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Use of prior manufacturer specifications with Bayesian logic eludes preliminary phase issues in quality control: an example in a hemostasis laboratory

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The present study seeks to demonstrate the feasibility of avoiding the preliminary phase, which is mandatory in all conventional approaches for internal quality control (IQC) management. Apart from savings on the resources consumed by the preliminary phase, the alternative approach described here is able to detect any analytic problems during the startup and provide a foundation for subsequent conventional assessment. A new dynamically updated predictive control chart (PCC) is used. Being Bayesian in concept, it utilizes available prior information. The manufacturer's prior quality control target value, the manufacturer's maximum acceptable interassay coefficient of variation value and the interassay standard deviation value defined during method validation in each laboratory, allow online IQC management. An Excel template, downloadable from journal website, allows easy implementation of this alternative approach in any laboratory. In the practical case of prothrombin percentage measurement, PCC gave no false alarms with respect to the 1_{ks} rule (with same 5% false-alarm probability on a single control sample) during an overlap phase between two IQC batches. Moreover, PCCs were as effective as the 1_{ks} rule in detecting increases in both random and systematic error after the minimal preliminary phase required by medical biology guidelines. PCCs can improve efficiency in medical biology laboratories. *Blood Coagul Fibrinolysis* 26:590–596

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Introduction

ISO standard 15189 (2012) says that 'the laboratory shall design internal quality control systems that verify the attainment of the intended quality of results' [1]. Internal quality control (IQC) plans are primarily intended to ensure respect of the specifications for which the method was selected and validated [2,3]. Although it is generally agreed that method acceptability should be assessed with respect to the biological variability of the parameters concerned, there is less agreement as to the actual set of parameters [4–6]. Moreover, the laboratory must choose control material concentrations equal or near to clinical decision thresholds, to ensure the validity of decisions made [3,7]. Finally, there must be no matrix effect vitiating inference from results for patient samples [3,8]. Many laboratories continue to use the 1_{2s} QC rule without considering the relationship of analytical performance to quality requirements [9,10]. The standard statistical process control paradigm requires two phases in process reading: model parameters [interassay standard deviation (SD) and control chart target] are estimated during phase I ('preliminary phase'), while actual online testing starts at phase II. In phase I, the process is assumed to be in the in-control state, with independent identically distributed observations, which provide estimates of the underlying statistical model. The longer the phase I, the more accurate the estimates, but also the more likely that the process will deviate from the in-control state. In case of alarms during phase I, standard practice implements an iterative procedure, removing alarms and recalculating control limits until alarms cease [11]. Phase II IQC management can be drawn and problems identified only once phase I is completed. Isolated problematic data points in phase I will impact phase II, which will be using contaminated parameter estimates [12–14]. Furthermore, control chart construction is static, based on phase I data only, despite the need to refine control limits as phase II data come in [15].

Conventional statistical process control provides a variety of tools for medication laboratories: Shewhart-type control charts [16], Cumulative Sum (CUSUM) [17], or Exponentially Weighted Moving Average (EWMA) [18,19]; in all these methods, interassay SD and target control chart value should be estimated in advance. A first estimate of interassay SD is made during the method validation phase, using at least 30 IQC results [14]. The target value (mean value) of the control chart is determined using at least 20 IQC results collected during overlap with the previous IQC batch [15]. If the control material is not changed between the validation phase and method startup (i.e. no change in IQC matrix), the preliminary phase for the new IQC batch serves mainly to re-estimate the control chart target value, without necessarily revising

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the interassay SD estimated in the method validation phase [14].

Given the technical requirements of standard 15189 and economic considerations, the most efficient attitude is for laboratories to acquire analytic systems using the reagents and equipment of a single manufacturer, thereby simultaneously acquiring pretested methods. Manufacturers have robust knowledge of their analytic systems' performance, determined on multiple reagent batches. This long assessment process enables them to estimate precisely the maximum allowable interassay SD on a method using their own control materials. Before launching a method, each laboratory should at the very least check that its own interassay SD is lower than the manufacturer's allowable value [1,8]. Manufacturers also determine precisely the target value expected on the control material. The allowable prior analytic SD and control material target value can serve as supports for specifications to be respected. The objection that the method is not tailored to clinical and biological expectations does not hold if methods are originally selected as precisely as possible. This strategy implicitly fully acknowledges biological and clinical specifications.

A Bayesian IQC plan ensures that the method is under statistical control with respect to prior manufacturer specifications, minimizing first-order risk that could lead to false rejection, notably during the process startup phase [20,21]. Using a Bayesian model in a concrete case, we shall demonstrate that there is no need for a preliminary phase to bring a method under control when introducing a new IQC batch. We shall further demonstrate that the Bayesian model is at least as effective as the 1_{ks} rule (with same 5% false alarm probability on a single control sample) in detecting either a sudden rise in the random error or a persistent shift during startup. The details of the description and mathematical construction of the Bayesian 'predictive control chart' are given in the Appendix.

Reagent and automated coagulation analyzer for the case study

The manufacturer, Stago (Asnières, France), provided $m = 20$ prothrombin time (PT) values in percentages, which they had determined in a preliminary phase on one of their own STA R automated coagulation analyzers [analyzer: STA R; reagents: STA – Neoplastine CI Plus STAGO (Asnières, France); NB: STA-Unicalibrator STAGO (Asnières, France)]. In France, PT is expressed as seconds and as percentage. The present study uses percentages, to enhance the discriminatory power of the calculations and figures. Stago provides percentage calibration of PT, with normal plasma as reference (STA – Unicalibrator).

The control material was a normal control sample (STA-COAG CONTROL N). The acceptability of the 20 control values was confirmed by the fact that they had been collected during a phase of overlap with another control batch with the same reference (STA-COAG CONTROL N), which in turn had been collected with respect to the 1_{2s} rule acceptation. In the batch in question, the range given by Stago (prior range) was 76–102%, thus with a prior target value of $\hat{\mu} = 89\%$. Stago also reported that the coefficient of variation (CV) for this material should not exceed 5% when the method has to be validated in each individual laboratory. This means that the interassay SD should not exceed 4.45 ($\hat{\sigma}$) for a normal control sample (STA-COAG CONTROL N) for which the expected target value is 89% PT. In point of fact, in the checking phase, the interassay SD was 2.52 ($\hat{\tau}$) for this particular control (STA-COAG CONTROL N) [8,18].

Demonstration of how the preliminary phase can be avoided

At the end of the preliminary phase, performed on the 20 values, the mean ($\bar{x}$) was estimated at 82% and the interassay SD at 2.53, while the control limits were set at ± 3.016 so that a 5% false alarm probability (FAP) is achieved for the whole sequence of the 20 values (Fig. 1a). We will call this 1_{3s} method. To be equivalent with the PCC we select the 1_{3s} chart that plots the control limits at 3.01599 SD from the centerline, achieving a 5% overall FAP.

PCC identified no outliers during a preliminary phase well controlled by the overlap phase (Fig. 1b): that is, PCC is not subject to false rejection with $\hat{\tau}$ equal to 2.52 (Fig. 1b).

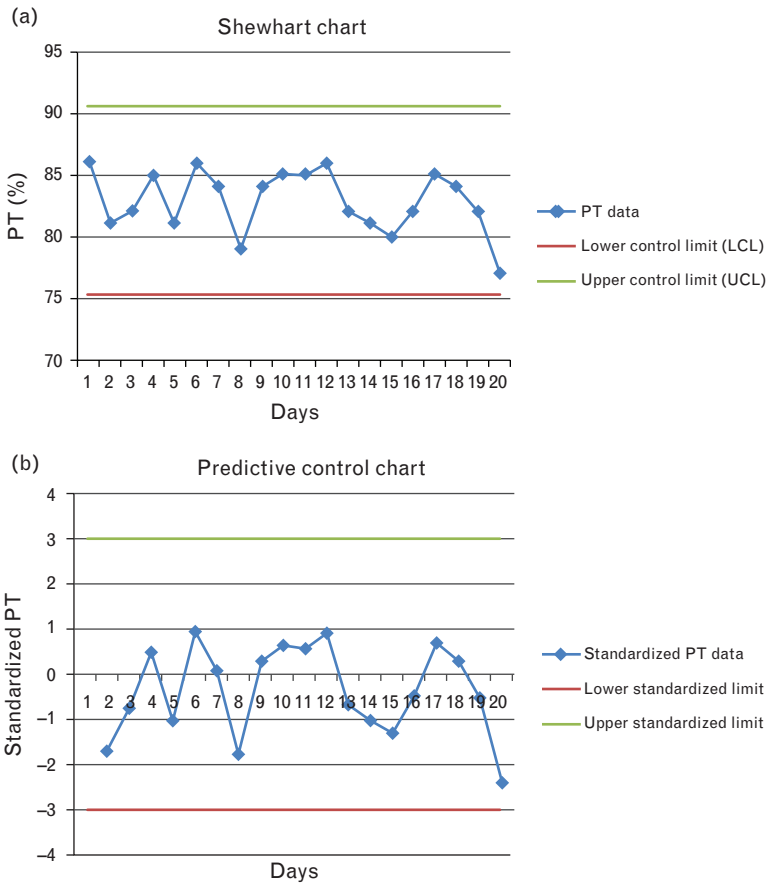
The experiment can be reproduced using the 'PCC template' Excel spreadsheet, downloadable on the journal website. First, the manufacturer's data should be entered as follows: 'Manufacturer's prior internal quality control target value' (manufacturer control materials with assigned values): $\hat{\mu} = 89\%$ in the case study, 'Manufacturer's maximum acceptable coefficient of variation (%)' on methods, with reagents and device both provided by the manufacturer (technical notices specifying the maximum acceptable interassay CV): CV = 5% in the case study.

The spreadsheet automatically calculates the 'Manufacturer's maximum acceptable interassay SD ($\hat{\sigma}$)' (i.e. $\hat{\sigma} = \hat{\mu} \times CV$): $\hat{\sigma} = 4.45$ in the case study. Next, you enter 'Own interassay SD estimated at method checking phase ($\hat{\tau}$)':

$\hat{\tau} = 2.52$ in the case study.

The control results are already entered on the spreadsheet by default. The spreadsheet also calculates the mean value (target control chart value) from 20 of the IQC results entered, excluding any associated with an Alarm (Outliers). The laboratory can thus revert to a conventional control chart, using the target value calculated from the PCC, safe in the knowledge that no outliers (actually loss of statistical control) of have been

Fig. 1



(a) Shewhart chart constructed from the 20 consecutive prothrombin time (PT) (%) values collected during the preliminary phase (mean value = 82% and inter assay SD = 2.5); lower and upper limits at mean ± 3.016 SD. (b) Predictive control chart (PCC) constructed from the 20 standardized consecutive values calculated from the 20 consecutive PT (%) values collected during the preliminary phase with interassay SD (τ) = 2.52 (see theorem in predictive control chart construction).

included with respect to the manufacturer's data and the laboratory's own environment ('Own interassay SD' estimated at method checking phase).

Demonstration that the Bayesian model maintains the method under control, taking the concrete case of two types of shift

1_{3s} rule detected big and gradual shifts simulated after the preliminary phase (Fig. 2a and 2b).

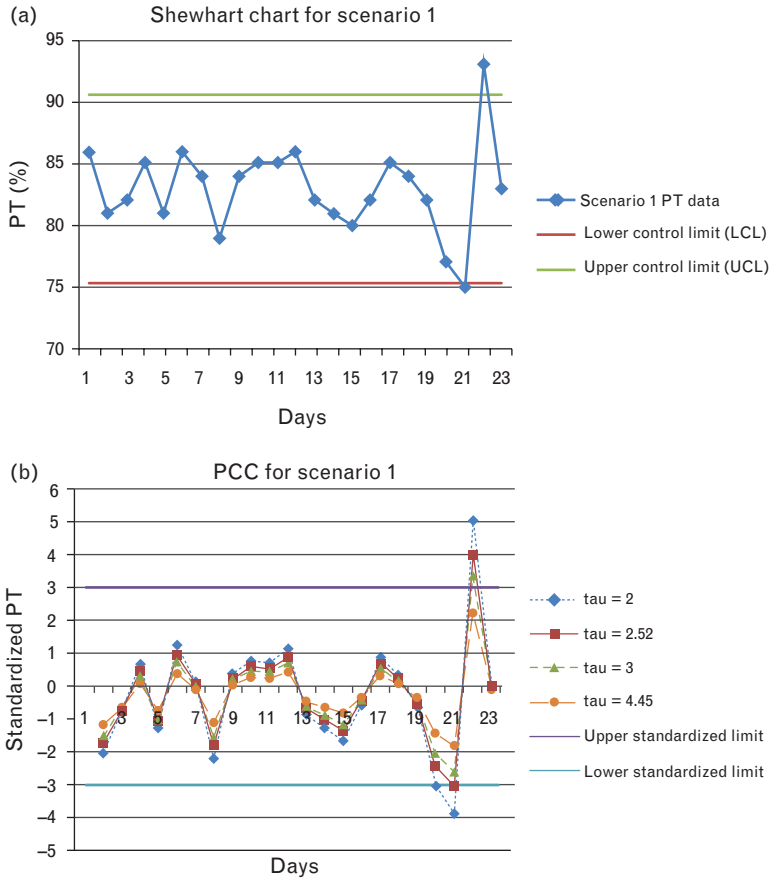
PCC and 1_{3s} rule detected big and gradual shifts simulated after the preliminary phase with $\hat{\tau}$ equal to 2.52. If $\hat{\tau}$ exceeds 2.52, the PCC is no longer able to detect all alarms like the 1_{3s} rule (Fig. 3a and 3b).

It is also possible to reproduce this on the 'PCC template' Excel spreadsheet (downloadable on the journal website), where the same prior data have been entered (see above). An alarm message is displayed when a control point is not under control.

Discussion

It is possible to run a preliminary phase in advance, using new control batches before actually changing batches. Control values are collected using those acceptable for the ongoing batch. As this step is very resource-costly, given the large number of biological parameters to be brought under control, it is generally kept as short as possible [15]. There is considerable technical and economic interest in getting round this preliminary phase problem, especially when measurement series are not frequent [20]. The laboratory may be thought to neglect the patient by relying on manufacturer specifications to define control value acceptability [2]; however, there is no single definition of biological specifications [4–6]. It is thus not unreasonable to use manufacturer specifications, if the analytic system is a good one. Manufacturers' prior control material target values and allowable analytic performance are derived from plentiful data harvested from multiple machines and reagent batches. It may, however, be objected that the laboratory's own specific

Fig. 2



Shift scenario 1 after the preliminary phase: big negative shift at day 21, big positive shift at day 22 and return to chart's target at day 23; (a) Shewhart chart with lower and upper limits at mean ± 3.016 SD. (b) Predictive control chart (PCC) with various choices of interassay SD (τ): 2, 2.52, 3, and 4.45.

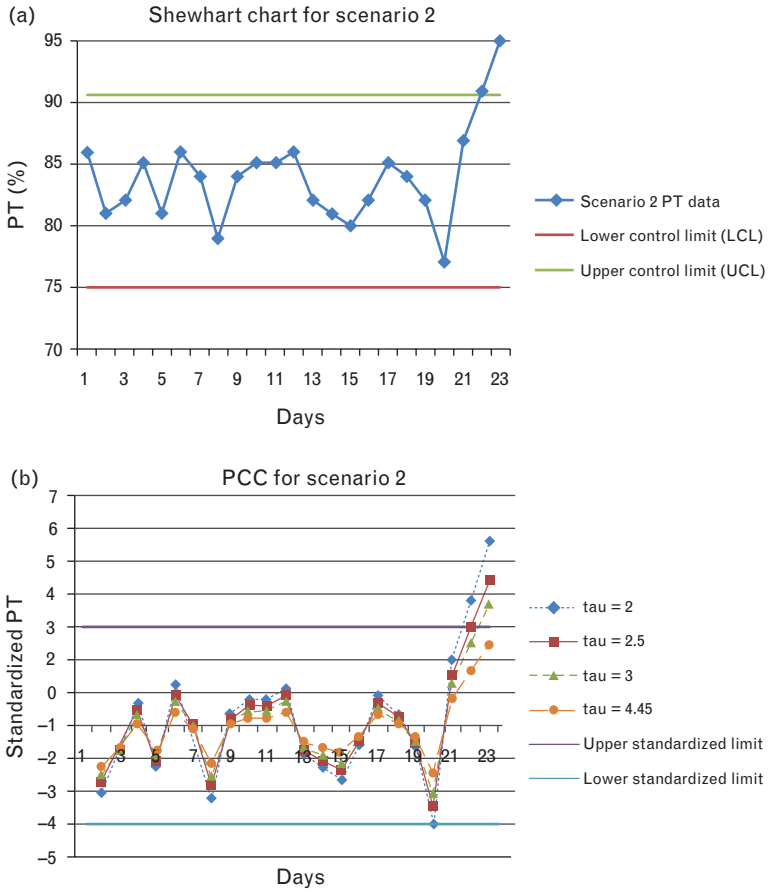
working environment is being neglected, although required for a conventional approach [2,3]. However, as new control values come in, the model will implement the individual laboratory's working conditions, conversely reducing the weight of the manufacturer specifications. Indeed, at day 23 in scenario 1 (Fig. 2b), a control value equal to the mean target value estimated from the preliminary phase (i.e. 82%) gives a standardized PCC value very close to 0 (i.e. −0.333).

Simulation studies show that the PCC has enhanced performance in detecting occasional or persistent shifts compared with 1_{ks} control charts especially while in the preliminary phase. It should be borne in mind that laboratories with good analytic practice (i.e. small interassay SD) will benefit the most from PCCs (Figs 2b and 3b). They are potentially in a better position to detect outliers than a laboratory with poorer analytic performance. Laboratories must therefore be as careful as possible in estimating prior interassay SD in the method validation phase. However, this prerequisite is well known and has been taken on board by the community.

The present study is (to the best of our knowledge) the first in the field of medical biology to focus on the validity of the prior information supplied by manufacturers. A PCC is able to take account of the laboratory environment so as to retarget the control chart (see standardized value for day 23 in scenario 1 Fig. 2a and b). On the contrary, the PCC approach demonstrates the importance of estimating the laboratory's particular interassay SD (τ) as precisely as possible so as not to impair the prior information provided by the manufacturer's maximum acceptable SD ($\hat{\sigma}$). In other words, a PCC founded on prior knowledge of manufacturer information such as prior internal quality control target and maximum acceptable interassay SD proves to be appropriate and very useful during the method startup phase.

Thus, both theoretically and practically, the laboratory is bringing its method under control as soon as it begins implementing its IQC values. This short-term Bayesian model can serve as a complement to a conventional approach, which can be reintroduced as soon as there

Fig. 3



Shift scenario 2 after the preliminary phase: gradual shift at days 21, 22 and 23; (a) Shewhart chart with lower and upper limits at mean ± 3.016 SD. (b) Predictive control chart (PCC) with various choices of interassay SD (τ): 2, 2.52, 3, and 4.45.

are enough reliable IQC data for it to be able to detect outliers during the process startup phase.

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Conflicts of interest

There are no conflicts of interest

Appendix: Predictive control chart description

Within the Bayesian approach, underlying parameters are considered to be random variables and, as such, have a distribution.

To control an unknown quality parameter θ (e.g. prothrombin time in a hemostasis laboratory), before any data are observed, θ will be modeled with a prior distribution reflecting the uncertainty of the unknown parameter. This can be elicited by manufacturer specifications, prior knowledge of the process under study, expert opinion and/or any archived data. We assume that:

$$\pi(\theta) \sim N(\mu, \sigma^2)$$

There are several ways of estimating the nuisance parameters μ and σ^2 like experts' opinion, prior data or manufacturer specifications. For the latter let us assume that, for a specific process, the manufacturer provides a range of normally distributed values$[L, U]$, where the data should have a high probability of being within these limits if the process is under the in-control state, along with a coefficient of variation CV. Then it is straightforward to obtain estimates of μ and σ^2 by:

$$\hat{\mu} = \frac{L+U}{2} \text{ and } \hat{\sigma}^2 = (\hat{\mu} \times \text{CV})^2$$

Once the prior distribution is set, data collection starts sequentially, allowing the unknown quantity θ to be measured with a certain error.

$$X_i|\theta \sim^{iid} N(\theta, \tau^2)$$

The parameter τ^2 refers to the measurement's accuracy and will depend on various laboratory factors: equipment used, technician's experience, and so on. τ^2 can be assessed independently in advance during in-lab method validation upstream of implementation, as the square of the interassay SD [14]. Thus, interassay SD may differ according to the degree of control over these nuisance parameters. The following case study includes a sensitivity analysis. As data arrive sequentially, they are combined with the prior distribution to provide the posterior distribution of the unknown parameter, via Bayes' theorem. If the process performs acceptably, the posterior distribution at any given time is the prior distribution for the upcoming observation. That is, the prior distribution is sequentially updated [22].

The goal is to derive a chart enabling online identification of isolated or persistent shifts (loss of control state), even with very few data points. This control chart is based on the predictive distribution.

Predictive control chart construction

We first calculate the posterior distribution: at some time k, we have the updated prior distribution $\pi(\theta|x_1,...,x_{k-1})$ for the parameter and observe a data point x_k with likelihood function $f(x_k|\theta)$. Bayes' theorem then gives the posterior distribution at time k:

$$p(\theta|x_1,...,x_k) = \frac{f(x_k|\theta)\pi(\theta|x_1,...,x_{k-1})}{\int f(x_k|\theta)\pi(\theta|x_1,...,x_{k-1})d\theta}$$

Next, the future observable will have the likelihood $f(x_{k+1}|\theta)$ and, before x_{k+1} is actually observed, we can derive the predictive distribution [23] by:

$$f(x_{k+1}|x_1,...,x_k) = \int f(x_{k+1}|\theta)p(\theta|x_1,...,x_k)d\theta$$

In the Normal prior – Normal likelihood scenario adopted here, both posterior and predictive distribution will be available in closed forms and can be obtained recursively as the following theorem shows (for a proof see [24]):

Theorem: If the initial prior distribution of the unknown parameter is:

$$\theta \sim N(\mu, \sigma^2)$$

and the data constitute a random sample with likelihood:

$$X_k|\theta \sim^{iid} N(\theta, \tau^2)$$

then the posterior distribution at time $k = 1, 2, ...$ will be given by:

$$\theta|X_1, X_2, ..., X_k \sim N(\hat{\theta}_k, \hat{\sigma}_k^2)$$

and the predictive distribution will be:

$$X_{k+1}|X_1, X_2, ..., X_k \sim N(\hat{\theta}_k, \hat{\sigma}_k^2 + \tau^2)$$

where

$$\hat{\theta}_k = \frac{\hat{\sigma}_{k-1}^2 x_k + \tau^2 \hat{\theta}_{k-1}}{\hat{\sigma}_{k-1}^2 + \tau^2} = w_k x_k + (1 - w_k)\hat{\theta}_{k-1}$$

$$\hat{\sigma}_k^2 = \frac{\hat{\sigma}_{k-1}^2 \tau^2}{\hat{\sigma}_{k-1}^2 + \tau^2} = w_k \tau^2 = (1 - w_k)\hat{\sigma}_{k-1}^2$$

$$w_k = \frac{\hat{\sigma}_{k-1}^2}{\hat{\sigma}_{k-1}^2 + \tau^2},\ \hat{\sigma}_0^2 = \sigma^2 \text{ and } \hat{\theta}_0 = \mu$$

The predictive mean combines information from the prior setting and the incoming data; as k increases, the effect of the prior distribution decays. Similarly, the variance of the predictive distribution will decrease as k increases, converging on τ^2 [24]. Thus, with the prior distribution being dynamically updated, the effect of prior choices will decay, as long as we avoid very extreme choices for the variance parameters.

At each time k ($k \geq 1$), we know the predictive distribution $X_{k+1}|X_1, ..., X_k$, for the future data point X_{k+1}. To construct a control chart, this predictive distribution can be summarized using an interval. Specifically, we obtain a $100(1-\alpha)\%$ coverage interval for the future observable X_{k+1}. The shortest possible interval (containing the more probable values) can be obtained, since the predictive distribution is normally distributed, by taking $\alpha/2$ probability out of each tail, symmetrically around the mean interval. The endpoints of this predictive interval will provide the control limits for the upcoming observation x_{k+1}. Note that the control limits obtained from the predictive distribution are probabilistic (i.e. the next observable has a probability of $1-\alpha$ of being within these limits). This is radically different from traditional Shewhart-type chart control limits (e.g. 1_{2s}) that can be used for testing a point null hypothesis: that is, we are able to reject or not the null hypothesis that the unknown parameter θ equals some constant value [21].

As mentioned, the mean and variance of the predictive distribution are constantly updated, the latter decreasing as more data become available. The updated centerline and control limits become available sequentially and are used to draw the future observation x_{k+1}, once it becomes available. To ease the procedure and provide a chart with fixed control limits, we can standardize the upcoming observation before plotting. Specifically, since:

$$X_{k+1}|X_1, X_2, ..., X_k \sim N(\hat{\theta}_k, \hat{\sigma}_k^2 + \tau^2) \Rightarrow Z_{k+1}$$
$$= \frac{X_{k+1} - \hat{\theta}_k}{\sqrt{\hat{\sigma}_k^2 + \tau^2}} \sim N(0,1)$$

once $X_{k+1} = x_{k+1}$ is observed, we calculate and plot the standardized value:

$$z_{k+1} = \frac{x_{k+1} - \hat{\theta}_k}{\sqrt{\hat{\sigma}_k^2 + \tau^2}}$$

This allows fixed control limits throughout the process, placed at $\pm z_{\alpha/2}$. Thus, the steps in constructing the PCC are as follows:

1. Decide the appropriate α value and plot the control limits at $\pm z_{\alpha/2}$ (centerline at zero).
2. Once a data point $x_k (k \geq 1)$ becomes available, calculate the predictive mean and variance of the future observable $X_{k+1}|X_1, X_2, ..., X_k$ based on the theorem.
3. Once x_{k+1} becomes available, standardize it to obtain z_{k+1} and plot it in the control chart.
4. If z_{k+1} falls
   a. within the limits, then the data conform to the in control scenario and the process will continue to operate: that is, we replace k by $k+1$ as subscript and move back to step 2;
   b. outside the predictive limits, it is an outlier, providing an alarm that the process has moved away from the in control state.

The predictive distribution is first available right after x_1 becomes available; thus, charting can start from the second data point on. In the first step of PCC construction, we need to specify the appropriate α value. This value will determine the performance of the control chart, because its choice is a compromise between detection power and false alarm rate.

We base our decision regarding α on the FAP performance metric [25], which is defined as the probability of getting at least one false alarm in the m observations of the preliminary phase. So, assuming independence among successive times and setting the control limits at $\pm z_{\alpha/2}$ in a finite horizon of $m-1$ observations (since charting will not include the first data point), the value of α as a function of FAP and the number of data points m will be:

$$\alpha = 1 - (1 - FAP)^{1/(m-1)}$$

The choice of the appropriate FAP (α) value will reflect the laboratory's policy with respect to the costs associated with type I error (falsely rejecting the hypothesis that the process is under control) and type II error (failing to reject the hypothesis that the process is under control). If type I error is quite expensive compared with type II, we will select a small FAP (α) value, moving the control limits away from the center line. On the contrary, if the converse is true (i.e., type II is more important), we use a large FAP (α) value, moving the limits closer to the centerline.

The PCC can be easily implemented; an Excel template is available as supplementary material http://links.lww.com/BCF/A17.

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