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Review

A primer on patient-based quality control techniques

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ABSTRACT

Background: Patient-based Quality Control techniques have been described for more than fifty years and have been widely used routinely in hematology for forty. However, because of practical issues they have not been widely utilised in clinical chemistry laboratories. But recently because of the availability of middleware and a greater appreciation of the benefits of these processes there has been a willingness to investigate their use as a QC tool.

Content: This Review describes the development of various patient-based quality control techniques from the earliest Average of Normals approach including the Moving Average, Moving Median and Moving Sum of Outliers. Variations such as weighting, transformation and annealing are discussed. Integrating patient-based QC and conventional QC is discussed as the problem of sub-populations.

Summary: Patient-based QC methods will become more widespread as their benefits are more fully understood and middleware becomes available that allows laboratories to implement these techniques with their patient populations.

1. Introduction

In 1963, Dorsey described the average of (patient) normals (AoN) of mean corpuscular hemoglobin as a means of quality control (QC) for the Coulter Counter [1]. Shortly afterwards in 1965, Hoffman and Waid [2] proposed a 'new' way of performing QC in clinical chemistry, which was so simple it could be described as; at the end of each day, average the patient's test values that fall within the normal range and plot this "average of normals" on a control chart. In essence, these early versions of patient-based quality control were the averages of blocks of patients from appropriate assays that were treated like any other QC procedure plotted as a Levey Jennings chart with flagging at 2 or 3 SD.

Bull et al. [3] in 1974 produced the first workable average of normals calculation in pathology for mean corpuscular volume, mean corpuscular hemoglobin and mean corpuscular hemoglobin concentration (later hemoglobin), which was subsequently adopted by most hematology cell counter manufacturers. Bull introduced a moving average as well as a trimmed mean and a moving median. However, in an analysis of Bull's algorithms using power functions, Cembrowski et al. [4] showed that a conventional QC strategy was more powerful at detecting random error and more convenient. AoN was examined as a strategy for clinical chemistry laboratories as well (citations) where it was found that AoN worked best with precise assays measuring analytes with little population variation and where there were few outliers(citation?). In the era of batch analysis in the chemistry laboratory another question was what should the technologist do if the AoN flagged? The common answer was to run conventional QC. Consequently, there didn't appear to be any benefit when analytical runs were bracketed by QC samples and patient results were not released unless the bracketed QC was within established limits.

Bull's algorithm became a part of the QC operations in the hematology laboratory, probably because of the lack of suitable, stable control materials whereas in clinical chemistry the concepts were seen as interesting, but impractical because of the need to have large blocks and the need to manually perform the calculations.

2. Why use patient-based QC

There are a number of advantages of the AoN and MA QC techniques (Table 1). The perception of non-commutability of conventional QC, conventional QC materials may not be available or impractical for some assays, and PBQC has little to no cost. As analysers have become more reliable laboratories run fewer QC samples [5], often as few as one event per day. This increases the number of patient samples

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Table 1
Comparison between routine internal quality control and patient-based quality control approaches.

Routine internal quality control	Patient-based quality control
Advantages	
Well-established practice with standard guidelines/recommendation	Potentially continuous assessment of assay performance
Relatively simple concept to adopt	Relatively low cost of implementation
Relatively simple set up initially	Assessment of assay performance based on actual patient data/sample
Relatively simple laboratory analysis and interpretation	Allows direct correlation with clinical impact
Most instrument/middleware routinely supports this function	Potentially more sensitive and specific in detecting error
Performance on error detection is independent on underlying patient population, biological characteristics, test volume	No issues with commutability
Disadvantages	
Intermittent assessment of assay performance	Lack of standard guidelines and recommendation on implementation
High cost of implementation	Requires more in-depth understanding of statistics, biological and analytical characteristics of individual test for implementation and interpretation
Potential issue with commutability	Potentially more difficult to set up initially
Potential lot-to-lot changes that requires additional resources to manage	Requires more advanced laboratory informatics to extract data and/or perform analysis in an automated fashion
Lack of direct correlation with clinical impact	Liable to influence from patient population changes, e.g. clinic sessions, health screening initiatives
Potentially less sensitive and specific in detecting error	Requires relatively high volume of patient result to be effective

reported before a systematic error (SE) or bias event is detected by a subsequent QC failure. How labs may deal with failure and when they could or would repeat samples during the failure period are concerning [6].

Given the relative infrequency of conventional QC events, an effectively continuous QC process such as the AoN or MA becomes attractive, particularly if the trend of patient results is monitored in real time and the trend easily interpretable. Key to the successful implementation of a continuous patient-based QC strategy is the adoption of clear procedures for the laboratory technologist to follow in rerunning samples and detecting the point in the analytical run where the error become apparent. Conventional QC is a statistical process based on measuring the same sample multiple times and comparing the latest result to a well-defined mean (target) and standard deviation (control limits). Using a patient-based QC technique is a different process where every new patient result generates a new calculation and is a new statistical test. In a sense, an AoN or MA approach is more of a risk-based approach using the patient population characteristics to detect a shift in the measured population mean. Effectively the continuous nature of the AoN or MA approach serves as a supplement to the conventional QC process as the AoN may detect the development of a SE that conventional QC cannot.

As the capabilities of widely used middleware programs have advanced patient-based QC techniques are being adopted (Table 2). The timing of the availability of these programs is fortuitous as the consolidation of laboratories, and large number of screening tests performed on community patients, leads to higher testing volumes, which presumably represents a more stable population.

3. Techniques

Generally, most patient-based QC techniques use a mean or median value derived from the laboratory's patient population with control limits based on the population SD, perhaps normalized by the block size. There is however some debate concerning the utility of population SD-based control limits. Depending on the patient population served, inpatient vs. ambulatory patients, the SD limits can vary resulting in either very narrow or wide control limits. Additional differences in strategies occur depending whether the calculation of the mean (or median) is continuous and if all samples have the same weight in the calculation, and how the impact of outliers is addressed.

The terms AoN and MA are frequently used synonymously in many publications; for the purposes of clarity and accuracy we will define these two terms differently below.

Table 2
General considerations for implementing patient-based quality control.

General considerations
1. Understand the biological and analytical characteristics of the test of interest, e.g. reference intervals, pathological values, biological and analytical variation.
2. Understand the patient population characteristics served by the laboratory, e.g. periodic patient population changes due to clinic sessions or clinical services.
3. Understand the capability of the laboratory information system, e.g. which data can be extracted and analysed.
4. Decide the patient population to be extracted and analysed; may only include a subpopulation, e.g. the wellness clinic.
5. Extract a set of representative historical data and examine its distribution (training dataset). Extract a separate set of historical data for validation purposes.
6. Decide the block size and truncation limits; calculate the target (e.g. mean or median) and control limits.
7. Examine the performance of the parameters on the validation dataset and refine the parameter as necessary. Alternately, simulation exercise can also be performed.
8. Decide on the follow up actions for flagged error.
9. Document process and protocol. Educate all staff and build confidence and competence.
Implement the algorithm and monitor its performance and refine the parameters when necessary.

4. Average of normals (AoN)

The AoN can be best understood when compared to a traditional bracketing QC strategy used for batch testing. The AoN is determined for a particular assay by calculating the average value for a block of consecutive patient results that have had 'extreme values' that exceed the truncation limits trimmed from the distribution. The patient population should as much as possible approximate a 'normal' or 'healthy' population, e.g. from a health screening population. This average value is then compared to the predetermined population average and control limits. Thus, the AoN rule is defined by the truncation limits (originally defined as the assay reference interval), the number (n) of patient results within truncation limits that are averaged; and the control limits. If the average patient value for the block is outside of the control limits an AoN rule rejection occurs. The AoN rule is evaluated once every n + 1 patient results and the frequency of AoN evaluations depends on the number of results averaged.

Early published assessments of AoN methods showed that conventional QC assessment was more sensitive for SE detection as compared to the AoN and related methods [4,7–9]. These early publications of AoN error detection sensitivity were varied. In one manuscript, Reed [8] analysed AoN mathematically using three cohorts of non-diseased

patients, diseased patients with suppressed results, and diseased patients with elevated results. Reed proposed two changes to Hoffman's procedure: the first was to calculate the average of a fixed number of results ("block average"), rather than the daily average of a variable number of results, and the second was to set truncation limits based on result distribution rather than the reference interval. Reed showed that truncation improved error detection but did not state how to optimize the truncation limits. He observed that control limits might be invalidated by anything that changes the constancy of the distribution of patients' results such as patient distribution changes (male versus female, seasonal changes, time of day, ill versus healthy, inpatient versus outpatient).

Cembrowski et al. showed that the performance of an AoN rule depends on the number of results averaged and the degree of biologic variability relative to analytic variability [9]. They demonstrated that the most important determinants of the AoN statistical power for error detection were the ratio of population standard deviation to the analytical method standard deviation ratio (SDR, which can be thought of as 'signal to noise ratio'), the number of patients averaged (n, or block size), the control limits, the truncation limits (those patients excluded) and the proportion of the population that is excluded by the truncation limits. Using power function curves, Cembrowski et al. showed that AoN error detection capability was often poor compared to conventional QC [4].

5. Moving average (MA)

The MA rule is similar in composition to the AoN in that both employ an unweighted patient average. The MA, in contrast to the AoN, is continuously recalculated, so as a new eligible patient analyte result is produced, it is added to the moving average and the earliest patient result, which was used n (the block size) samples ago is dropped. The MA rule is defined by the inclusion criteria - what patient results are included in the average; the number (n) of patient results averaged, and the control limits. As with the AoN if the average exceeds the control limits a MA rule rejection occurs. In contrast to the AoN strategy, patient results are continuously released, meaning that the power of the MA rule is dependent upon how many patient samples are affected prior the detection of the SE condition. The number of patient samples affected prior to SE detection is dependent upon the error size, the control limits, and the n used in the MA protocol.

To minimize the number of affected samples that would require reanalysis and correction following detection of SE Fleming and Katayev introduced a "release from the back" strategy, where the earliest result within the MA block is released only after the moving block passed the control limits. This strategy effectively quarantined patient results from being reported until they had passed a MA QC. Fleming and Katayev evaluated their rolling block averages and medians for patient-based QC with 28 chemistry analytes. They identified an optimal block size of 50 for all analytes in their study and found that truncation limits were needed for 24 assays. Their continuous QC strategy reduced the use of traditional QC materials by 75%– 80% and reduced their repeat analysis by 50% [10].

6. Annealing

In contrast to the uniform block size strategy, Ng et al. [16] used the probabilistic method, simulated annealing, to optimize MA parameters that minimized a cost function. The simulated annealing algorithm stochastically varied the n, and upper and lower truncation limits while maintaining fixed control limits [15]. In their publication Ng et al. applied their optimization strategy to 23 assays in a hospital-based laboratory with a mixture of inpatients and ambulatory patient samples. Rather than compare the performance of the MA to traditional QC, Ng et al. calculated the average number of patients affected until error detected (ANP_{ed}) as described previously by Ye et al. [23]. The authors also compared the performance of their optimized MA protocols to those established utilizing the strategy outlined by Cembrowski et al. [4]. In general, the protocols determined by the simulated annealing algorithm detected an induced SE condition more rapidly (lower ANP_{ed}) than those established using the SDR with the greatest differences observed for skewed population distributions.

Ng et al. were also able to show an improved error detection ability (lower ANP_{ed}) by establishing separate inpatient and ambulatory patient protocols as the population distribution for these groups show substantially different means and standard deviations [16].

7. Exponentially Adjusted Weighted Moving Mean (EAMM) and Trend (T)EAMM

The EAMM control chart was initially described in the clinical chemistry literature by Neubauer citing its widespread use in manufacturing industry [11]. Subsequently Linnet [12] used simulations to compare the power of the exponentially weighted moving averages (EWMA) rule, essentially a generalisation of Bull's algorithm, to the commonly used rules in clinical chemistry. He showed that for small to moderately large errors (systematic errors up to 2–3 standard deviations), the EWMA rule outperformed simple ($N = 1$) and multi-rule ($N = 2$–6) traditional QC strategies. At all error levels, the EWMA rule was superior to the multi-rule.

The EAMM was further investigated by Smith and Kroft in 1995 and again in 1996 by the refinement, Trend EAMM (TEAMM), the continuous signal analogue of EAMM [13,14]. The EWMA rule computes a weighted average and is described by the inclusion criteria – i.e. what patient results are included, a weight coefficient (λ), and control limits. If the EWMA value is outside the control limits an EWMA rule rejection occurs. EWMA block size affects performance with larger block size associated with better error detection and lower false rejection.

As with MA, the EWMA rule is evaluated with each new eligible patient result. The EWMA calculation includes all results back to the first result at start-up and is highly responsive to small biases for assays where the SDR is small. EWMA sensitivity however rapidly decreases as SDR increases. In clinical use the loss of sensitivity to small biases may however be irrelevant as small biases may be insignificant compared to the between-individual variation within the population. With EWMA small biases may therefore not affect diagnostic decisions if for instance the assay were to be used as a screening procedure. Conversely small biases may assume profound importance for assays that are used monitor an individual patient over time in a critical care setting.

Utilizing computer simulation to optimize block sizes and weighting variables, Smith and Kroft demonstrated that the TEAMM showed better medical utility than EAMM, and patient-based QC with TEAMM performed as well as traditional QC with Westgard multi-rules.

8. Median

The moving median approach has also been described to monitor assay performance [17]. The moving median is more resistant to effects of outliers and is more stable than MA even with skewed population distributions, such as the transaminases and antibody titres. The median is independent of the skewedness of the underlying distribution. However, the standard error of the median can be difficult to estimate. The interpretation of the control parameter is also more complex than a conventional Levey-Jennings control chart.

9. Transformation

There are a number of transformations, such as a log or square root transformation, that have been suggested to convert patient data into a more normal distribution. Transformations have the effect of narrowing the distribution of patient results, minimizing the effect of outlier results. An appropriate transformation may improve an AoN or MA by

"normalizing" a skewed distribution such as those observed for the transaminases or creatine kinase.

While transformations in theory have to potential to improve error detection, we are only aware of one article that discusses the utility of transformation. In their article [10], Fleming and Katayev discuss how they applied transformations to visually skewed distributions as part of their 'release from the back' MA strategy. While it is logically assumed that the transformation would improve the performance of their technique, the authors did not discuss the performance of their protocols as compared to protocols developed for untransformed data nor did they delineate which transformation (e.g. natural log or square root) was better for each analyte. In the same article, the authors also reported the moving median of untransformed and transformed patient data. Following their data experiments, the authors selected those transformations that gave the best performance in regard to error detection. However, it is unclear how the different transformations compared in regard to error detection, perhaps because there is no concise way in which to summarize this data.

From the standpoint of implementing a strategy at least one commercial vendor has software that can transform the stream of patient data in real-time thus permitting the use of this technique.

10. Moving sum of outliers

Liu et al. developed a patient-based QC technique, which monitors the proportion of abnormal results for an individual assay [18]. Using the example of a small positive shift (0.03 μg/L) in a prostate-specific antigen (PSA) assay, they showed that conventional internal quality control has poor probability of error detection. Yet, such positive shift can raise the PSA concentration sufficiently to convert the remission status to possible relapse for post-prostatectomy patients. The moving sum of number of outlier positive results (MovSO) identifies when a previous proportion of abnormal patients for an assay changes. The MovSO will fluctuate around a normal distribution. As a result, control limits that are based on population distribution can be set. In the presence of a sustained shift that is equal to or greater than a critical bias, the proportion of patients with positive results will increase. Over time, the moving sum of number of positive patient results will exceed the control limit [18]. When assessed by ANP_{ed}, the MovSO performed significantly better than the AoN approach, which is relatively insensitive to small biases, in the PSA example above. The MovSO technique is particularly suited for detecting small bias in assays that may result in a change in clinical interpretation (e.g. cardiac troponin).

11. Percentage of the reference interval outliers

Another approach that is conceptually similar to what has been described above compares the sum of the percentage of results above and below the reference interval with predefined thresholds for bias detection. This method has been shown to be suitable for monitoring the performance of multiple laboratories within a network that uses the same instruments and the reagent lot [19].

12. Moving standard deviation of patients

Liu et al. [20] have developed a moving patient SD (MovSD) based on the population statistics used in the moving average calculation. Increased analytical imprecision is not currently well monitored and routine QC procedures are not able to readily detect increased imprecision. This MovSD can detect an increased analytical imprecision better than external/traditional QC and AoN. Additionally, the MovSD method was shown to significantly decrease the number of affected patient results (ANP_{ed}) resulting in the earlier detection of the combination of new onset of bias and an increase in random error, a situation that may happen with a reagent lot change. The reason for this improved error detection is that when there is a positive systematic bias, the mean will increase. This will lead to a tandem increase in the standard deviation of the results. The increased standard deviation of the block makes it is easier to trigger the control limit of the MovSD method. Similarly, when a negative bias develops the MovSD will decrease and exceed the lower limits.

13. How to use Patient-based QC

Most publications suggest a hybrid QC system of patient-based QC used as a warning system for the development of SE which can then be confirmed or rejected by the use of conventional QC material. Parvin has compared both conventional QC and risk-based approaches to investigate the power of QC rules to detect bias [21,22] and has evaluated the power of the EWMA compared with a conventional QC strategy [23]. Using the conventional approach of probability of error detection does not provide useful information in patient-based QC methods, as each new point incorporated into the mean calculation is essentially a new statistical test. The method he has developed used the ANP_{ed} and the average number of patient samples that contain unacceptable analytic error because of an out-of-control error condition (ANP_{TE}). A test result is considered unacceptable if its analytic error exceeds the total allowable error (TEa) requirements for the analyte. In the specific case of serum potassium, he found that the EWMA was more powerful than conventional (6 hourly) QC and that a combination of both techniques had greatest power at detecting bias changes [24].

The general principles of troubleshooting an out-of-control situation in AoN approaches should be similar to that of conventional QC. Broad guidelines such as those described in the recent opinion paper arising from a series of quality control workshops conducted by the Australasian Association of Clinical Biochemists provides a succinct checklist that covers various important areas and should be considered. These include, for example, checking instrument error log, review of internal QC charts, and review of maintenance logs, among others [25].

There are other suggested approaches that exclude the use conventional QC such as that of Liu et al. who have suggested using stored patient samples [26]. To verify an analytical shift, three archived samples from the analytically stable period should be retested. The probability of Type-1 error (i.e., false rejection) and power (i.e., detecting true analytical shift) of this rule are both high.

Other authors [27] have suggested a combination of patient-based QC and EQA to obviate the need for conventional QC, although the reader is cautioned to vet these ideas through the lens of local testing regulations.

14. Population problem

As with all patient-based QC approaches, variations in the patient population by time of day (e.g., inpatient phlebotomy schedules) or day of week (e.g., specialist clinics on certain days) could decrease the reliability of the method. All patient-based QC methods are most effective for high volume assays performed on stable populations, for example community patients. This makes it difficult to identify if the shift in distribution is caused by a change in the patients that are being measured, for example more patients with chronic renal failure coming from a clinic on a certain day of the week, or a true change in analytical performance of a method. As aptly put by some authors, the objective is to monitor the analytical performance of the method, not the patients being tested that day [16].

Some methods have been developed that lessen the impact of subpopulations with more variation in results such as truncation of outliers, annealing methods or splitting subpopulations [16,26] and determining separate AoN parameters. However, these methods are prone decreased sensitivity to bias because of smaller numbers of eligible patients. But with the greater interoperability of the LIS and the next generation electronic medical record a solution may be at hand. Being able to utilise, in real time, information available about patients from

different databases would allow laboratories to match their laboratory trends with clinical information and diagnosis [28]. Furthermore, certain tests are not performed in patients from a 'normal' population (e.g., tumour markers, therapeutic drug monitoring, cardiac markers, endocrine hormones), thereby challenging the above assumption [29].

15. Conclusion

Patient-based QC programs are currently widely used in some form or another, all of which have been locally developed. The low cost and relatively high sensitivity of the technique, particularly in community-based practice makes it very attractive. It is likely that equipment manufacturers will implement on their high-volume instruments embedded middleware that will perform these calculations soon. The risk may be that laboratorians who do not understand the basis of the calculation may not fully utilise the power of the technique and either set the parameters too wide and miss error or too narrow and react to too many false positives. Like all QC practices, the power of the technique is only as strong as the setting of the right parameters, interpretation and the follow-up action on a flag.

One of the problems that has arisen has been that now on high throughput analyers there are no QC samples bookending a block of patient samples that can be released when the second QC passes. This can lead to the potential of large numbers of samples needing to be repeated if a failure occurs between QCs and patient results are released. The blocks of patients used in the patient-based QC processes provide a means to overcome this problem [10] and combined with effective lookback processes [26,30] patients with unacceptable error can be identified.

It is clear that a combination of techniques will provide the best protection against erroneous results being reported and that the QC technique selected will depend upon the situation.

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