Letter to the Editor

Knowledge, attitude, and practice of patient-based real-time quality control in Australasia

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Patient-based real-time quality control (PBRTQC) involves monitoring an assay using patient samples rather than internal quality control (QC) material (1,2). The principle behind PBRTQC is simple, by monitoring the moving trend (e.g., mean, or median) of the analyte value of patient samples one can infer the ongoing assay performance in real-time (i.e., the performance is monitored as each new result is generated). If the patient population remains stable, then a shift in the moving trend of patient results represents a potential change in the analytical performance of the assay. The advantages of this approach are that the sample(s) are commutable, it is inexpensive, the rules are relatively simple to interpret and there is virtually continuous monitoring of the assay. The disadvantages are that the laboratory needs to understand their patient population and how they may change during the day, week, or year and the initial change of mindset required to adopt the system.

However, whilst there have been several published implementations, it is unclear how this technique is being practiced in the general laboratory (3-5). Recently, there was a workshop organised by the Australian Association of Clinical Biochemists to present different PBRTQC models and to investigate current knowledge and barriers to the implementation of the technique. As part of this workshop, which was attended by 96 participants, a survey of participants was conducted prior to the event to gather information about the knowledge, attitude, and practice of PBRTQC. The questionnaire was structured in the form of a Knowledge, Attitudes, and Practices (KAP) tool.

There were 31 respondents in the survey or a 33% response rate. The respondents provided informed consent prior to the start of the survey. There were 15 closed-ended Likert-scale items and three open-ended questions in the survey. The results of the survey are aggregated and summarized. No individually identifiable information was collected. The responses to the survey questions are given in *Table 1* (Knowledge), *Table 2* (Attitudes), and *Table 3* (Practices) below.

When asked about what the respondents feel is the main gap in their knowledge regarding PBRTQC, 55% answered a lack of experience with the parameters of PBRTQC whereas 32% reported a lack of basic knowledge of PBRTQC. Additionally, in the 12 months preceding the survey, 45% of the respondents had felt PBRTQC would have been useful to their laboratory's quality strategy. These included instrument issues that would have been detected earlier with PBRTQC, assays that drift between scheduled QC samples, changes in reagent lots not detected by conventional QC, and new lot number of QC material. When asked about the barriers and challenges in adopting PBRTQC in the respondent's laboratory, 32% reported informatics or middleware availability as the main hindrance while 23% mentioned a lack of experience or knowledge in

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Table 1 Responses to the knowledge questions survey on PBRTQC

#	Are the following facts, correct?	Correct response	Yes (%)	No (%)	Do not know! (%)
K1	The main parameters of PBRTQC are the moving statistics (i.e., statistical algorithm), truncation limits, data transformation, block size, and control limits	Yes	77	0	23
K2	PBRTQC avoids the commutability issue seen with internal quality control	Yes	90	3	7
K3	PBRTQC only uses the moving average algorithm	No	13	53	33
K4	PBRTQC can effectively detect outlier/flier/random spurious results	Yes	36	45	19
K5	PBRTQC uses existing patient samples for repeat testing to confirm a suspected analytical error	No	29	48	23
K6	PBRTQC must be applied in middleware or laboratory information system	Yes	55	16	29

The results are presented in percentage terms (out of 31 respondents). PBRTQC, patient-based real-time quality control.

Table 2 Responses to the attitude questions survey on PBRTQC

#	Likert-scale of 1–5	Very low	Low	Neutral	High	Very high
A1	To what extent do you agree that PBRTQC should be applied in your laboratory?	0	7	19	52	23
A2	How confident are you in setting up a working PBRTQC algorithm?	23	36	33	10	0
A3	How confident are you in troubleshooting a PBRTQC flag?	10	23	26	36	7
A4	To what extent do you feel is a possibility of your laboratory adopting PBRTQC in the next 12 months?	16	10	32	29	13
A5	To what extent do you feel PBRTQC will benefit the overall quality strategy if your laboratory adopts PBRTQC?	3	3	16	48	29

The results are presented in percentage terms (out of 31 respondents). PBRTQC, patient-based real-time quality control.

Table 3 Responses to the practice questions survey on PBRTQC

#	In the past 12 months, how often did you practice the following?	Never	Sometimes	Often	Always
P1	Read publications related to PBRTQC	19	65	10	7
P2	Set up a PBRTQC algorithm	87	7	7	0
P3	Used PBRTQC in the laboratory	77	13	3	7
P4	Troubleshoot PBRTQC flags	84	7	10	0

The results are presented in percentage terms (out of 31 respondents). PBRTQC, patient-based real-time quality control.

this area of practice.

PBRTQC is very topical, but there is no information available about the knowledge, attitude, practice, and barriers to implementation. This survey provides the first structured data collection process that can help fill that information gap.

When we examine the structured component of the survey, we find that there is a reasonable knowledge of the benefits and theory of PBRTQC. There is a positive attitude to the advantages of a PBRTQC implementation, but little experience with setting parameters. There was a 40% expectation of implementing PBRTQC in the respondents' laboratories. There is also enough interest that the literature is being read by participants, so there is an awareness of the concepts. This was also reflected in the large number of attendees at the workshop, about one-third of those at the

conference to which the workshop was attached.

In the open questions, the lack of experience with setting up PBRTQC was again emphasized, though 45% could see where the implementation would have been useful in the last year. These comments related to failures of conventional QC to detect significant error due to poor QC strategy (6,7). The major limitation to implementation is the lack of software/middleware available to implement PBRTQC. The requirements are well defined (8,9); however, there is an opportunity for suppliers of instrumentation to offer PBRTQC and other support software that can improve patient outcomes and laboratory efficiency (10).

The limitations of this survey were a bias in the motivation of attendees at the workshop in that they were interested in PBRTQC and the relatively low response rate.

There is no doubt that PBRTQC represents a disruptive technique that will improve QC systems and patient outcomes. The barriers to implementation are education, which the professional associations are providing, and onboard software to provide the routines needed. The profession needs the active support of the manufacturers of analytical systems and middleware providers to fill this implementation gap.

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Footnote

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