Application of Six sigma on sodium parameter for total error evaluation

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Introduction

We present a study performed in PNAEQ on the implementation of *six sigma* methodology in evaluating the sodium parameter to the total error (TE) resulting from laboratory measurements of the participants in the program, in order to mitigate systematic errors and improve quality of measurements in laboratories.
The implementation of this tool is based on DMAIC cycle which breaks down into five distinct stages to achieve the desired improvement, from definition, preparation and analysis of the objectives proposed until monitoring after implemented in the organization, in order to control and ensure the success of this improvement, avoiding the possible deviations.

Sodium was selected because disturbances more frequently in subjects are related to the concentration of this ion and feeding is the main source of sodium in the body. The salt intake is directly related to the risk of mortality associated with cardiovascular disease. The reference values in plasma are between 136 and 145 mmol/l [1].

Objectives

Of the different objectives it proposes the EQA, this project aims to assess the improvement in the quality of laboratory measurements from by evaluation of the TE in the parameter of sodium, according to allowable total error in existing tables. After implementing the corrective actions to reduce the TE the main goal is to get a sigma level higher than the current sigma.

Material and Methods

We selected a sample of 12 participating laboratories consistent in the period 2009-2012, whose geographical location is uniform throughout the country.
We analyzed the results in the reports of EQA for the samples sent by PNAEQ, related to methods and coefficient of variation (CV), intra-laboratory and inter-laboratory. To verify the evolution of the performance of the participants over time, we established monitoring points in 1978, 1982-1983 and 1993-1994.

The determination of sodium concentration is performed mainly by two automated methods: selective electrode (M656) and dry Chemistry (M661) in the study period.

As for the total error, it is the combined effect between internal quality control (IQC) of each laboratory and the external quality avaluation (EQA), being given by:

$$TE = |Bias| + z \times CV$$

Bias is related to EQA and CV to IQC, both expressed in %.

z is the multiplying factor based on Normal Distribution N~(μ,σ) and assumes the value of 1,65 for a confidence level of 95% in one-side distribution .

The aplication of six sigma by DMAIC approach involves the determination of sigma level as follows:

1. Calculation of the new mean and standard deviation to sodium parameter in the years of study.
2. Elimination of outliers based on limits: $\overline{X}$-2s e $\overline{X}$+2s
3. After verification the normality of the results, based on specification limit (or allowable total error) for sodium, determination of the probability is given by:

$$P(TE \geq 4{,}9) = P\left(z \geq \frac{4{,}9 - \mu}{\sigma}\right) = y$$

4. The sigma level is the value on the sigma table corresponding to:

$$DPMO = y \times 10^6$$

Results

According to the control points is an inevitable trend of improvement in CV values. In 1978, there were manual methods with different equipments and the CV was around 4,3%. Between 1982 and 1983 were semi-automated methods and between 1993 and 1994 the fully automated methods were added. In nowadays the methods use are fully automated by selective electrode (M 656) and dry chemistry (M 661) (Figure 1).

2nd program of AEQ:

- 21 participants
- 2 samplings
- CV = 2,94%
- 2 semi-automated methods:
  - Selective electrode
  - Flame photometry

33th program of AEQ:

- 70 participants
- 2 samplings
- CV = 1,66%
- 2 automated methods:
  - Selective electrode by potenciometry
  - Dry Chemistry by potenciometry

1978 | 1982 / 1983 | 1993 / 1994 | 2012

Pilot program of AEQ:

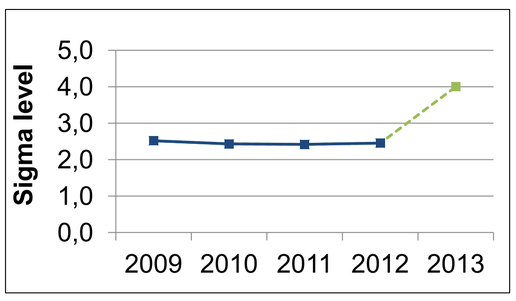
- 10 participants
- 1 sampling
- CV = 4,25%
- 2 manual methods:
  - Colorimetry
  - Flame photometry

14th program of AEQ:

- 103 participants
- 2 samplings
- CV = 2,65%
- 4 methods:
  - Selective electrode (manual and automated)
  - Flame photometry (manual and automated)

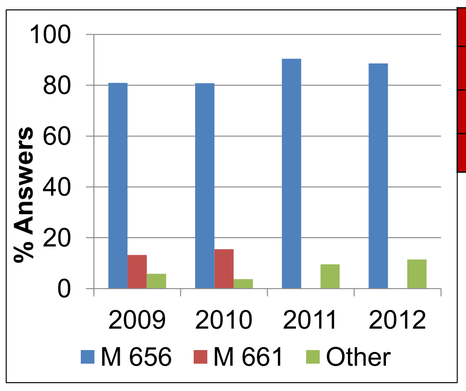
Figure 1: Chronology of the AEQ program on INSA.

The current sigma level calculated for each year of study can be seen on the Graph 3 and in the future this study proposes increase the sigma in 2,3 to achieve a sigma level of 4.



Graph 3: The current and future sigma level .

CV analysis throughout the study period, considering all PNAEQ participants, is decreasing in last years of the study period, from which the method dry chemistry (M 661) is no longer used the determination of sodium (Graph 1).



Years	2009	2010	2011	2012
Nº Answers	156	149	94	70
%CV	2,24	2,49	1,67	1,66
sd	3,21	3,43	2,28	2,41

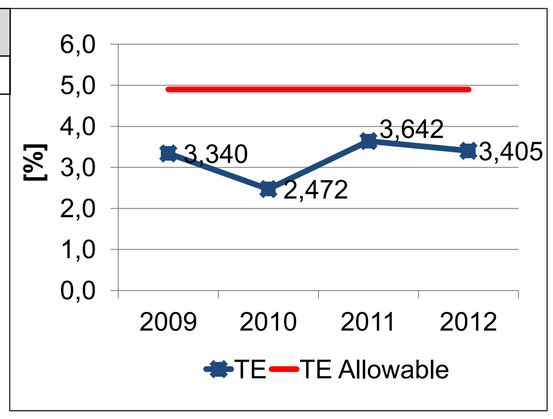
Table 1: Data from study period.

Graph 1: Percentage of answers in each method of sodium determination.

After TE determination of the sample of participants in study, according to the Carmen Ricós tables for the TE allowable of 0,9% [2], the entire sample exceeds this value. However, considering the AEFA tables with 4,9% for TE allowable [3], there are still participants that exceed the value:

Years	2009	2010	2011	2012
% Answers	14,3	22,2	25,0	33,3

Table 2: Percentage of answers that exceeds the TE allowable according to AEFA's tables.



Graph 2: TE presented by the sampling of 12 laboratories and TE allowable.

Conclusion:

- By the historical EQA programs there was an evolution in the methodology for sodium determination, and the current fully automated methodology contributed to decrease of %CV.
- Through analysis of the methods during the period of study, it is concluded that by adopting the same method can be achieved less variability and more harmonization in results between laboratories.
- Considering AEFA tables, referring to the Spanish population, which are similar to the Portuguese, there is a small percentage of laboratories that exceed the allowable TE. The AEFA's tables were construcedt based on their EQA programs, whose specifications were determined calculating the median of the data from their database, in the cases that statistical robustness was found, specifications were obtained by the state of the art.
- Some participants don't determine the TE, as recommended by PNAEQ when testing EQA. It's determination is essential for improving the measurements, because it is an indicator of quality limit for the imprecision and inaccuracy. Therefore, although the entire sample of participants in the study use the same method, there are inherent failures in the way is running action.
- With the implementation of some recomendations, like as the education of laboratory professionals to the importance of the total error or other alternative method as the calculation of uncertainties, is essencial to get improvment in the quality of the measurments and achieve the sigma level 4.

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References:
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