An integrated solution using bench spreadsheets to monitor Quality control indicators and performance in medicine laboratories

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Introduction and Aim

Laboratory Quality Control (LQC) in medical laboratories is a tool to monitor the procedures of pre analytical, intra analytical and post analytical phases. The data statistic analyze allow the quantification of the random errors using the variation coefficients (CV%) obtained by Internal Quality Control (IQC) and the systematic errors (bias%), from the results of External Quality Control (EQC). These results are combined to calculate the Total Error (TE) and Measurement of Uncertainty (MAU), that allows the knowledge of the precision and accuracy and follow the performance of laboratory by comparison with the quality specifications. The main **objective is to present a tool as a bench spreadsheet developed in National Institute of Health Doctor Ricardo Jorge (INSA), aiming to help the national and portuguese speaking countries laboratories, to calculate the main indicators of the LQC: TE, Sigma level and MU using IQC and EQC results, in a simplified way.**

Methods

It was developed a Microsoft Office Excel spreadsheet to collect information about IQC results (CV% two/three IQC levels), EQC results (Bias % obtained of several schemes), summary, formulas and references, as well as laboratory quality specification chosen (eg. EFLM biological variation data base). In the spreadsheet, formulas were included to calculate, the quality indicators: TE, Sigma level, MU by "top-down" approach (combined and expanded by a coverage factor of 2). This tool was validated with biochemistry and hematology parameters data obtained in 2021. The specific cells of spreadsheets (e.g., formulas) were protected.

Formulas

$$\textbf{Bias}\ (\%) = \frac{EQC\ result - EQC\ consensus\ mean}{EQC\ consensus\ mean} \times 100$$

$$\boldsymbol{TE}(\%) = |bias\%| + 1.65 \times CV\%$$

$$Sigma = \frac{ET_{Desirable} - bias\%}{CV\%}$$

$$\mathrm{MU} = \left(\sqrt{\mu(bias)^2 + \mu(CV)^2}\right) \times 2$$

$$\mu(bias) = \sqrt{RMS_{bia}{}^2 + \left(\frac{EQC\ CV\%}{\sqrt{Number\ of\ EQC\ participants}}\right)}$$

$$\mu(CV) = RMS\ IQC\ CV\%$$

Results

The effectiveness of the indicators calculation with the spreadsheet was evaluated, based on the results of the Laboratory of Clinical Chemistry and Haematology of INSA (2021).

PLT x 10^9/L whole blood-IQC results -2021				
Level	N	Number of batches	PLT count mean	CV % quadratic mean
Level I	138	6	76	2,0
Level II	138	6	288	2,0
Level III	134	6	443	1,8

PLT x 10^9/L whole blood				
	Uncertainty			
	Level I	Level II	Level III	Total
u(Rw) (%)	2,0	2,0	1,8	2,0
u (bias)(%)	3,2	3,3	4,0	3,4
Uc (%)	3,8	3,9	4,4	3,9
MU (%)	8	8	9	8

PLT x 109/L whole blood-EQA results-2021		
	Number of Surveys	Bias (%) quadratic mean
Level I	6	3,2
Level II	11	3,3
Level III	3	4,0

Total error
5
6 Sigma
4

	Consense Value Mean (x10^9/L)		Uncertainty (by levels)
Level I	63	±	5
Levell II	190	±	15
Level III	515	±	45

Table 1- Exemple of the use of spreadsheet for calculation of the indicators of platelets (x10^9/L)-2021

PARAMETERS	CV (%)				Bias (%)				TE (%)				MU (%)				Sigma
	Lab CV%	Specifications[1]			Lab Bias%	Specifications[1]			Lab TE %	Specifications[1]			Lab MU %	Specifications[1]			Lab Sigma
		Min.	Des.	Opt.		Min.	Des.	Opt.		Min.	Des.	Opt.		Min.	Des.	Opt.	
Glucose	2.3	3.75	2.5	1.25	2.4	3.57	2.38	1.19	6	9.74	6.49	3.25	10	7.5	5	2.5	2
Total cholesterol	2.7	3.98	2.65	1.33	1.7	6.43	4.29	2.14	6	12.97	8.64	4.32	9	7.9	5.3	2.6	3
Triglycerides	2.3	15	10	5	0.2	15.8	10.54	5.27	4	40.49	26.99	13.49	6	30	20	10	12
Haemoglobin	0.7	2.0	1.4	0.7	0.8	2.4	1.6	0.8	2	4.1	2.7	1.4	4	4.1	2.7	1.4	4
White blood cells	1.6	8.1	5.4	2.7	1.7	7.4	4.9	2.5	6	20.7	13.8	6.9	10	16.2	10.8	5.4	6
Platelets	2.0	5.7	3.8	1.9	1.7	7.6	5.0	2.5	5	17.0	11.3	5.7	8	11.4	7.6	3.8	4

Table 2- Indicators obtained of Laboratory of Clinical Chemistry and Haematology of INSA (2021). 1 - EMFL (*European Federation of Chemistry and Laboratory Medicine) - 2022.*
Min. – Minimum; Des. – Desirable; Opt. - Optimal

In Table 1, are presented na exemple of the use of spreadsheet for calculation of the indicators of platelets. The results obtained for all parameters evaluated are described on Table 2. The results were compared with the quality specifications based on the EFLM's biological variation. The laboratory meets CV, Bias and TE specifications for all parameters evaluated. Most in the desirable and optimal level, and for triglycerides and white blood cells the three indicators reached the optimal level. Only the CV of cholesterol meets minimum level.

Conclusion

The bench spreadsheet allows to compile/ join the laboratory quality control data and in a simple way calculate the quality indicators, TE, Sigma level and MU.
The excel tool has proved to be an improvement to evaluate and monitor the indicators and allow, as well, compliance with the regulatory requirements for the accreditation of tests.
The technicians involved in this work are motivated to use this tool in laboratory routine.
Probably, an improvement to implement will be to recalculate the uncertainty value using the results of the CV%, obtained in a period of at least 6 months, and systematically monitoring the performance of the EQC results.
It is foreseen the dissemination and training in this spreadsheet in the sense of its use by professionals of portuguese-speaking countries in the scope of the Laboratory Quality Improvement Project for Portuguese-speaking countries (ProMeQuaLab).