22].

An interesting approach which has recently been considered in the SPC context is Bayesian hierarchical modelling (BHM) using, where necessary, computational methods such as Markov Chain Monte Carlo (MCMC). Application of these theoretical and computational frameworks to change point estimation in a clinical context facilitates modelling the process and also provides a way of making a set of inferences based on posterior distributions for the time and the magnitude of a change [23]. This approach has recently been considered by Assareh *et al.* [11] in change point investigation of two clinical outcomes.

All MLE estimators described above were developed assuming that the underlying distribution is stable over time. This assumption cannot often be satisfied in monitoring clinical outcomes as the mean of the process being monitored is highly correlated to individual characteristics of patients. Therefore it is required that the risk model, which explains patient mix, be taken into consideration in detection of true change points in control charts for different change types. Assareh *et al.* [24] and Assareh and Mengersen [25] recently proposed Bayesian modelling for estimation of changes in the rate of death and survival time after surgery among patients with varying pre-operation risk of death. In this setting the process mean is no longer stable and risk models explain in-control state of the process.

The motivation of this study arose from a monitoring program of mortality of patients admitted to an Intensive care Unit (ICU) in a local hospital, Brisbane, Australia. The Acute Physiology and Chronic Health Evaluation II (APACHE II), an ICU scoring system [26], is used to quantify and express patient mix in quality control charting. APACHE II predicts the probability (p) of mortality based on a logistic regression given 12 physiological measurements taken in the first 24 hours after admission to ICU, as well as chronic health status and age. In this program detection of the true change point in control charts at the presence of linear trend disturbances, as a part of root cause efforts, is sought.

In this paper we model and detect the change point in a Bayesian framework. The change points are estimated assuming that the underlying change is a linear trend. In this scenario, we model the linear trend in the odds ratio of risk of a Bernoulli process. We analyze and discuss the performance of the Bayesian change point model through posterior estimates and probability based intervals. We review risk-adjusted control charts in Section 2. The model is demonstrated and evaluated in Sections 3-5. We then compare the Bayesian estimator with CUSUM and EWMA built-in estimators in Section 6 and summarize the study and obtained results in Section 7.

II. RISK-ADJUSTED CONTROL CHARTS

The probability of death of a patient who has undergone cardiac surgery is affected by the rate of mortality of cardiac

surgery within the hospital and also patient's covariates such as age, gender, co-morbidities and etc. Risk-adjusted control charts (RACUSUM) are monitoring tools designed to detect changes in a process parameter of interest, such as probability of mortality, where the process outcomes are affected by covariates, such as patient mix. In these procedures, risk models are used to adjust control charts in a way that the effects of covariates for each input, patient say, would be taken into account.

A risk-adjusted CUSUM (RACUSUM) control chart is a sequential monitoring scheme that accumulates evidence of the performance of the process and signals when either a significant deterioration or improvement is detected, where the weight of evidence has been adjusted according to patient's prior risk [5].

For the i^{th} patient, we observe an outcome y_i where $y_i \in (0, 1)$. This leads to a set of Bernoulli data. The RACUSUM continuously evaluates a hypothesis of an unchanged risk-adjusted odds ratio, OR_0 , against an alternative hypothesis of changed odds ratio, OR_1 , in the Bernoulli process [10]. A weight W_i , the so-called CUSUM score, is given to each patient considering the observed outcomes y_i and their prior risks p_i ,

$$W_i^\pm = \begin{cases} \log\left[\frac{(1-p_i+OR_0 \times p_i) \times OR_1}{1-p_i+OR_1 \times p_i}\right] & \text{if } y_i = 0 \\ \log\left[\frac{1-p_i+OR_0 \times p_i}{1-p_i+OR_1 \times p_i}\right] & \text{if } y_i = 1. \end{cases} \quad (1)$$

Upper and lower CUSUM statistics are obtained through $X_i^+ = \max\{0, X_{i-1}^+ + W_i^+\}$ and $X_i^- = \min\{0, X_{i-1}^- - W_i^-\}$, respectively, and then plotted over i . Often the null hypothesis, OR_0 , is set to 1 and CUSUM statistics, X_0^+ and X_0^- , are initialized at 0. Therefore an increase in the odds ratio, $OR_1 > 1$, is detected when a plotted X_i^+ exceeds a specified decision threshold h^+ ; conversely, if X_i^- falls below a specified decision threshold h^- , the RACUSUM charts signals that a decrease in the odds ratio, $OR_1 < 1$, has occurred. See Steiner *et al.* [5] for more details.

A risk-adjusted EWMA (RAEWMA) control chart is a monitoring procedure in which an exponentially weighted estimate of the observed process mean is continuously compared to the corresponding predicted process mean obtained through the underlying risk model. The EWMA statistic of the observed mean is obtained through $Z_{oi} = \lambda \times y_i + (1 - \lambda) \times Z_{oi-1}$. Z_{oi} is then plotted in a control chart constructed with $Z_{pi} = \lambda \times p_i + (1 - \lambda) \times Z_{pi-1}$ as the center line and control limits of $Z_{pi} \pm L \times \sigma_{Z_{pi}}$ where the variance of the predicted mean is equal to $\sigma_{Z_{pi}}^2 = \lambda^2 \times p_i(1 - p_i) + (1 - \lambda)^2 \times \sigma_{Z_{pi-1}}^2$. We let $\sigma_{Z_{p0}}^2 = 0$ and initialize both running means, Z_{o0} and Z_{p0} , at the overall observed mean, p_0 say, in the calibration stage of the risk model and control chart (so-called Phase 1 in an industrial context); see Cook [6] and Cook *et al.* [10] for more details. The smoothing constant λ of EWMA charts is determined considering the size of shift that is desired to be detected and the overall process mean; see Somerville *et al.* [27] for more details.

The magnitude of the decision thresholds in the RACUSUM, h^+ and h^- , and the coefficient of the control limits in RAEWMA control charts, L , are determined in a way that the charts have a specified performance in terms

of false alarm and detection of shifts in odds ratio; see Montgomery [1] and Steiner *et al.* [5] for more details. The proposed initialization may also be altered to achieve better performance in the detection of changes that immediately occur after control chart initialization, see Steiner [28] and Knoth [29] for more details on fast initial response (FIR). It should be noted that there exists an alternative for risk-adjusted EWMA in which the focus is on estimation of probability of death using pseudo observations and Bayesian methods [10]. This formulation would not be considered in this study; see Grigg & Spiegelhalter [7] for more details.

III. CHANGE POINT MODEL

Statistical inferences for a quantity of interest in a Bayesian framework are described as the modification of the uncertainty about their value in the light of evidence, and Bayes' theorem precisely specifies how this modification should be made as below:

$$Posterior \propto Likelihood \times Prior, \quad (2)$$

where "Prior" is the state of knowledge about the quantity of interest in terms of a probability distribution before data are observed; "Likelihood" is a model underlying the observations, and "Posterior" is the state of knowledge about the quantity after data are observed, which also is in the form of a probability distribution.

For monitoring a process with dichotomous outcomes, survival say, where no covariates contribute to the outcomes and standard control charts are applied, the observations y_i , $i = 1, \dots, T$, are considered as samples that independently come from a Bernoulli distribution. Assume that such process is initially in-control with a known rate of p_0 . At an unknown point in time, τ , the Bernoulli rate parameter changes from its in-control state of p_0 to p_1 , $p_1 = p_0 + \delta$ and $p_1 \neq p_0$. The general Bernoulli process step change model can thus be parameterized as follows:

$$pr(y_i | p_i) = \begin{cases} p_0^{y_i} (1 - p_0)^{1-y_i} & \text{if } i = 1, 2, \dots, \tau \\ p_1^{y_i} (1 - p_1)^{1-y_i} & \text{if } i = \tau + 1, \dots, T. \end{cases} \quad (3)$$

However this formulation is not sustained where the in-control rate is not stable due to covariate contributions. In other words in risk-adjusted charting procedures, we let the process mean vary over observations and we control the variable observed rate against the corresponding expected rate obtained through the risk models. In this setting, a Bernoulli process is in the in-control state when observations can be statistically expressed by the underlying risk models, taking into account their individual covariates. The risk-adjusted control chart signals when observations tend to violate the underlying risk model.

To express an in-control process and construct a change point model, where covariates exist, we apply the common parameter of odds ratio, OR , which is frequently used for design of control charts in a clinical monitoring context [5]. In this setting, $OR_0 = 1$ is identical to no change and departing from that through $OR_1 = OR_0 + \beta \times t$ leads to a linear trend with a slope of size β over time t in the Bernoulli process.

To model a change point in the presence of covariates, consider a Bernoulli process y_i , $i = 1, \dots, T$, that is initially

in-control, with independent observations coming from a Bernoulli distribution with known variable rates p_{0i} that can be explained by an underlying risk model $p_{0i} | x_i \sim f(x_i)$, where $f(\cdot)$ is a link function and x is a vector of covariates. At an unknown point in time, τ , the Bernoulli rate parameter changes from its in-control state of p_{0i} to p_{1i} obtained through

$$OR_1 = OR_0 + \beta \times (i - \tau) = \frac{p_{1i}/1 - p_{1i}}{p_{0i}/1 - p_{0i}} \quad (4)$$

and

$$p_{1i} = \frac{(OR_0 + \beta \times (i - \tau)) \times p_{0i}/(1 - p_{0i})}{1 + ((OR_0 + \beta \times (i - \tau)) \times p_{0i}/(1 - p_{0i}))}, \quad (5)$$

where $OR_1 \neq 1$ and > 0 so that $p_{1i} \neq p_{0i}$, $i = \tau, \dots, T$.

The Bernoulli process linear trend change model in the presence of covariates can thus be parameterized as follows:

$$pr(y_i | p_i) = \begin{cases} p_{0i}^{y_i} (1 - p_{0i})^{1-y_i} & \text{if } i = 1, 2, \dots, \tau \\ p_{1i}^{y_i} (1 - p_{1i})^{1-y_i} & \text{if } i = \tau + 1, \dots, T. \end{cases} \quad (6)$$

Modeling a linear trend in terms of odds ratios benefits the change point model since no constraint on each p_{1i} , $i = \tau, \dots, T$, is needed. In this parametrization, any $\beta > 0$ corresponds to $OR_1 > 1$ that induces an increase in the rate. This type of change is analogous to linear trend models in a Bernoulli process rate without covariates. Equivalently, a negative slope, $\beta < 0$, causes a fall; however such disturbance cannot last long since OR_1 is restricted to be positive. Therefore for simplicity, we limit the investigation to increasing linear trends scenarios where $\beta > 0$.

As seen in Equation (5), although a specific magnitude of change induces in the odds ratio, the obtained out-of control rates, p_{1i} , $i = \tau, \dots, T$, are affected differently; see Section IV for more details.

Relating this to Equation (2), $pr(\cdot | \cdot)$ is the likelihood that underlies the observations; the time, τ , and the magnitude of the slope, β , in the linear trend in odds ratio are the unknown parameters of interest; and the posterior distributions of these parameters will be investigated in the change point analysis. Assume that the process delivering y_i is monitored by a control chart that signals at time T .

We assign a zero left truncated normal distribution ($\mu = 0, \sigma^2 = k$) $I(0, \infty)$ for β as prior distributions where k is study-specific. In the followings, we set $k = 1$, giving a relatively informed priors for the magnitude of the slope change in an in-control rate as the control chart is sensitive enough to detect very large shifts and estimate associated change points. Other distributions such as uniform and Gamma might also be of interest for β since it is assumed to be a positive value; see Gelman *et al.* [23] for more details on selection of prior distributions. We place a uniform distribution on the range of $(1, T-1)$ as a prior for τ where T is set to the time of the signal of control charts. See the Appendix for the linear trend change model code in WinBUGS.

IV. EVALUATION

We used Monte Carlo simulation to study the performance of the constructed BHM in linear trend detection following a signal from RACUSUM and RAEWMA control charts when

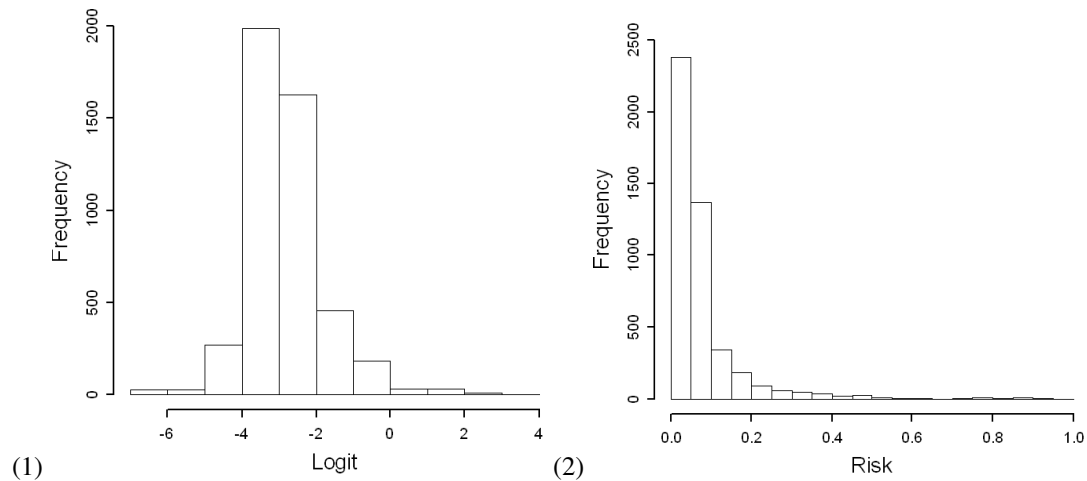


Fig. 1. Distribution of calculated (1) logit of APACHE II scores $logit(p)$; and (2) probability of mortality for 4644 patients who admitted to ICU during 2000-2009.

a change in odds ratio is simulated to occur at $\tau = 500$. However, to extend to the results that would be obtained in practice, we considered a dataset of available APACHE II scores that was routinely collected over 2000-2009 in the pilot hospital for construction of baseline risks in the control charts.

Figure 1-1 shows the calculated logit of APACHE II scores ($logit(p)$) for 4644 patients who were admitted to ICU. The scores led to a distribution of logit values with a mean of -2.53 and a variance of 1.05. The distribution of the obtained probability of death over patients is also shown in Figure 1-2. This led to an overall risk of death of 0.082 with a variance of 0.012 among patients in the pilot hospital.

To generate observations of a process in the in-control state $y_i, i = 1, \dots, \tau$, we first randomly generated associated risks, $p_{0i}, i = 1, \dots, \tau$, from a normal distribution ($\mu = -2.53, \sigma^2 = 1.05$) and then drew binary outcomes from a Bernoulli distribution with rates of $p_{0i}, i = 1, \dots, \tau$. Plotting the obtained observations when the associated risks are considered results in risk-adjusted control charts that are in-control. However other distributions such as Beta and uniform distributions with proper parameters or even sampling randomly from the baseline data can be applied to generate risks directly.

Because we know that the process is in-control, if an out-of-control observation was generated in the simulation of the early 500 in-control observations, it was taken as a false alarm and the simulation was restarted. However, in practice a false alarm may lead to stopping the process and analyzing root causes. When no cause is found, the process would follow without adjustment.

To form an increasing linear trend in odds ratio, we then induced trends with a slope of sizes $\beta = \{0.0025, 0.005, 0.01, 0.025, 0.05, 0.1\}$ and generated observations until the control charts signalled. The effect of such drifts should be considered in two ways, over different baseline risk and time.

These slopes led to different shift sizes in the in-control process rate, p_{0i} , for the i^{th} patient after the occurrence of the change. As shown in Figure 2 patients with a more extreme risk of mortality are less affected compared to patients who have a probability of around 0.5 at $i = 600$, after 100

observations coming from an out-of-control process caused by linear trend disturbances of size β . This effect remains consistent over next patients where the size of the change in odds ratio increases by time. Patients with more extreme risks of mortality are less affected compared to patients who have a probability of around 0.5.

The effect of a linear trend with a positive slope of size $\beta = 0.025$ in odds ratio is demonstrated in Figure 3 over time, next patients say. The resultant distributions are more over-dispersed and shifted to the right and concentrates on higher values of risks in comparison with the observed risks in Figure 1-2. As seen in Figure 3-1 for the 550th patient, when the odds ratio increases and reaches to $\delta_1 = 2.25$, the overall risk increases to 0.15 with a variance of 0.021. This increase in the risk almost doubles after the next 150 patients, reaching to an overall risk of 0.28 with a variance of 0.033, see Figure 3-4.

To form an increasing linear trend in odds ratio, we then induced trends with a slope of sizes $\beta = \{0.0025, 0.005, 0.01, 0.025, 0.05, 0.1\}$ and generated observations until the control charts signalled. We constructed risk-adjusted control charts using the procedures discussed in Section II. We designed RACUSUM to detect a doubling and a halving of the odds ratio in the in-control rate, $p_0 = 0.082$, and have an in-control average run length (ARL_0) of approximately 3000 observations. We used Monte Carlo

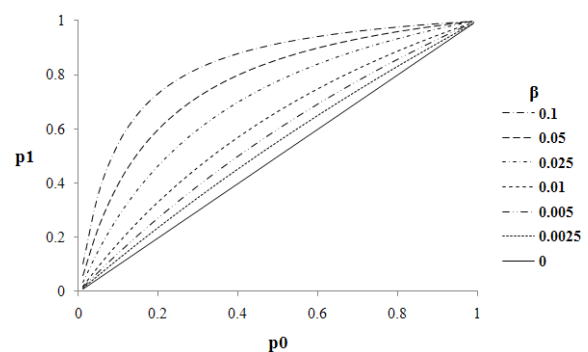


Fig. 2. Effect of linear trend disturbances with a slope of β occurred at $i = 500$ in odds ratio of an in-control Bernoulli process for the 600th patient with a baseline risk of p_0 .

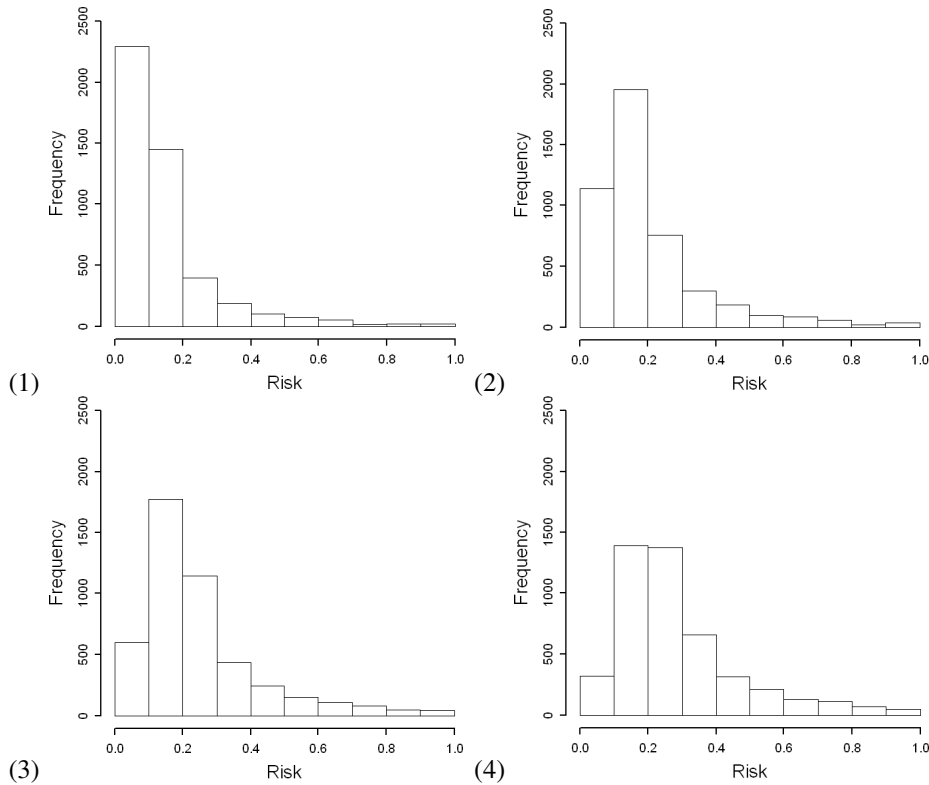


Fig. 3. Distribution of observable probability of mortality after (1) 50, (2) 100, (3) 150 and (4) 200 observations since occurrence of a linear trend disturbance with a slope of size $\beta = 0.025$ in odds ratio for 4644 patients who admitted to ICU during 2000-2009.

simulation to determine decision intervals, h^\pm . However other approaches may be of interest; see Steiner *et al.* [5]. This setting led to decision intervals of $h^+ = 5.85$ and $h^- = 5.33$. As two sided charts were considered, the negative values of h^- were used. The associated CUSUM scores were also obtained through Equation (1) where y_i is 0 and 1, respectively.

We set the smoothing constant of RAEWMA to $\lambda = 0.01$ as the in-control rate was low and detection of small changes was desired; see Somerville *et al.* [27], Cook [6] and [7] for more details. The value of L was calibrated so that the same in-control average run length (ARL_0) as the RACUSUM was obtained. The resultant chart had $L = 2.83$. A negative lower control limit in the RAEWMA was replaced by zero.

The linear trend disturbances and control charts were simulated in the R package (<http://www.r-project.org>). To obtain posterior distributions of the time and the magnitude of the changes we used the R2WinBUGS interface [30] to generate 100,000 samples through MCMC iterations in WinBUGS [31] for all change point scenarios with the first 20000 samples ignored as burn-in. We then analyzed the results using the CODA package in R [32]. See the Appendix for the linear trend change model code in WinBUGS.

V. PERFORMANCE ANALYSIS

To demonstrate the achievable results of Bayesian change point detection in risk-adjusted control charts, we induced a linear trend with a slope of size $\beta = 0.25$ at time $\tau = 500$ in an in-control binary process with an overall death rate of $p_0 = 0.082$. RACUSUM and RAEWMA, respectively, detected an increase in the odds ratio and signalled at the 595th and 565th observations, corresponding to delays of

95 and 65 observations as shown in Figure 4-a1, b1. The posterior distributions of time and magnitude of the change were then obtained using MCMC discussed in Section IV. For both control charts, the distribution of the time of the change, τ , concentrates on the values closer to 500th observation as seen in Figure 4-a2, b2. The posteriors for the magnitude of the change, β , also approximately identified the exact change size as they highly concentrate on values of less than 0.05 shown in Figure 4-a3, b3. As expected, there exist slight differences between the distributions obtained following RACUSUM and RAEWMA signals since non-identical series of binary values were used for two procedures.

Table I summarizes the obtained posteriors. If the posterior was asymmetric and skewed, the mode of the posteriors was used as an estimator for the change point model parameter (τ and β_1). As shown, the Bayesian estimator of the time outperforms chart's signals, particularly for the RACUSUM with a delay of three observations. However, the magnitude of the slope of the linear trend tends to be over overestimated by the Bayesian estimator, obtaining 0.051 and 0.041 for RACUSUM and RAEWMA charts, respectively. Having said that, these estimates must be studied in conjunction with their

TABLE I
POSTERIOR ESTIMATES (MODE, SD.) OF LINEAR TREND CHANGE POINT MODEL PARAMETERS (τ AND β) FOLLOWING SIGNALS (RL) FROM RACUSUM ($(h^+, h^-) = (5.85, 5.33)$) AND RAEWMA CHARTS ($\lambda = 0.01$ AND $L = 2.83$) WHERE $E(p_0) = 0.082$ AND $\tau = 500$. STANDARD DEVIATIONS ARE SHOWN IN PARENTHESES.

β	RACUSUM			RAEWMA		
	RL	$\hat{\tau}$	$\hat{\beta}$	RL	$\hat{\tau}$	$\hat{\beta}$
0.025	595	503.0 (34.9)	0.051 (0.14)	565	513.9 (22.9)	0.042 (0.13)

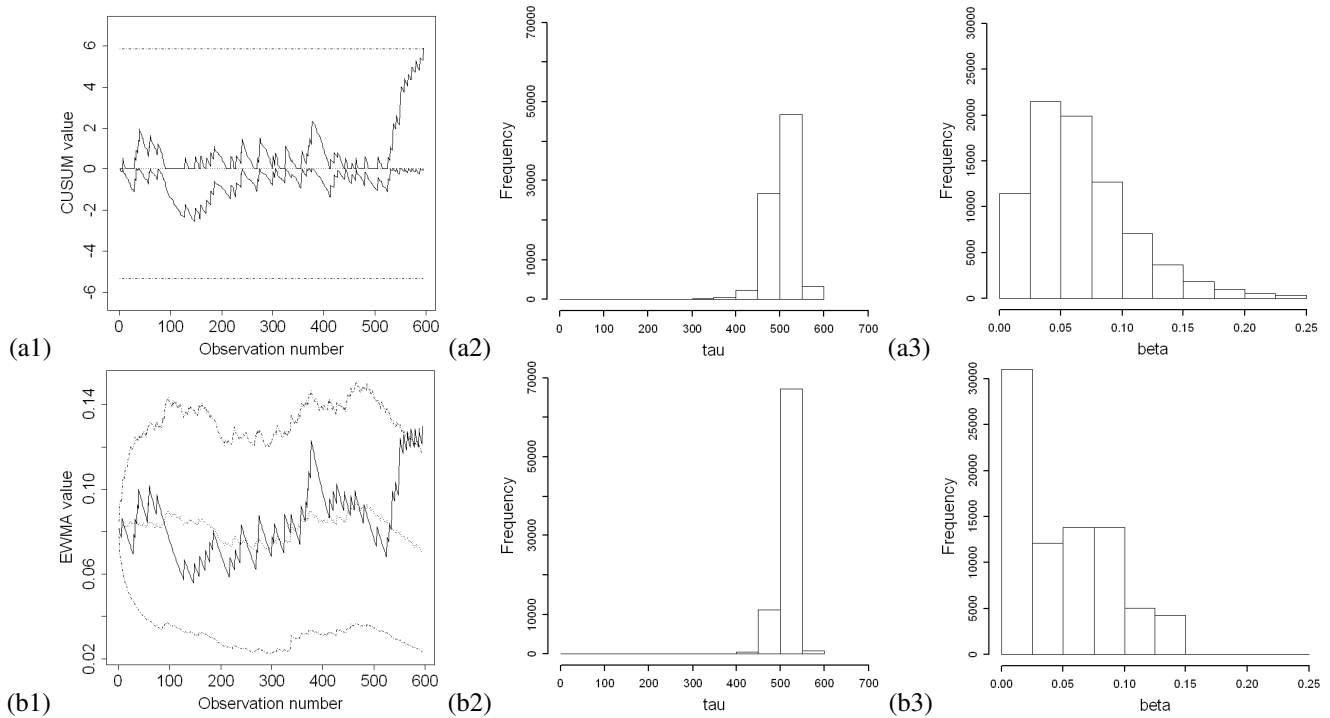


Fig. 4. Risk-adjusted (a1) CUSUM $((h^+, h^-) = (5.85, 5.33))$ and (b1) EWMA $(\lambda = 0.01 \text{ and } L = 2.83)$ control charts and obtained posterior distributions of (a2, b2) time τ and (a3, b3) magnitude β of an induced linear trend with a slope of size $\beta = 0.025$ in odds ratio where $E(p_0) = 0.082$ and $\tau = 500$.

corresponding standard deviations.

Applying the Bayesian framework enables us to construct probability based intervals around estimated parameters. A credible interval (CI) is a posterior probability based interval which involves those values of highest probability in the posterior density of the parameter of interest. Table II presents 50% and 80% credible intervals for the estimated time and the magnitude of slope of the linear trend disturbance in odds ratio for RACUSUM and RAEWMA control charts. As expected, the CIs are affected by the dispersion and higher order behaviour of the posterior distributions. Under the same probability of 0.5 for the RACUSUM, the CI for the time of the change of size $\beta = 0.025$ in odds ratio covers 25 observations around the 500th observation whereas it increases to 35 observations for RAEWMA due to the larger standard deviation, see Table I.

Comparison of the 50% and 80% CIs for the estimated time for the RACUSUM chart reveals that the posterior distribution of the time tends to be left-skewed and the increase in the probability contracts the left boundary of the interval, from 496 to 476 in comparison with a shift of 10 observations in the right boundary. This result can also be seen for the RAEWMA chart. As shown in Table I and discussed above, magnitude of the changes are overestimated, however Table II indicates that the real sizes of slope are approximately contained in the respective posterior 50%

TABLE III
PROBABILITY OF THE OCCURRENCE OF THE CHANGE POINT IN THE LAST 25, 50 AND 100 OBSERVATIONS PRIOR TO SIGNALLING FOR RACUSUM $((h^+, h^-) = (5.85, 5.33))$ AND RAEWMA CHARTS $(\lambda = 0.01 \text{ AND } L = 2.83)$ WHERE $E(p_0) = 0.082$ AND $\tau = 500$.

β	RACUSUM			RAEWMA		
	25	50	100	25	50	100
0.025	0.02	0.04	0.70	0.04	0.57	0.98

and 80% CIs. Construction of probabilistic intervals can be extended to other sizes of slope and direction of linear trends in odds ratio.

Having a distribution for the time of the change enables us to make other probabilistic inferences. As an example, Table III shows the probability of the occurrence of the change point in the last {25, 50, 100} observations prior to signalling in the control charts. For a linear trend with a slope of size $\beta = 0.025$ in odds ratio, since the RACUSUM signals late (see Table I), it is unlikely that the change point occurred in the last 25 or 50 observations. In contrast, in the RAEWMA, where it signals earlier, the probability of occurrence in the last 25 observations is 0.57, then increases to 0.98 as the next 50 observations are included. These kind of probability computations and inferences can be extended to other change scenarios.

The above studies were based on a single sample drawn

TABLE II
CREDIBLE INTERVALS FOR LINEAR TREND CHANGE POINT MODEL PARAMETERS (τ AND β) FOLLOWING SIGNALS (RL) FROM RACUSUM $((h^+, h^-) = (5.85, 5.33))$ AND RAEWMA CHARTS $(\lambda = 0.01 \text{ AND } L = 2.83)$ WHERE $E(p_0) = 0.082$ AND $\tau = 500$.

β	Parameter	RACUSUM		RAEWMA	
		50%	80%	50%	80%
0.025	$\hat{\tau}$	(496,521)	(476,531)	(511,526)	(497,532)
	$\hat{\beta}$	(0.028,0.081)	(0.020,0.141)	(0.021,0.079)	(0.018,0.129)

TABLE IV

AVERAGE OF POSTERIOR ESTIMATES (MODE, SD.) OF LINEAR TREND CHANGE POINT MODEL PARAMETERS (τ AND β) FOR A DRIFT IN ODDS RATIO FOLLOWING SIGNALS (RL) FROM RACUSUM ($(h^+, h^-) = (5.85, 5.33)$) AND RAEWMA CHARTS ($\lambda = 0.01$ AND $L = 2.83$) WHERE $E(p_0) = 0.082$ AND $\tau = 500$. STANDARD DEVIATIONS ARE SHOWN IN PARENTHESES.

β	RACUSUM				RAEWMA			
	$E(RL)$	$E(\hat{\tau})$	$E(\sigma_{\hat{\tau}})$	$E(\hat{\beta})$	$E(RL)$	$E(\hat{\tau})$	$E(\sigma_{\hat{\tau}})$	$E(\hat{\beta})$
0.0025	920.8	740.1	151.7	0.006	861.8	763.0	114.9	0.008
	(101.5)	(94.8)	(77.6)	(0.004)	(95.8)	(94.5)	(31.5)	(0.003)
0.005	787.7	633.6	125.1	0.010	723.1	657.4	76.9	0.013
	(88.3)	(78.5)	(64.7)	(0.041)	(78.2)	(78.0)	(31.7)	(0.032)
0.01	689.0	579.7	76.4	0.022	655.5	591.5	59.7	0.028
	(33.5)	(41.8)	(36.6)	(0.050)	(36.4)	(31.2)	(31.1)	(0.044)
0.025	610.3	524.4	52.8	0.041	590.6	528.4	49.2	0.039
	(26.6)	(42.9)	(29.1)	(0.045)	(30.9)	(35.4)	(23.2)	(0.048)
0.05	583.3	514.7	37.8	0.081	569.3	513.7	42.9	0.078
	(17.5)	(20.4)	(17.3)	(0.027)	(16.6)	(21.1)	(19.9)	(1.034)
0.1	562.7	504.3	28.7	0.129	552.4	503.3	34.6	0.130
	(11.8)	(17.5)	(14.6)	(0.033)	(11.8)	(17.2)	(19.3)	(0.031)

from the underlying distribution. To investigate the behavior of the Bayesian estimator over different sample datasets, for different slope sizes of β , we replicated the simulation method explained in Section IV 100 times. Simulated datasets that were obvious outliers were excluded. Table IV shows the average of the estimated parameters obtained from the replicated datasets where there exists a linear trend in odds ratio.

Comparison of performance of RACUSUM and RAEWMA charts in Table IV reveals that, the RAEWMA detected increasing linear trend disturbances in odds ratio faster. This superiority drops from 59 observations for $\beta = 0.0025$ to 10 observations when the slope size reaches to $\beta = 0.1$. For a very small slope of size $\beta = 0.0025$, the average of the mode, $E(\hat{\tau})$, reports the 740th observation as the change point in RACUSUM, whereas the chart detected the change with a delay of 420 observations. This superiority persists for the RAEWMA chart, however a delay of 263 observations is still associated with the estimate of the time, τ , for $\beta = 0.0025$ following RAEWMA signal.

Table IV shows that, although the RACUSUM signals later than the alternative, RAEWMA, particularly over small to medium slope sizes, the average of posterior estimates for the time, $E(\hat{\tau})$, outperforms the estimates obtained for RAEWMA charts. A less delay of 23 observations is obtained for $\beta = 0.0025$ scenario. This delay drops when the slope size increases. Over medium to large sizes of slope, $\beta = \{0.025, 0.05, 0.1\}$, the bias of the Bayesian estimator, $E(\hat{\tau})$, did not exceed 24 observations for the RACUSUM. This bias slightly increased for the RAEWMA chart, reaching to 28 observations, yet significantly outperformed the chart's signal. At best, the RACUSUM and RAEWMA signals at the 562nd and 552nd observations for the most extreme jump in the slope of the linear trend in odds ratio were also outperformed by posterior modes, $E(\hat{\tau})$, that exhibited a bias of four and three observations, respectively.

Table IV indicates that in both risk-adjusted control charts, the variation of the Bayesian estimates for time tends to reduce when the magnitude of slope increases. The mean of the standard deviation of the posterior estimates of time, $E(\sigma_{\hat{\tau}})$, also decreases when the slope sizes increases. The average of the Bayesian estimates of the magnitude of the change, $E(\hat{\beta})$, shows that the posterior modes tend to overestimate slope sizes. As seen in Table IV, better estimates

are obtained in moderate to large slopes. Having said that, Bayesian estimates of the magnitude of the change must be studied in conjunction with their corresponding standard deviations. In this manner, analysis of credible intervals is effective.

VI. COMPARISON OF BAYESIAN ESTIMATOR WITH OTHER METHODS

To study the performance of the proposed Bayesian estimators in comparison with those introduced in Section I, we ran the available alternative, built-in estimators of Bernoulli EWMA and CUSUM charts, within the replications discussed in Section V. Based on Page [12] suggestion, if an increase in a process rate detected by CUSUM charts, an estimate of the change point is obtained through $\hat{\tau}_{cusum} = \max\{i : X_i^+ = 0\}$. We modified the built-in estimator of EWMA proposed by Nishina [14] and estimated the change point using $\hat{\tau}_{ewma} = \max\{i : Z_{oi} \leq Z_{pi}\}$ following signals of an increase in the Bernoulli rate.

Table V shows the average of the Bayesian estimates, τ_b , and detected change points provided by the built-in estimators of CUSUM, τ_{cusum} , and EWMA, τ_{ewma} , charts for drifts in the odds ratio, OR . The built-in estimators of EWMA and CUSUM charts outperform associated signals over all drifts in the odds ratio, however they tend to underestimate the exact change point when the magnitude of slope is large, $\beta = 0.1$. The CUSUM built-in estimator, $\hat{\tau}_{cusum}$, outperforms the alternative built-in estimator over small to moderate slopes, exactly over the same range of changes in which the Bayesian estimates obtained for RACUSUM are superior.

The Bayesian estimator, $\hat{\tau}_b$, is outperformed by both built-in estimators, $\hat{\tau}_{cusum}$ and $\hat{\tau}_{ewma}$, with less delays which is at most 35 observations obtained for RAEWMA for $\beta = 0.005$. Having said that, considering corresponding standard deviations over replications, the Bayesian estimator remains a reasonable alternative. The superiority of the built-in estimators drops when slope size increases since they tend to underestimate the time of the change, whereas the average of posterior modes estimates more accurately. Comparison of variation of estimated change points also supports the superiority of the Bayesian estimators over alternatives across linear trend with a small slope.

TABLE V

AVERAGE OF DETECTED TIME OF A LINEAR TREND CHANGE IN ODDS RATIO OBTAINED BY THE BAYESIAN ESTIMATOR (τ_b), CUSUM AND EWMA BUILT-IN ESTIMATORS FOLLOWING SIGNALS (RL) FROM RACUSUM ($(h^+, h^-) = (5.85, 5.33)$) AND RAEWMA CHARTS ($\lambda = 0.01$ AND $L = 2.83$) WHERE $E(p_0) = 0.082$ AND $\tau = 500$. STANDARD DEVIATIONS ARE SHOWN IN PARENTHESES.

β	RACUSUM			RAEWMA		
	$E(RL)$	$E(\hat{\tau}_{cusum})$	$E(\hat{\tau}_b)$	$E(RL)$	$E(\hat{\tau}_{ewma})$	$E(\hat{\tau}_b)$
0.0025	920.8	727.7	740.1	861.8	739.4	763.0
	(101.5)	(131.9)	(94.8)	(95.8)	(128.5)	(94.5)
0.005	787.7	605.8	633.6	723.1	622.3	657.4
	(88.3)	(110.2)	(78.5)	(78.2)	(103.9)	(78.0)
0.01	689.0	559.7	579.7	655.5	573.2	591.5
	(33.5)	(56.2)	(41.8)	(36.4)	(55.5)	(31.2)
0.025	610.3	513.1	524.4	590.6	514.0	528.4
	(26.6)	(62.6)	(42.9)	(30.9)	(67.6)	(35.4)
0.05	583.3	495.2	514.7	569.3	506.1	513.7
	(17.5)	(56.5)	(20.4)	(16.6)	(61.4)	(21.1)
0.1	562.7	483.4	504.3	552.4	497.8	503.3
	(11.8)	(45.7)	(17.5)	(11.8)	(63.2)	(17.2)

VII. CONCLUSION

Quality improvement programs and monitoring process for medical outcomes are now being widely implemented in the health context to achieve stability in outcomes through detection of shifts and investigation of potential causes. Obtaining accurate information about the time when a change occurred in the process has been recently considered within industrial and business context of quality control applications. Indeed, knowing the change point enhances efficiency of root causes analysis efforts by restricting the search to a tighter window of observations and related variables.

In this paper, using a Bayesian framework, we modeled change point detection for a clinical process with dichotomous outcomes, death and survival, where patient mix was present. We considered an increasing drift in odds ratio, caused by a linear trend with a positive slope, of the in-control rate. We constructed Bayesian hierarchical models and derived posterior distributions for change point estimates using MCMC. The performance of the Bayesian estimators were investigated through simulation when they were used in conjunction with well-known risk-adjusted CUSUM and EWMA control charts monitoring mortality rate in the ICU of the pilot hospital where risk of death was evaluated by APACHE II, a logistic prediction model. The results showed that the Bayesian estimates significantly outperform the RACUSUM and RAEWMA control charts in change detection over different scenarios of magnitude of slopes in drifts. We then compared the Bayesian estimator with built-in estimators of EWMA and CUSUM. Although the Bayesian estimator has outperformed by the built-in estimators, they remain a viable alternative when precision of the estimators are taken into account.

Apart from accuracy and precision criteria used for the comparison study, the posterior distributions for the time and the magnitude of a change enable us to construct probabilistic intervals around estimates and probabilistic inferences about the location of the change point. This is a significant advantage of the proposed Bayesian approach. Furthermore, flexibility of Bayesian hierarchical models, ease of extension to more complicated change scenarios such as decreasing linear trends, nonlinear trends, relief of analytic calculation of likelihood function, particularly for non-tractable likelihood functions and ease of coding with available packages should be considered as additional benefits of the proposed Bayesian

change point model for monitoring purposes.

The investigation conducted in this study was based on a specific in-control rate of mortality observed in the pilot hospital. Although it is expected that superiority of the proposed Bayesian estimator persists over other processes in which the in-control rate and the distribution of baseline risk may differ, the results obtained for estimators and control charts over various change scenarios motivates replication of the study using other patient mix profiles. Moreover modification of change point model elements such as replacing priors with more informative alternatives, or truncation of prior distributions based on type of signals and prior knowledge, may be of interest.

The two-step approach to change-point identification described in this paper has the advantage of building on control charts that may be already in place in practice (as in the pilot hospital). An alternative may be to retain the two-step approach but to use a Bayesian framework in both stages. There is now a substantial body of literature on Bayesian formulation of control charts and extensions such as monitoring processes with varying parameters [33], over-dispersed data [34], start-up and short runs [35], [36]. A further alternative is to consider a fully Bayesian, one-step approach, in which both the monitoring of the in-control process and the retrospective or prospective identification of changes is undertaken in the one analysis. This is the subject of further research.

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APPENDIX A

CHANGE POINT MODEL CODE IN WINBUGS

```

model {
  for(i in 1 : RLcsum)
  {
    y[i] ~ dbern(p[i])
    p[i]=x[i]+step(i-change)*-x[i]+
      ((1+beta*(i-change))*x[i])/
      (x[i]*((1+beta*(i-change))-1)+1)
  }
  RL=RLcsum-1
  beta ~ dnorm(0,1)I(0,)
  change ~ dunif(1,RL) }

```