Application of the Six Sigma methodology in the evaluation of the results in Cell Blood Count EQAS Program (PNAEQ)

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Introduction

The haemogram is one of the most frequently requested laboratory tests, in hospital and ambulatory. Therefore, given its importance in the clinical context, an evaluation was performed on the results of the clinical laboratories participating in PNAEQ's EQA Cell Blood program. The main objective of this work was to improve the Sigma quality level of the clinical laboratories and reduce the variability of their results.

Methods

The data used in this work is referred to the period from 2015 to 2017 and regarding each parameter, haemoglobin, platelets, leukocytes and erythrocytes, data from 24 control samples, distributed 4 times per year, was collected. The samples used were purchased from an EQA provider of Europe, and most of the samples were also used in the EQA program of that entity.

For the calculation of the Six Sigma metric, the inaccuracy (bias) associated to the result obtained by each laboratory for different parameters of each sample was determined and the outlier's treatment was performed. In the first approach, evaluation per sample, the Normality of each sample results was studied by applying the Kolmogorov-Smirnov test [Sigma level = P (X ≥ X admissable bias) x 10^6]. The Box-Cox transformation was applied whenever necessary. Regarding haemoglobin parameter, a second approach, namely the linear regression was applied to the results of 45 laboratories[(1)] [Sigma level= (TEa - Bias) / CVI]. This model allows establishing a comparison between the laboratories' results and the consensus value, obtained by the average of the participating laboratories. The Sigma quality level for both approaches was obtained considering the desirable quality specification based on the biological variation[(2)].

Results and discussion

After the statistical analysis of the results, the mean Sigma quality level in the sample approach was 1.71 (Figure 1), 2.22 (Figure 2), 1.57 (Figure 3) and 1.95 (Figure 4) for the parameter platelets, leukocytes, erythrocytes and haemoglobin, respectively. The mean Sigma quality level obtained in the laboratory approach for the parameter haemoglobin was 2.64 (Figure 5). Although the Sigma quality level ranged from 0.57 to 6.30, only 15 out of 45 laboratories had a Sigma quality level above 3 (Figure 6).

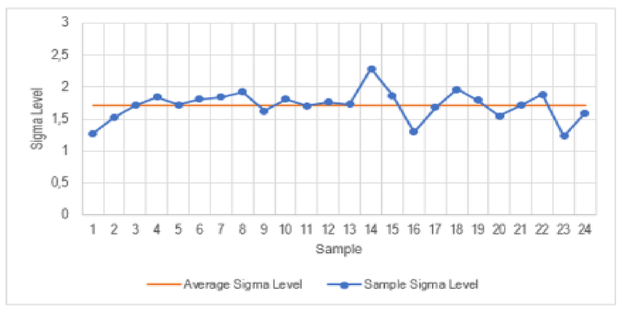

Figure 1: Sigma levels and their respective mean value for the parameter Platelets

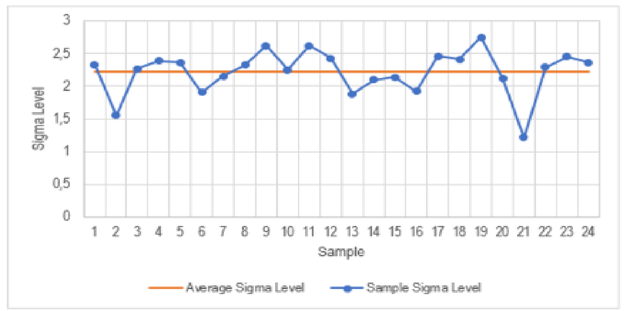

Figure 2: Sigma levels and their respective mean value for the parameter Leukocytes

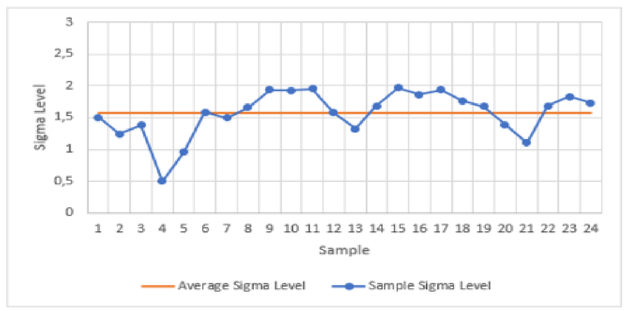

Figure 3: Sigma levels and their respective mean value for the parameter Erythrocytes

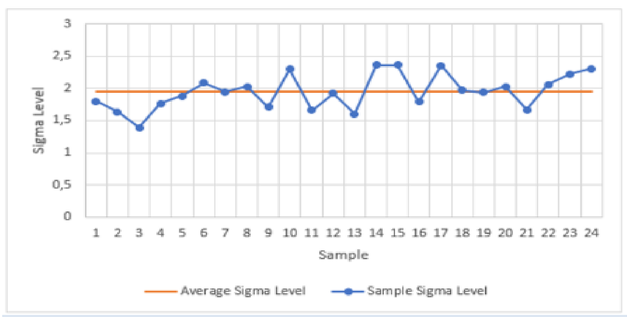

Figure 4: Sigma levels and their respective mean value for the parameter Hemoglobin

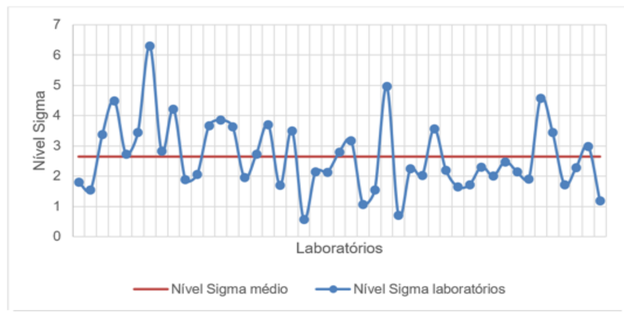

Figure 5: Sigma levels of laboratories and their respective mean value for the parameter Hemoglobin

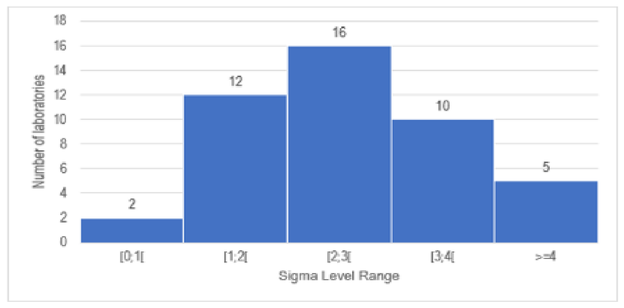

Figura 6: Histogram of Sigma levels of laboratories

Both approaches demonstrated a need to improve the analytical process performance. Therefore, in brainstorming meetings with the participants were identified, in the Analyze phase, some potential causes for the low performance. The most relevant causes consisted of the homogenization of the control sample, absence of corrective actions resulting from the EQA reports, control acceptance criteria and calibration of the equipment. Posteriorly, in the Improve phase, improvement actions were elaborated and implemented. Through the pilot test, it was possible to verify improvements in the analytical performance of the laboratories, obtaining a Sigma quality level of 2.58, 2.27, 1.87 and 2.62, for the parameter, platelets, leukocytes, erythrocytes and haemoglobin, respectively (Figure 7).

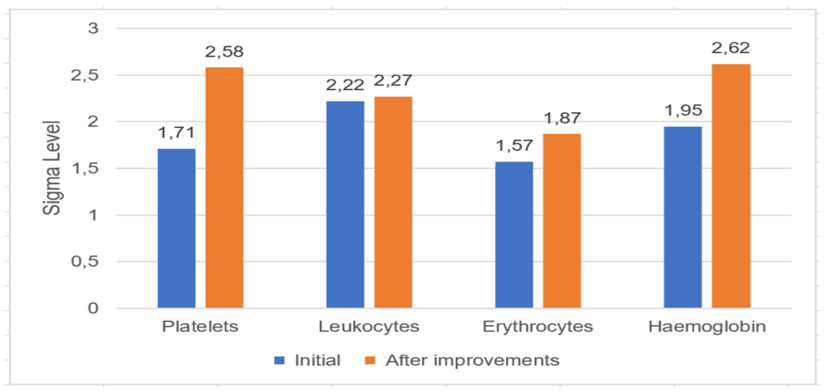

Figure 7: Improvements in the analytical performance of the laboratories

Conclusion

Continuous monitoring of the processes will be carried out, aiming to ensure that the implemented improvements continue to be practiced.
A comparison study between the participants of the European EQA Provider, should be carried out and performed the same sigma study.

References

(1) Meijer, P., De Maat, M. P. M., Kluft, C., Haverkate, F., & Van Houwelingen, H. C. (2002). 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.

(2) Westgard. (2014). Desirable Biological Variation Database specifications - Westgard. Retrieved July 3, 2018, from https://www.westgard.com/biodatabase1.htm

Abbreviation:
TEa – Total error allowed
CVI – Coefficient of variation

Note:This study was presented in Labquality Days in February 2019.