Background and Aim

Glycated hemoglobin (HbA1c) plays a crucial role in the monitoring and diagnosis of diabetes. In Portugal, 9.8% of the population has diabetes (HbA1c ≥ 6.5% or treatment with glucose-lowering medications). Six sigma metrics combine bias, precision, and allowable total error (Tea), and can be used for assessing the quality of the analytic phase. The main objective of this study was to apply a linear regression model for long-term evaluation of the precision and inaccuracy, and to analyze the sigma metric to evaluate the performance of laboratories in HbA1c quantification.

Methods

The long term analytical coefficient of variation (LCVAs), the total analytical bias and sigma were established. Participants were selected concerning laboratories that participated in all surveys. The assessment did not take into account the equipment used by each participant. The variables introduced to define the long-term performance in this model were the LCVAs and total analytical Bias obtained by comparing the laboratory individual results with the consensus mean value of each round, after outliers exclusion. The sigma value was calculated using the Tea obtained in the minimums analytical performance goals based on the biological variation.

Results

The consensus values, interlaboratory CV and number of outliers for the 12 surveys/samples used in the study are represented in Table 1. The median LCVAs was 2.4% (range 1.3%-5.2%), the median Total Bias was 2.0% (range 0.2%-6.0%) and median sigma value was 1.7 (range 0.1-4.6) (Table 2).

The LCVAs was less than 0.58 times the total biological variation (diagnostic testing) for 94% laboratories and was less than 0.75 times the within biological variation (monitoring testing) in 29% of the laboratories. Sixty five percent of the laboratories had a total bias less than 0.375 of the total biological variation (Table 3).

Forty one percent of the laboratories had a sigma value less than 2.0 and fifty nine percent had a sigma value equal or higher than 2.0, when evaluated with an allowable total error of 6.72%, based on minimum performance criteria of the biological variation (Figure 1).

Conclusion

As reflected by the results the overall performance needs to be improved. Despite 94% of the laboratories evaluated accomplished the minimum quality specifications for precision (diagnostic), only 65% and 29% of the laboratories met the quality specifications for Total Bias and imprecision (monitoring) respectively. The median sigma (1.7) was less than 2 and only 59% of the laboratories had a sigma greater than or equal to 2. It is a responsibility of clinical laboratories to continuously monitor the performance of the methods in use, both by the implementation of proper internal quality control, checking the daily alignment of the analytical system and evaluating the assay long-term imprecision by the participation in appropriately organized external quality assessment schemes.

Assessment of the quality on the sigma scale has the advantage of providing evidence of global laboratory performance taking into account random and systematic errors, and should be used for identifying and prioritizing improvements that are needed in the analytical quality of laboratory examinations.

References