Research Article

Spreadsheet for patient-based quality control analysis and evaluation (SPAE)

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Abstract

Introduction: Patient-based quality control (PBQC) is an alternate quality control technique to conventional (internal) quality control. It uses patient results generated for clinical care to monitor the analytical performance through statistical analysis. The use of PBQC in routine laboratory is impeded by lack of familiarity and appropriate informatics tool.

Method: A Spreadsheet for PBQC Analysis and Evaluation (SPAE, based on Microsoft Excel) is developed. It incorporates IFCC recommended features for PBQC informatics tool that has been automated, including data visualization, data (Box-Cox) transformation, extreme value treatment (winsorization) and user parameter selection (block size, acceptable false positive rate, desirable bias for detection).

Results: Following parameter selection and data input, the spreadsheet automatically calculates the winsorization limits, transformed values, performance verification metrics such as false positive rates and number of results affected before error detection (NPed) – a performance metric for how sensitive the PBQC model detects the predefined error (bias). The verified PBQC model can be used for routine monitoring. The performance of the spreadsheet tool was verified against an independent model based on Python. Laboratory users can download the tool at https://github.com/HuiQi96/PBQC/blob/main/ PBQC_model_v2.2.zip.

Discussion: The SPAE is a simple-to-use desktop tool that lowers the barrier for laboratory users to adopt PBQC in their quality control system. In addition, the spreadsheet can be used as an educational tool, such as when conducting a workshop, to help laboratory users better familiarize themselves with the PBQC concepts and used for independent verification of the output of another informatics tool.

Introduction

Patient-based quality control (PBQC) uses patient results generated for routine care to monitor for potential changes in analytical performance [1-3]. It has gained recognition as an alternative quality control practice to conventional quality control in the latest ISO 15189:2023 document [2]. However, the routine implementation of PBQC is beset by the lack of suitable informatics capability in the instrument middleware or laboratory information system [3,4]. This report describes and provides a fully functional, end-to-end informatics tool encoded in a spreadsheet (Microsoft Excel, Spreadsheet for patient-based quality control analysis and evaluation, SPAE) to lower the barrier of adopting PBQC in routine laboratory practice (downloadable from https://github.com/HuiQi96/PBQC/blob/main/PBQC_model_v2.2.zip). In addition, the spreadsheet can be used as an educational tool, such as when conducting a workshop, to help laboratory users better familiarize themselves with the PBQC concepts and used for independent verification of the output of another informatics tool. Laboratory users are encouraged to get acquainted with basic PBQC concepts before using the spreadsheet tool [1-3].

Material and Methods

The following features were considered during the development of the spreadsheet tool, considering the recommendations from the IFCC Working Group on Patient-Based Real-Time Quality Control [6,7]. These include:

1. Ability to visualize the distribution of the laboratory data to assess for skewness and the need for data transformation to approximate normal distribution
2. Ability to select appropriate PBQC model and parameters, including block size, acceptable false positive rate (which determines the control limits), the acceptable bias for detection, winsorization limit (which converts extreme values to the predefined limit), perform auto-optimized Box-Cox transformation of data (if necessary)
3. Ability to assess the effect of the selected parameters above on the performance of the PBQC model (see below)
4. Ability to verify the performance of the PBQC model using established performance parameters such as false positive rates, detection rates and numbers of patient results affected before error detection (NPed)
5. Ability to monitor the ongoing performance (i.e. error detection) using the selected and verified PBQC model and an alert of any error detected

These features were coded into five separate spreadsheets ('Input', 'Training', 'Verification', 'Output', 'Routine'. For this tool, the moving average and moving median are adopted as the PBQC algorithms. The laboratory user can directly input their local data to customize the PBQC parameter setting for optimal performance in routine practice. Visualization tools were also coded to show the overall data distribution (in the histogram) and in control charts to allow users to better appreciate the effects of different parameters on the PBQC model.

Results

Figure 1 shows the 'Input' spreadsheet where laboratory users can define the acceptable false positive rate (%), the desirable magnitude of bias (expressed as %) to be detected, Box-Cox transformation ('Yes' / 'No'), winsorization (%) and three choices of block size. The acceptable false positive rate affects the control limit of the PBQC model. It can be determined based upon the operational consideration and risk tolerance of the laboratory. A higher acceptable false positive rate will tighten the control limit and improve error detection but can produce higher false alarm (as defined by the user). For example, a 5% false alarm rate for a laboratory analyzing 1000 samples will produce 50 PBQC false alarms daily. Generally, keeping the false positive rate as low as possible is desirable, starting with 0%.

The user defines the desirable magnitude of bias (%) to be detected, which may be determined according to the Milan consensus (e.g., biological variation, or state-of-the-art). The predefined bias will be used to assess the performance of the PBQC model subsequently during the verification step. Box-Cox transformation may be selected if the data distribution appears skewed. When selected, the spreadsheet will determine the optimal lambda based on the distribution of the laboratory data to approximate a normal distribution.

Winsorization is the statistical technique to convert an extreme laboratory value to a predefined limit. For example, if a winsorization limit of 150 mmol/L is selected, a laboratory value of 165 mmol/L will be converted to 150 mmol/L. This conversion helps reduce the effects of outlier (or extreme) results while keeping the data instead of removing it and is preferred [5]. The selection of 'Winsorization %' in the tool will convert the most extreme data outside the predefined percentages bilaterally to the below-mentioned limits. For example, a winsorization limit of 95% will convert the highest 2.5% and the lowest 2.5% values to the winsorization limit. Winsorization is recommended if extreme values are common in the laboratory. However, it should generally be kept at >90% (i.e., not more than the most extreme 10% laboratory values are converted to the winsorization limits). An overly strong winsorization setting (e.g., 60%, thereby converting the 'most' extreme 40% laboratory data) can overly constrain the distribution of the laboratory data, leading to a poorer bias detection rate.

The three choices of block size for the moving average and moving median algorithms can be defined and adjusted based on the performance seen during the verification step. In general, a larger block size has the effect of reducing the variability of the moving statistics, which produces smaller control limits. While a smaller control limit may be associated with better error detection capability, the improvement may be offset by the need

for more samples within the (larger) block size to be affected by the error before the moving statistics exceed the control limits. Moreover, the smaller control limits (due to larger block size) may also be associated with increased false positive rate. The interplay between block size, NPed (a metric for sensitivity for error detection) and false positive rate requires simulation and depends on the distribution of the data.

Figure 1: 'Input' spreadsheet where laboratory users can define the acceptable false positive rate (%), desirable bias detection (%), winsorization (%) and block size.

Predefined setting	
Acceptable False Positive Rate(%)	0
Desirable bias for detection (%)	5
Box-cox transformation	No
Box-cox lambda	#N/A
Winsorisation %	98
Winsorisation lower limit	#NUM!
Winsorisation upper Limit	#NUM!

Method parameters	
Method1	Med
Method2	Avg
Block size1, n1	5
Block size2, n2	10
Block size3, n3	20

Column	Method	block size, n	lower control limit	upper control limit
MMed1	Med	5	#NUM!	#NUM!
MMed2	Med	10	#NUM!	#NUM!
MMed3	Med	20	#NUM!	#NUM!
MAvg1	Avg	5	#NUM!	#NUM!
MAvg2	Avg	10	#NUM!	#NUM!
MAvg3	Avg	20	#NUM!	#NUM!

Once the preliminary settings are made, the laboratory user can input historical data of their laboratory into the 'Training' spreadsheet (Figure 2). The format for data input should include 'ID' (e.g. sample ID), 'date' (in "YYYY-MM-DD" format) and measurement (the numerical laboratory results) into the blue cells. It is recommended that at least six months, and ideally one year, of data, be used to ensure adequate variation in the data is incorporated into the model. Of note, the laboratory should first remove data with any symbols (e.g. "<", ">" or "#" etc.) or non-numerical (e.g. "NA", "INV", "Error", "INSUFF" etc.) from the dataset prior to input into the spreadsheet. Examples of such data may include results falling outside analytical measurement interval or those associated with errors such as insufficient sample.

Once the 'Training' is input, the optimal lambda (if Box-Cox transformation was selected) and winsorization limits (if a predefined percentage is input) will automatically be calculated and displayed in the 'Input' page (Figure 3). A frequency histogram is automatically produced to allow the user to visualize the distribution of the laboratory data for skewness (to determine whether Box-Cox transformation is necessary) and the presence of extreme values (to determine how much winsorization is required). In the example in Figure 3, the Box-Cox transformation was not selected since the data appeared normally distributed. Still, a mild winsorization (99.5%) was chosen to transform the most extreme 0.5% of laboratory results (bilaterally). The control limits for each block size of the moving average and median algorithms are also auto-calculated and displayed.

Figure 2: 'Training' spreadsheet where the laboratory user inputs at least 6-12 months of historical laboratory results.

ID	date	measurement
1	2020-01-01	138.00
2	2020-01-01	141.00
3	2020-01-01	145.00
4	2020-01-01	139.00
5	2020-01-01	137.00
6	2020-01-01	141.00
7	2020-01-01	140.00
8	2020-01-01	143.00
9	2020-01-01	140.00
10	2020-01-01	140.00
11	2020-01-01	144.00
12	2020-01-01	141.00
13	2020-01-01	141.00
14	2020-01-01	140.00
15	2020-01-01	139.00
16	2020-01-01	141.00
17	2020-01-01	137.00
18	2020-01-01	135.00
19	2020-01-01	137.00
20	2020-01-01	136.00
21	2020-01-01	141.00
22	2020-01-01	138.00
23	2020-01-01	137.00

Result	
min date=	2020-01-01
max date=	2020-10-26
min date (number)=	43831
max date (number)=	44130
number of days=	300

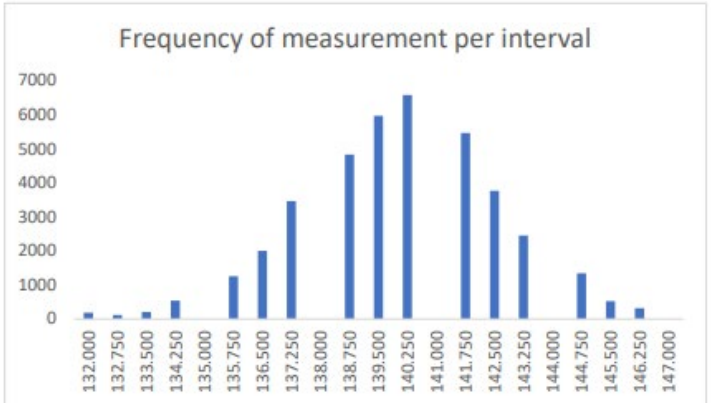


Figure 3: 'Input' spreadsheet shows the auto-populated parameters, including winsorization limits (if defined) and control limits of each block size of the moving average and moving average algorithms once the data has been entered into the 'Training' spreadsheet.

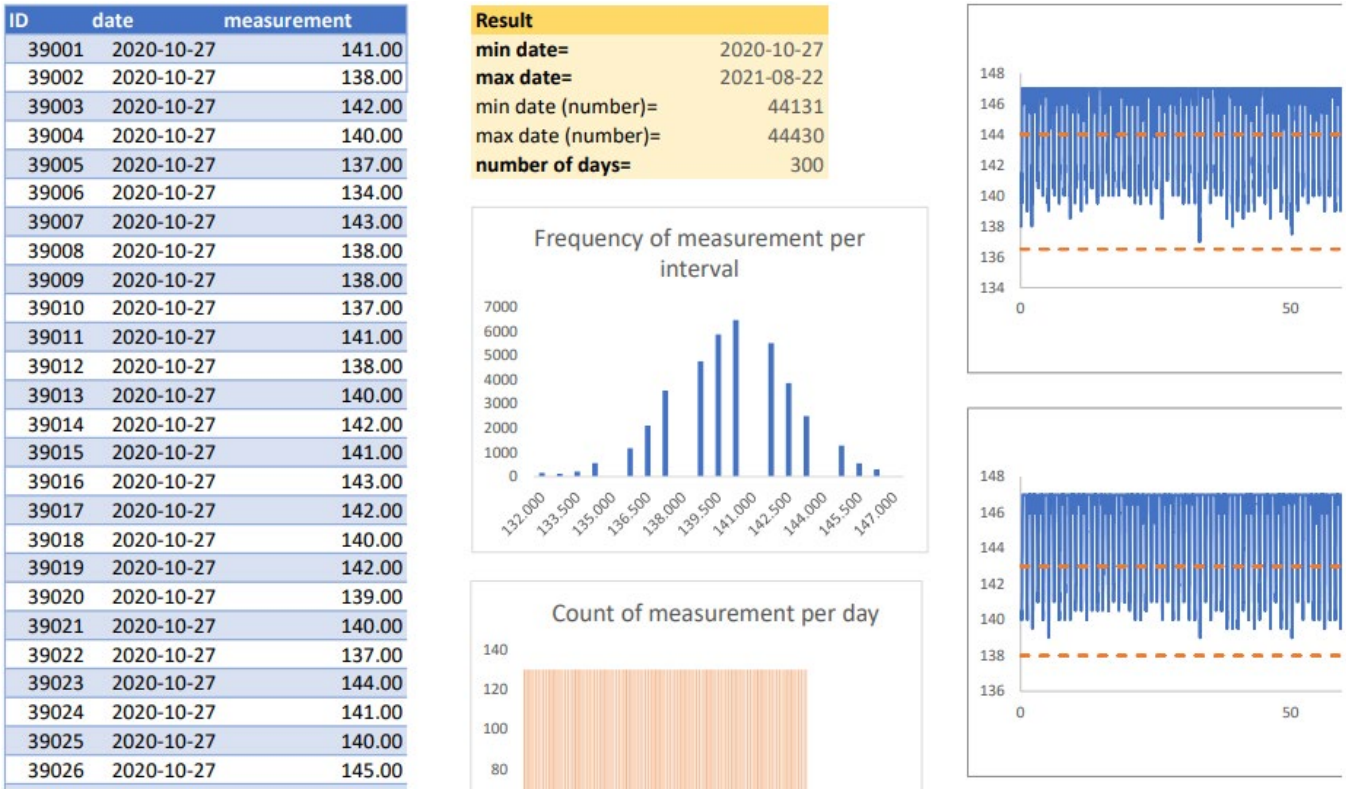
Predefined setting	
Acceptable False Positive Rate(%)	0
Desirable bias for detection (%)	5
Box-cox transformation	No
Box-cox lambda	#N/A
Winsorisation %	99.5
Winsorisation lower limit	132.000
Winsorisation upper Limit	147.000

Method parameters	
Method1	Med
Method2	Avg
Block size1, n1	10
Block size2, n2	20
Block size3, n3	30

Column	Method	block size, n	lower control limit	upper control limit
MMed1	**Med**	**10**	136.500	144.000
MMed2	**Med**	**20**	138.000	143.000
MMed3	**Med**	**30**	138.000	142.500
MAvg1	**Avg**	**10**	137.200	143.400
MAvg2	**Avg**	**20**	138.300	142.550
MAvg3	**Avg**	**30**	138.800	142.233

Next, the laboratory user can input another set of (verification) data in the blue cells of the 'Verification' spreadsheet. Here, the predefined 'desirable bias to be detected (%)' will be introduced into the verification dataset (i.e., bias is simulated in the 'verification' dataset). The bias will be introduced once for each day of data in the verification dataset. Several charts are shown, including the data distribution, the number of results for each day of the dataset, and the control charts of the data with the simulated bias introduced (Figure 4).

Figure 4: 'Verification' spreadsheet shows the distribution of the data, the number of measurements for each day, and the control charts showing the data with the simulated bias.



ID	date	measurement
39001	2020-10-27	141.00
39002	2020-10-27	138.00
39003	2020-10-27	142.00
39004	2020-10-27	140.00
39005	2020-10-27	137.00
39006	2020-10-27	134.00
39007	2020-10-27	143.00
39008	2020-10-27	138.00
39009	2020-10-27	138.00
39010	2020-10-27	137.00
39011	2020-10-27	141.00
39012	2020-10-27	138.00
39013	2020-10-27	140.00
39014	2020-10-27	142.00
39015	2020-10-27	141.00
39016	2020-10-27	143.00
39017	2020-10-27	142.00
39018	2020-10-27	140.00
39019	2020-10-27	142.00
39020	2020-10-27	139.00
39021	2020-10-27	140.00
39022	2020-10-27	137.00
39023	2020-10-27	144.00
39024	2020-10-27	141.00
39025	2020-10-27	140.00
39026	2020-10-27	145.00

Following this, the performance parameter of the PBQC model, based on the parameters selected, will be displayed in the 'Output' spreadsheet for each block size (Figure 5). The parameters include percentage detected (i.e., number of days of bias detected/ number of days bias was introduced), ANPed (average number of patient results affected before error detected, which is the average number of patient results between the bias is introduced and the bias is detected). MNPed (median NPed), 95Nped (95th percentile Nped), false positive (false alarm before bias introduction). Each performance criteria will be automatically ranked with the highest-performing parameter highlighted in the green cell. An overall best combination of the best parameters (i.e., the combination with the greatest number of highest performing parameter/ green cells) will be indicated as 'Preferred' and applied in the 'Routine' spreadsheet. Details of the parameter selected is also displayed at the bottom of the spreadsheet. The laboratory user may further tune/ modify the PBQC parameters in the 'Input' spreadsheet to improve the performance of the PBQC model as necessary.

Figure 5: The 'Output' spreadsheet shows the performance parameters of the user-defined PBQC models. The best-performing parameters are highlighted in green cells, and the PBQC model producing the preferred (overall best) combination of performance is indicated.

Method	block size	Perc detected(%)	ANPed	MNPed	95NPed	False positive (%)	Preferred
Med	10	100	5	5	6	0	Preferred
Med	20	100	8	8	11	0	
Med	30	100	11	12	15	0	
Avg	10	100	5	5	7	0.015	
Avg	20	100	7	7	9	0.0125	
Avg	30	100	8	8	12	0.01	

Best metrics	
max per detected (%)	100
min ANPed	5
min MNPed	5
min 95NPed	6
min fasle positive (%)	0

Method parameters for real-time data	Value
Method	Med
Block size	10
lower control limit	136.500
upper control limit	144.000
Acceptable False Positive Rate(%)	0
Desirable bias for detection (%)	5
Box-cox transformation	No
Boc-cox lambda	#N/A
Winsorisation %	99.5
Winsorisation lower limit	132.000
Winsorisation upper Limit	147.000

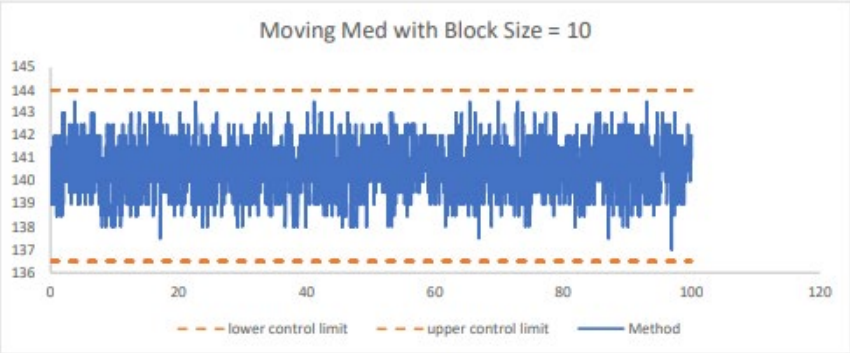
Recommended preferred set of method Parameters is Moving Med with Block Size = 10 to detect 5% bias for 0% of Acceptable False Positve Rate

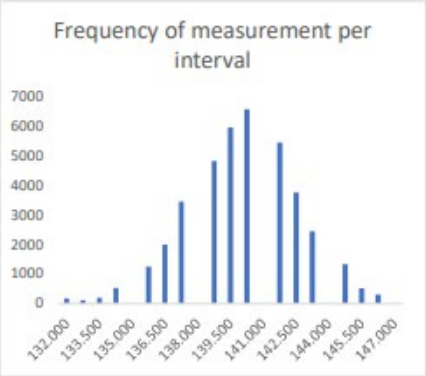
Once the laboratory user is satisfied with the performance of the PBQC model, routine laboratory data can be input into the 'Routine' spreadsheet. The optimized parameters based on the 'Verification' spreadsheet will be automatically adopted. A control chart shows the running PBQC model, and if bias is detected, it will be indicated in the box (Figure 6). The performance of the spreadsheet tool was independently verified using an independent PBQC model built using the same parameters in Python (see Supplemental Material).

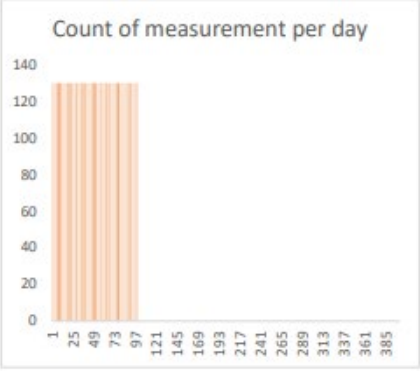
Figure 6: 'Routine' spreadsheet shows the user-optimized PBQC model running with routine laboratory data. Any bias detected will be flagged and displayed in the box.

ID	date	measurement
78001	2021-08-23	139.00
78002	2021-08-23	144.00
78003	2021-08-23	144.00
78004	2021-08-23	137.00
78005	2021-08-23	141.00
78006	2021-08-23	139.00
78007	2021-08-23	140.00
78008	2021-08-23	141.00
78009	2021-08-23	139.00
78010	2021-08-23	140.00
78011	2021-08-23	138.00
78012	2021-08-23	139.00
78013	2021-08-23	141.00
78014	2021-08-23	139.00
78015	2021-08-23	145.00
78016	2021-08-23	141.00
78017	2021-08-23	139.00
78018	2021-08-23	138.00
78019	2021-08-23	140.00
78020	2021-08-23	142.00
78021	2021-08-23	139.00
78022	2021-08-23	143.00
78023	2021-08-23	136.00
78024	2021-08-23	141.00
78025	2021-08-23	138.00
78026	2021-08-23	141.00
78027	2021-08-23	136.00
78028	2021-08-23	143.00
78029	2021-08-23	140.00
78030	2021-08-23	141.00
78031	2021-08-23	143.00
78032	2021-08-23	142.00
78033	2021-08-23	141.00
78034	2021-08-23	139.00
78035	2021-08-23	144.00
78036	2021-08-23	144.00
78037	2021-08-23	134.00
78038	2021-08-23	140.00
78039	2021-08-23	139.00

Result	Value
min date=	2021-08-23
max date=	2021-11-30
min date (number)=	44431
max date (number)=	44530
number of days=	100
average count per day =	130
number of positive detected =	0
percentage of positive detected (%)=	0
first sequence number of positive detected =	0
first day of positive detected =	0
first date of positive detected =	NONE







Discussion

Patient-based quality control has several advantages over conventional internal quality control. They include better error detection capability, fewer concerns over non-commutability and potentially lower costs to perform. However, the main barriers to adoption include a lack of informatics capability and familiarity with parameter selection/ optimization [3]. This report introduced a spreadsheet tool containing many of the recommended features for a PBQC informatics tool [6,7]. The SPAE tool was deliberately coded as a spreadsheet (Microsoft Excel) owing to its generally widespread use, as well as avoiding concerns related to privacy and cybersecurity when using web-based tools. It is envisioned that laboratory users can download this tool from https://github.com/HuiQi96/PBQC/blob/main/PBQC_model_v2.2.zip and perform the desired analysis from a desktop computer.

The SPAE tool also allows the user to input the key PBQC parameters and visualization the changes in data distribution or control chart to better appreciate the interaction between the PBQC parameters and the data distribution and PBQC performance. This should allow the laboratory users to gain familiarity and confidence with the PBQC concepts and techniques. Additionally, more complex optimization functions have been deliberately automated to simplify user experience. The SPAE tool is suitable for running PBQC retrospectively, either periodically to assess for potential errors missed by conventional internal quality control approaches or when an analytical error is suspected (e.g. due to failed internal quality control). This spreadsheet is also well suited as an educational tool for laboratory users.

A limitation of the SPAE is the lack of direct integration with the laboratory information system, which necessitates separate data extraction to perform PBQC. Nonetheless, this spreadsheet tool may serve as a baseline template for interested middleware or laboratory information system vendors to consider emulating in their software to implement some of the recommended features [6]. Another limitation of this tool is the availability of only two standard, simple PBQC models (moving average and moving median), which may limit its detection of more specialized errors such as increased imprecision (more optimally detected by the moving standard deviation approach [8]) or small biases (potentially more optimally detected by the moving positive rate [8,9]). The use of spreadsheet, while convenient and more commonly accessible, is computationally less efficient. When large amount of data is input into the tool or a computer with lower processor specification, it may take some time (up to a few minutes) to complete the analysis.

The SPAE described in this study adds to a growing list of freely available tool for implementing PBQC to meet varying laboratory requirements. They include an online parameter optimization tool [5] and the QC Constellation [10], which provides more complex PBQC algorithms (e.g., exponentially weighted moving average and cumulative sum algorithms). Collectively, this improves the accessibility of the PBQC informatics tool and reduces the barrier for adoption.

Research Funding
None received.

Author contributions
Hui Qi Low, Tze Ping Loh, Chun Yee Lim: Conceptualisation, Development, Investigation, Software, Analysis, Write-up. Hyun-Ki Kim, Sollip Kim, Tony Badrick: Writing – review and editing.

Conflict of Interests
None to declare.

Ethics approval
Not applicable as this study did not involve human subjects.

Consent for Publication
Consent to submit has been received explicitly from all co-authors, as well as from the responsible authorities. Authors whose names appear on the submission have contributed sufficiently to the scientific work and therefore share collective responsibility and accountability for the results.

Data availability
The data and spreadsheet tool described in this study is available as Supplemental Material accompanying this study.

Acknowledgement
This spreadsheet tool has been developed as part of a one-day workshop to educate and promote the use of patient-based quality control under the APFCB traveling lectureship program. Interested reader may contact the corresponding author for further details on the workshop.

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Supplemental Material

A: Screenshot from PBQC python code.

A.1 Input:
A.1.1: Predefined setting table.

predefined setting	value
Accpetable False Positive Rate (%)	0
Desirable bias for detection (%)	5
Box-cox Transformation	No
Box-cox lambda	None
Winsorisation (%)	99.5
Winsorisation lower limit	132.0
Winsorisation upper limit	147.0

A.1.2: Method parameter table.

Method parameters	value
Method1	Med
Method2	Avg
blocksize1, n1	10
blocksize2, n2	20
blocksize3, n3	30
number start added bias per day	30

A.1.3 Control limit table.

Method	block size	lower control limit	upper control limit	column
Med	10	136.5	144.0	**MMed1**
	20	138.0	143.0	**MMed2**
	30	138.0	142.5	**MMed3**
Avg	10	137.2	143.4	**MAvg1**
	20	138.3	142.55	**MAvg2**
	30	138.8	142.233333	**MAvg3**

A.2 Output:

A.2.1 Performance result table.

Method	block size	Percentage of detection (%)	ANPed	MNPed	95NPed	False positive (%)	Sum Best	Preferred
Med	10	100.0	4.0	5.0	6.0	0.0	5	Preferred
	20	100.0	8.0	8.0	11.0	0.0	2	NaN
	30	100.0	11.0	11.0	15.0	0.0	2	NaN
Avg	10	100.0	4.0	5.0	7.0	0.015385	3	NaN
	20	100.0	6.0	7.0	9.0	0.012821	1	NaN
	30	100.0	8.0	8.0	12.0	0.010256	1	NaN

A.2.2 Method parameter for routine table.

Method parameters for real-time data	value
Method	Med
Block size	10
lower control limit	136.5
upper control limit	144.0
Acceptable False Positive Rate(%)	0
Desirable bias for detection (%)	5
Box-cox Transformation	No
Box-cox lambda	None
Winsorisation (%)	99.5
Winsorisation lower limit	132.0
Winsorisation upper limit	147.0

A.3 Routine

A.3.1: Routine summary table.

Result	value
min date	2021-08-23
max date	2021-11-30
number of days	100
average count per day	130.0
number of positive detected	0
percentage of positive detected(%)	0.0
first sequence number of positive detected	NaN
first day of positive detected	NaN
first date of positive detected	NaT

A.3.2 Control chart with selected moving statistic result.