EQA total haemoglobine quantification – Long-term analytical performance for thirty Portuguese Laboratories

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Aim

Total haemoglobin is one of the most frequently ordered laboratory tests, both in the hospital and ambulatory. Haemoglobin concentration provides information about the status of anaemia in the population and guides many clinical diagnoses and therapeutic interventions. Portuguese External Quality Evaluation Program (PNAEQ) provides 4 survey per year with 2 samples each since it is important for medical laboratories to know about the stability and performance of their methods over the time.
The main objective of this study was to apply a linear regression model for long-term evaluation of the performance of laboratories in haemoglobin quantification by comparing the laboratory individual results with the consensus mean of each round, after outliers exclusion. To evaluate the performance of the laboratory, the long-term analytical CV (LCVa) and the total analytical bias were established.

Methods

A linear regression model was applied to quantitative haemoglobin results to evaluate the long-term analytical performance of thirty of the participating laboratories in the PNAEQ external quality assessment programme (2014-2016), using the results of twelve blood EDTA samples with different hemoglobin concentrations[1], from 6 surveys (2 samples each). Participants were randomly selected concerning laboratories from hospital (10) and ambulatory (20). To assess the long-term performance in this model the long-term analytical CV (LCVa) and total analytical Bias were used. Two laboratories were excluded from the analysis (1 outlier and 1 user of point-of-care equipment). We evaluate also the number of laboratories that fulfill the widely accepted analytical performance goals based on the biological variation.[2,3]
All statistical analyses were performed with Microsoft Excel namely with “Long-term calculation file” provided by Piet Meijer.

Results

The consensus values used on the analysis are presented on Table 1.
The median of LCVa was 1,4% (range 0,4%-3,1%) and of Total Bias 1,1% (range 0,1%-3,3%) (Table 2). According to the specification goals we found that the LCVa was less than 0,58 times the total biological variation (diagnostic testing) for all laboratories (100%) and was less than 0,5 times the within biological variation (monitoring testing) in 62 % of the laboratories.83% of the laboratories had a total bias less than 0,25 of the total biological variation (Table 3).
The frequency distribuition of the laboratories LCVa and Total Bias are represented on graphics 1 and 2.

Table 1: *Consensus values, interlaboratory CV and number of outliers for the 12 surveys/samples used in the study*

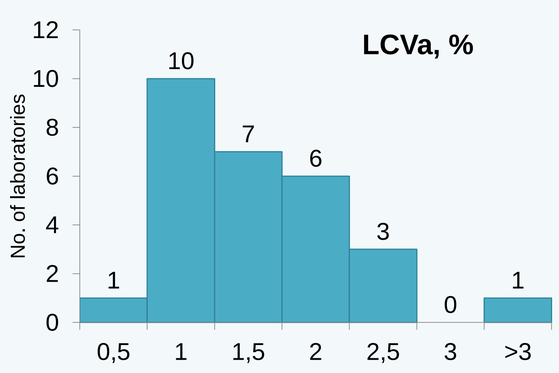
Survey/ Sample	No. of participants	Consensus value, g/L	CV, %	No. of outliers
4114	65	65,2	2,47	8
4214	65	136,9	1,78	7
1115	72	137,7	1,45	9
1215	72	93,3	1,66	10
2115	70	151,5	3,05	3
2215	70	170,4	5,58	3
3115	75	106,8	2,20	4
3215	75	150,3	2,02	4
4115	76	135,5	2,14	3
4215	76	135,4	2,19	4
1116	66	128,0	1,51	5
1216	66	135,0	1,23	5

Table 2: *Discriptive analysis of Long-term analytical CV and total Bias results*

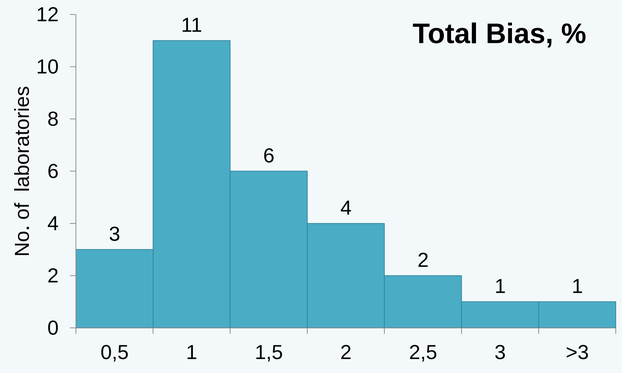
	LCVa, %	Bias, %
n	28	28
Mean	1,4	1,3
Median	1,4	1,1
Range	0,4-3,1	0,1-3,3

Table 3: *“Desirable” performance goals and quality specifications for Haemoglobin. [CV_t – Total biologic variation; Cv_i – Within subject variation; CV_b – Between suject variation] and percentage of laboratories in the study within the desirable performance goals*

	“Desirable” Performance goals Hb, g/L	Quality specifications Hb, g/L	Laboratories within the desirable performance goals, %
Imprecision (Diagnostic) %	< 0,58 CV_t ($\sqrt{(CV_i^2 + CV_b^2)}$)	4,3	**100**
Imprecision (Monitoring) %	< 0,5 CV_i	1,4	**62**
Total Bias%	0,25 $\sqrt{(CV_i^2 + CV_b^2)}$	1,8	**83**



Graph 1: *Histogram of the individual LCVa values (%) for haemoglobin for the 28 laboratories included in the study*



Graph 2: *Histogram of the individual Total Bias values (%) for haemoglobin for the 28 laboratories included in the study*

Discussion and Conclusion

As reflected by the results the overall performance remained satisfactory. All laboratories evaluated accomplished the quality specifications for imprecision (diagnostic) and 83% for Total Bias. However only 62% met the quality specification as imprecision (monitoring). It is important to make aware for the standardization of analytical procedures, namely calibrations of equipments, and continuous monitoring of laboratory good practices.

Participation in External Quality Assessment schemes is of extreme importance, as it provides information to the laboratory about its own method performance both in a single survey as well as over time and allows the evaluation of the needs for improvements.

It’s highly recommendable the internal investigation of significantly discordant results aiming the continuous improvement of quality diagnostic services.

Referências

1 - Piet Meijer et all; Long-Term Analytical Performance of Hemostasis Field Methods as Assessed by Evaluation of the Results of an External Quality Assessment Program for Antithrombin; Clinical Chemistry 48:7 1011–1015 (2002).
2 - Desirable Biological Variation Database specifications available in https://www.westgard.com/biodatabase1.htm
3 - Fraser CG *et al.* Proposals for setting generally applicable quality goals solely based on biology. *Ann Clin Biochem 1997; 34: 8 – 12.*

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