

# Monitoring Clinical Indicators

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## Abstract

A new control chart for monitoring clinical indicator (CI) data based upon the beta-binomial posterior predictive (BBPP) distribution was compared with the more commonly used Bernoulli cumulative sum (Bernoulli CUSUM) chart. Run lengths were simulated for 3894 parameter combinations. For the case where the underlying proportion of cases with an event of interest had to be estimated, the BBPP chart was shown to have the desired smaller out-of-control ARL in 71.6% of the simulations. This effect was greatest in the parameter space having the:

- mean proportion across all healthcare providers (HCPs),  $\pi$ ,  $< 0.1$ ;
  - percentage change in the underlying proportion (required for Bernoulli CUSUM chart),  $\Delta$ ,  $0.15 < \Delta < 0.35$ ;
  - number of admissions at risk of the event of interest at the  $i^{\text{th}}$  HCP,  $D_i$ ,  $< 30$ ;
  - proportion of admissions having the event of interest at the  $i^{\text{th}}$  HCP,  $\theta_i$ ,  $< 0.1$ ;
- across all values for the standard deviation between HCPs,  $\sigma$ .

*Keywords:* Bayesian, Bernoulli CUSUM, Beta-binomial model, posterior predictive models.

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## 1. Introduction

Clinical indicators (CIs) are increasingly being used to assess, compare and improve the care provided by hospitals and physicians [1-4]. Since 1993, Australian hospitals preparing for accreditation, or re-accreditation, with the Australian Council on Healthcare Standards (ACHS) have been required to provide data on sets of CIs. The ACHS routinely collates this information in 6-month periods and in 2007 received data from 689 Australian and New Zealand healthcare providers (HCPs) on 360 CIs across 23 specialties [7].

The ACHS CIs relate to specific clinical outcomes or processes. They are defined by the ACHS as measures of the clinical management and outcome of patient care, which are not exact standards against which hospitals must measure their clinical performance but rather are designed as screening tools that can alert to possible problems or opportunities to improve patient care [4]. The CI data can be reported as proportions. The numerator represents the number of patients who incur an 'event of interest' and the

denominator represents the number of patients at risk of the event.

In 2000, new methods for analysing and reporting the CI data which draw the focus towards system-wide improvements were adopted by the ACHS [5]. Bayesian hierarchical models have been an integral part of this analysis and reporting [5]. Since 2004 the reports have been complemented by individual HCP reports which identify the individual HCP's performance compared with both the entire system and themselves based on trend analysis of their 6-monthly rates.

These reports involve retrospective analysis and reporting. Retrospective analyses in healthcare usually provide insight into where quality improvement is required [6]. Coupled with the estimated potential gains and trend analyses, these reports provide a solid foundation for such investigation.

Such reports, however, could be complemented by tools, such as control charts, that enable HCPs to monitor their performance during the 6-months, rather than only waiting for the retrospective reports. This paper describes a new control chart

based upon the BBPP distribution and how it compares with the commonly utilised Bernoulli CUSUM chart.

## 2. Background

### Bernoulli CUSUM charts

The CUSUM control chart first proposed by Page is based on sums of observations [7]. The chart uses one statistic for detecting a positive shift in the process level and another statistic for detecting a negative shift in the process level. The value plotted for detecting a positive shift is  $y_t = \max(0, y_{t-1}) + x_t - s$  where  $y_0 = 0$ ,  $x_t$  represents the number of non-conforming items obtained for sample number  $t$  and  $s$  is a reference parameter of the chart. Reynolds and Stoumbos developed the Bernoulli CUSUM chart incorporating the log-likelihood ratio (LLR) parameter as the fixed reference value,  $s = \ln [(1-p_0)/(1-p_1)] / \ln [p_1 (1-p_0) / p_0 (1-p_1)]$ , based upon the in-control proportion,  $p_0$ , and the out-of-control threshold proportion,  $p_1$  [8]. They found that the Bernoulli CUSUM detects changes in the true underlying proportion faster than Shewhart p-charts, and is more efficient than a standard CUSUM chart. The chart behaves optimally [9] and is sensitive and accurate in the CI setting [10]. Woodall found that the Bernoulli CUSUM chart is more efficient than the previously used Poisson-based CUSUM charts as sub-grouping is not needed, meaning there is no need for assuming a constant underlying rate and there is no time-delay due to grouping [10].

The lower and upper control limits for the Bernoulli CUSUM chart are  $-\ln[(1-\alpha)/\beta] / 2\ln[p_1 (1-p_0) / p_0 (1-p_1)]$  and  $\ln[(1-\beta)/\alpha] / 2\ln[p_1 (1-p_0) / p_0 (1-p_1)]$  respectively [8]. The sensitivity of the control limits depends on the specified values of the Type I and II error rates,  $\alpha$  and  $\beta$  respectively. It is accepted practice that when  $\alpha$  is set at 0.05 that  $\beta$  be set at 0.20 and when  $\alpha$  is set at 0.10 then  $\beta$  should be set at 0.10 [11-13]. Spiegelhalter et al. recommend that values of  $\alpha$  and  $\beta$  should remain equal, meaning that there are equal chances of making Type I and Type II errors. Further, when monitoring single units it is recommended that the specified values of  $\alpha$  and  $\beta$  be no larger than 0.10, with smaller values giving more rigorous limits [14].

### BBPP chart

For the beta-binomial two-stage hierarchical model, the individual HCP's proportion of admissions having the event of interest,  $\theta_i$ , is assumed to be drawn from a beta distribution with parameters  $\pi$  and  $M$ , where  $\pi$  represents the mean CI proportion and the *spread parameter*,  $M$ , indicates the spread of proportions among the hospitals and is inversely related to the variance of the proportions between HCPs,  $\sigma^2 = \pi(1-\pi)/(1+M)$ . Thus  $\theta_i \sim \text{Beta}(\pi, M)$ . The observed count of events of interest at the  $i^{\text{th}}$  HCP,  $O_i$ , is assumed to follow a binomial distribution,  $O_i \sim \text{binomial}(D_i, \theta_i)$ , where  $D_i$  is the number of patients at risk of the event of interest at the  $i^{\text{th}}$  HCP.

The beta-binomial posterior predictive (BBPP) distribution gives the probability of observing a future number of occurrences of the event of interest at the  $i^{\text{th}}$  HCP,  $O_i^F$ , from the total number of future admissions,  $D_i^F$ . To reflect the binomial sampling variation in the  $O_i^F$  we have  $O_i^F \sim \text{binomial}(D_i^F, \theta_i)$ . The beta-binomial posterior predictive distribution is given by

$$p(O_i^F | D_i^F, O_i, D_i, \pi, M) = \binom{D_i^F}{O_i^F} \frac{\Gamma(D_i + M) \Gamma(O_i^F + O_i + \pi M) \Gamma(D_i^F + D_i - O_i^F - O_i + M - \pi M)}{\Gamma(O_i + \pi M) \Gamma(D_i - O_i + M - \pi M) \Gamma(D_i^F + D_i + M)}$$

## 3. Method

### BBPP Chart construction

For a given CI and HCP the BBPP probabilities for  $O_i^F \in [0, \dots, D_i^F]$  are obtained for each  $D_i^F$ . For lower and upper control limits equivalent to setting  $\alpha$  to 0.05, the 2.5<sup>th</sup> and 97.5<sup>th</sup> percentiles of the BBPP distribution are obtained for each  $D_i^F$ . This is repeated for each  $D_i^F$ .

### Tested Parameter Space

Whilst the BBPP distribution-based chart is applicable more widely than the healthcare setting, the investigation was conducted with this field, and the ACHS CIs, as its focus. This helped determine the parameter space to explore. A factorial design experiment for the set of parameters  $\pi$ ,  $\sigma$ ,  $\theta_i$ ,  $D_i$ ,  $O_i$  and  $\Delta$  as defined in the abstract was conducted to compare the two

charts. The values for each of the parameters were:

$\pi$  : 0.01, 0.025, 0.05, 0.10, 0.15, 0.20, 0.25

$\sigma$  :  $0.10\pi$ ,  $0.25\pi$ ,  $0.50\pi$ ,  $\pi$

$D_i$  : 10, 30, 50, 100, 200, 300, 400

$\theta_i$  :  $0.10\pi$ ,  $0.50\pi$ ,  $\pi$ ,  $1.50\pi$ ,  $2\pi$

$\Delta$  : 0.05, 0.10, 0.20, 0.50 (all positive shifts (increases) in the underlying proportion)

$D_i^F$  : 3, 4, ..., 499, 500

$O_i^F$  : 0, 1, ...,  $D_i^F$

For consistency with the 95% control limits chosen in the BBPP model,  $\alpha$  was set to 0.05 for the Bernoulli CUSUM chart. Further, as this research is monitoring single units,  $\beta$  was set to 0.05 to be consistent with Spiegelhalter et al. [14].

#### Average Run Lengths

The simulation generated a run based on a series of Bernoulli trials,  $x_t$ , with probability of success,  $\theta_i$ . For the Bernoulli CUSUM chart the cumulative sum,  $y_t = \max(0, y_{t-1}) + x_t - s$ , was plotted as the run, whereas for the BBPP chart the actual cumulative sum of the Bernoulli trials was plotted. The run length (time until the run breaches the limits of the chart) was recorded and repeated 1000 times to obtain an average run length (ARL).

This paper focuses on the above run lengths calculated under the condition that the underlying proportion increased. This produced the 'out-of-control ARL' and refers to the expected number of points plotted before we detect the change in the underlying proportion (a breach of the limits when there has been a change in the proportion).

The above was repeated for the Bernoulli CUSUM under two further conditions. The first assumed the true underlying proportion was known; the second involved estimation of the proportion of admissions that incurred an event of interest. In the former case the value for  $p_0$  was  $\theta_i$  and  $p_1 = (1+\Delta)p_0$ , whilst in the second  $p_0$  is  $O_i/D_i$ . This paper focuses on the comparisons based upon the latter, which is the more likely event in practice.

#### Determining significance

Practical significance has been used instead of statistical significance to compare the two charts' ARLs as statistical significance is greatly affected by the number of simulations. 1000 replications were used in this study to support reliable estimates of the ARLs for each chart.

A practically significant difference in the time between the two charts detecting a change in the underlying proportion was set at one day. The ACHS routinely reports upon data collected in six-month periods (i.e., 182 days). Hence the threshold of practical significance, one day, is equivalent to  $D_i / 182$ , assuming that the admissions are uniformly distributed across the six-month period. For the study's range of  $D_i$ , namely 10 to 400, this equates to a range for the number of patients at risk of an event per day of 0.05 to 2.20. Given the relatively small upper value, the practical significance threshold was set at zero.

#### 4. Results

Overall the BBPP chart had the desired lower out-of-control ARL (mean 237 (SE 4.6) and median 259) than the Bernoulli CUSUM chart (mean 334 (SE 6.0) and median ARL 467) for detecting the tested increases in the underlying mean proportion of admissions having the event of interest. Comparing the differences between the charts' out-of-control ARLs, BBPP-CUSUM, reveals that the BBPP chart has a lower out-of-control ARL in 71.6% of the simulations conducted. The average difference was -97 (SE 2.7), ranging from -497 to 387.

Parallel boxplots against each of the parameters and co-plots (conditioning scatter plots displaying how two variables are related, conditional on the values of another variable) suggested a parameter space may exist where the BBPP chart's out-of-control ARL was lower than the Bernoulli CUSUM chart's ARL. Recursive partitioning and the logistic regression model of the odds in favour of the BBPP chart having the lower out-of-control ARL identified the parameters  $\theta_i$ ,  $\Delta$  and  $\sigma$  as having the greatest influence on the BBPP chart having the lower out-of-control ARL. This effect was greatest in the parameter space having  $\pi < 0.1$ ,  $0.15 < \Delta < 0.35$ ,  $D_i < 30$ ,  $\theta_i < 0.1$  across all values for  $\sigma$ .

## 5. Discussion

The non-Bayesian CUSUM charts have been commonly applied to the monitoring of healthcare data. However, there appears to be a parameter space in which the Bayesian-based BBPP control chart detects changes in the underlying proportion more quickly than the CUSUM alternative.

Neither chart consistently performs better than the other at detecting changes in the underlying proportion across the entire parameter space explored. Given the existing knowledge about CIs and their likely  $\pi$ ,  $D_i$  and  $\theta_i$  values it is feasible to consider using a particular chart for a given CI. Further investigation, including the comparison of the in-control ARLs, will help in establishing a decision process for utilising either chart for a given CI.

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