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In this issue:

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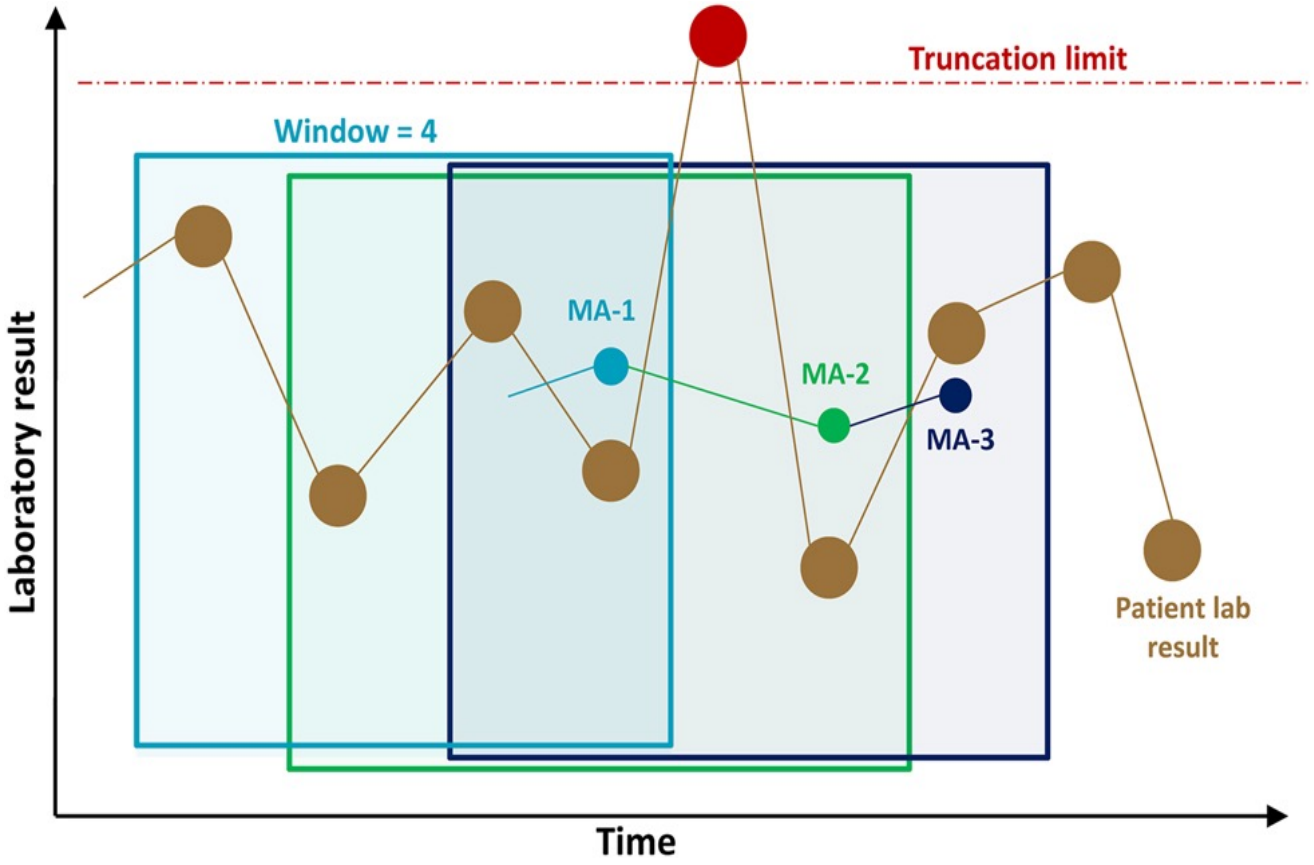

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MOVING AVERAGE - CAN IT REDUCE THE BURDEN OF QUALITY CONTROL IN CLINICAL LABS?

Analytical quality control is one of the key tasks facing biochemists in a medical laboratory. This is accomplished by running both internal quality control(daily) and external quality control (usually monthly or at specified interval). However, this traditional type of quality control has its own limitations, like, first of all, its intermittency, and the problem of commutability. Due to the intermittency of performing traditional quality control, there is a risk that the analytical bias that occurs between two control measurements will remain undetected leading to the release of erroneous results in this period. In addition, the potential non-commutability between control materials and real patient samples compromises the sensitivity and specificity of this type of control.

Therefore, there is always a need for real time monitoring of IQC which will detect any deviation of any parameter on real time basis and not retrospectively. This need has led to the advent of the concept of “Moving Average”. Moving average (MA) means calculating the average value from a set of patient results and further using that value for control purposes. It is called “moving” because the MA is recalculated every time a new result is received, which means data is continuously updated and evaluated as patient samples are analysed. The idea of a MA was presented by Hoffman and Waid in 1965, suggesting a follow-up of the average of normals (AON) for control purpose.

However, there are many intricate issues regarding this control concept. The most significant problems concern the local determination of optimal MA procedures for each analyte, the potential of the existing laboratory information system (LIS) for MA implementation, lack of guidelines for dealing with situations when MA control is out of acceptable limits, and the impact of laboratory

testing volume (daily number of samples and required tests) on the effectiveness of this form of control. The formation of the Working group on patient-based real-time quality control by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has further emphasized the importance of this topic at the global level.

The most commonly used algorithms for calculating MA values are: simple MA, exponentially weighted moving average (EWMA) and Bull's algorithm. Except Bull's algorithm, mainly used on haematological analysers, the most used algorithms for calculating MA values are simple MA and EWMA.

Simple MA is calculated using the formula: $z(t) = x(t) / n + x(t - 1) / n + x(t - 2) / n + ... + x(t - n + 1) / n$, where z(t) is the calculated mean value on the result number t, x is the result, and n is the block size. The size of the block is the number of consecutive test results that are used for calculating an MA value in a simple MA algorithm. Exponentially weighted MA is calculated using the formula: $z(t) = \lambda x(t) + (1 - \lambda) z(t - 1)$, where z (t) is the calculated mean value on the result number t, x is the result, and λ is the weighting factor. A weighting factor is a coefficient that determines how much current and previous test results affect calculation in the EWMA algorithm. It can take values between 0 and 1. The upper and lower control limits of each MA procedure are established as the maximum and the minimum value of the MA. In this way, false alarms should be almost completely avoided in routine practice. These minimum and maximum values are obtained for each combination of the calculation formula and truncation limits. Truncation limits are the endpoints of concentration ranges of examined analytes that are included in MA calculation. The choice of truncation limits depends on the patient population with which the laboratory is working i.e. whether they are out-patient based or admitted patients. Based on the spread in the concentration values of examined analytes, different truncation limits are tested.

Therefore, the main objective is to establish an MA procedure for each analyte that would be capable of detecting a clinically significant bias within the daily number of tests, which would otherwise not

be detected till the next morning, or until the next measurement of the control sample. Establishing such procedures should allow us to develop a quality control plan that will not require additional measurements of commercial control samples, even in the case of tests with low sigma values. Allowable total error (TEa) can be considered as clinically significant bias.

The below table shows the graphical presentation of an MA of serum Creatinine –

CREATININE

Measurement time	Measured value	MA value	MA alarm
12.12.2019 07:57:44	71,00	77,23	N
12.12.2019 07:58:24	70,00	76,51	N
12.12.2019 07:59:23	89,00	77,76	N
12.12.2019 08:00:03	54,00	75,38	N
12.12.2019 08:00:53	112,00	79,04	N
12.12.2019 08:02:05	67,00	77,84	N
12.12.2019 08:02:45	81,00	78,16	N
12.12.2019 08:03:25	100,00	80,34	N
12.12.2019 08:04:01	98,00	82,11	N
12.12.2019 08:04:42	69,00	80,80	N
12.12.2019 08:05:36	119,00	84,62	N
12.12.2019 08:06:39	97,00	85,85	N
12.12.2019 08:07:15	144,00	91,67	D
12.12.2019 08:08:04	100,00	92,50	D
12.12.2019 08:09:20	69,00	90,15	N
12.12.2019 08:10:01	84,00	89,54	N
12.12.2019 08:10:41	86,00	89,18	N
12.12.2019 08:11:40	75,00	87,76	N
12.12.2019 08:12:11	90,00	87,99	N
12.12.2019 08:13:14	68,00	85,99	N
12.12.2019 08:13:50	63,00	83,69	N
12.12.2019 08:14:22	75,00	82,82	N
12.12.2019 08:15:07	61,00	80,64	N
12.12.2019 08:15:51	81,00	80,68	N

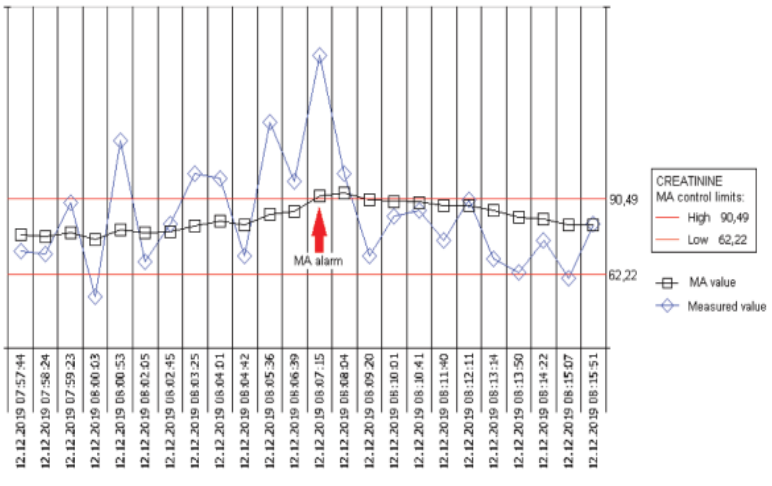

Figure 1. Table and graph presentation of an MA alarm for creatinine from the LIS. The values for control limits are expressed in µmol/L. In the table: the letter "D" means "Yes" and the letter "N" means "No". MA – moving average.

A comparison of Moving Average and Statistical Internal Quality Control

Characteristic	Moving Average QC	Internal QC
QC frequency	Continuous	Fixed Interval
Commutability	Commutable	Risk of non-commutability
Controllable diagnostic phases	Preanalytical and analytical	Analytical phase
QC level	One level dependent on patient population and MA settings	Multiple adjustable levels
Error detection	Bias	Bias and imprecision
Optimization and Validation	Graphical/Power function analysis / TEa detection probability	Statistics (SD)/ sigma metrics/
Operational costs	MA-QC alarm work-up	QC materials, QC analysis and QC alarm work-up

Conclusion:

Although MA practical application in clinical chemistry lab is faced with many limitations but many statistical tools are in place as well as coming to the forefront which will make this tool optimised for detection of clinically significant bias in patient samples. Further work needs to be done for implementation of optimized MA procedures in LIS and examination of their characteristics as continuous quality control in real time.

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