SIX SIGMA METHODOLOGY TO EVALUATE AND IMPROVE THE RESULTS OF THREE PARAMETERS OF CLINICAL CHEMISTRY EVALUATION QUALITY ASSESSMENT PROGRAM

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Introduction

From the PNAEQ's Clinical Chemistry Program, three analytes were chosen to evaluate the quality assessment: Total Cholesterol, LDL Cholesterol and Triglycerides. Results from 2018 to 2020 were studied in order to evaluate and develop actions that allow the participants to reduce the variability of the results and improve their Sigma quality level in order to provide a better service to the patients.

Methods

The method selected to evaluate and improve the program's results is DMAIC: define, measure, analyse, improve and control. To calculate the Sigma quality level, two approaches were used. The first begins with the determination of the results' inaccuracy (bias) and the removal of outliers. The available data is then separated by sample, method and equipment to understand if there are significant differences between the data sets. Considering the result of this analysis, the normality of each set is studied applying the Kolmogorov-Smirnov test and the Box-Cox transformation when normality is not verified. Then it's possible to calculate the defects per million opportunities (DPMO) and the Sigma quality level. This first approach only considers inaccuracy (bias).

The second approach relies on a linear regression model developed to assess both inaccuracy and imprecision based only on data from AEQ programs.[1] This second approach was only used for the Total Cholesterol and Triglycerides analytes and for 2020's results. Both approaches compare the laboratory results to the consensus values for each sample, and both determine the Sigma quality level considering specifications based on biological variation at the desirable level[2]: in the first approach considering the bias specification and in the second approach the total analytical error specification.

Results

Having defined the project in the Define phase, in the Measure step it was possible to determine the mean Sigma quality levels by parameter and year. The results are presented in Table 1. When comparing Sigma levels, it is essential to specify the method and level of biological variation because it is showed that it might produce different results. The laboratories' sigma levels are graphically presented for the Total Cholesterol and Triglycerides parameters in Figure 1 and 2, respectively.

Table 1: Sigma levels calculated through the first and second methods

	1st Method			2nd Method
Parameters	2018	2019	2020	2020
Total Cholesterol	2,2	2,1	2,0	2,4
LDL Cholesterol	1,5	1,6	2,6	---
Triglycerides	3,1	3,3	3,3	7,7

Both methods demonstrate the need to improve the results especially from the Total Cholesterol and LDL Cholesterol analytes.

The Triglycerides parameter might present better results due to having a significantly higher biological variability. The two methods show different results due to their distinct calculation methods and because they analyse different data sets.

The Analyse step consists in identifying potential causes for the low performance using tools like Brainstorming and the Ishikawa Diagram, and then organizing the causes by order of priority. The conclusions showed that inadequate training or experience and the incorrect transcription of the results were the main causes for the gap between the present and desired performance.

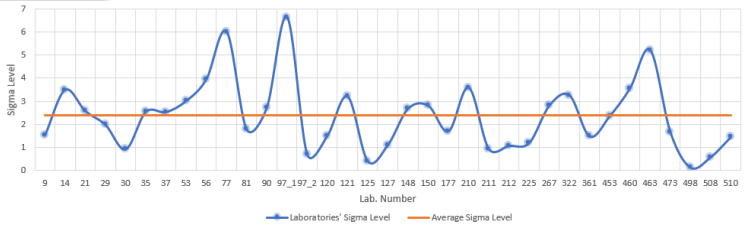

Figure 1: Laboratories' sigma levels and mean value for the parameter Total Cholesterol in 2020

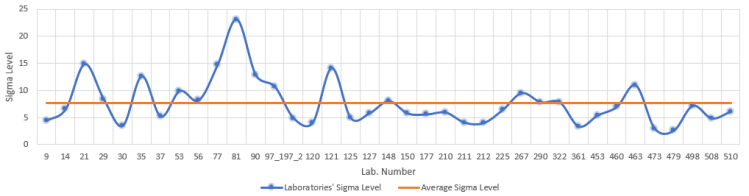

Figure 2: Laboratories' sigma levels and mean value for the parameter Triglycerides in 2020

The Improve and Control phases are still being developed. In the Improve phase, improvement actions must be developed and analysed considering the implementation's cost, impact and speed. Then, an implementation plan must be developed. The Control phase has the purpose to maintain the results of the improvement actions.

Conclusions

The Six Sigma methodology presents a structured approach to problem solving not only in a manufacturing environment but also in the service sector as in the case studied. When implemented within external quality assessment programs, it provides a metric that allows laboratories to compare their performance with each other and evaluate the accuracy of their results. The main causes for a lower quality level identified by this study were inadequate training or experience and the incorrect transcription of the results. Improvement actions must be developed to better these issues in order to increase the quality of the service provided.

[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] European Federation of Clinical Chemistry and Laboratory Medicine database (2020). Retrieved February 15, 2021, from https://biologicalvariation.eu/meta_calculations