Evaluation of quality control viral load HIV results from two laboratories in Maputo, after the 3rd Congress of Laboratory Quality Control for Portuguese-Speaking Countries, Mozambique.

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Introduction

The Project of Laboratory Quality Improvement for Portuguese Speaking Countries (ProMeQuaLab) is based on three major work tools: education, training and monitoring of quality control measures, in order to build capacity to implement and sustain good laboratory practices.
Since 2015, a biennial congress on quality control is organised which includes also courses in this field. The third edition of the Congress was held in Mozambique in May 2019. Theoretical and practical courses concerning internal (CQI) and external quality control (EQA), calculation of Total Error (TE) and Measurement Uncertainty (MU) were held. Two practical work sessions were organized, with the trainers of the quality control courses and trainees from two laboratories, Centro Criança Dream (Dream) and Laboratório de Virologia Molecular (INS) in Maputo (Mozambique), to applied the statistical tools to evaluate their quality control results of viral load HIV from 2018. Evaluation of viral load is strongly recommended by WHO for monitoring response to retroviral treatment.

Objective

The objective of this work was the implementation of the concepts and tools of the assessment of bias and uncertainty presented in the quality control courses and their application on the quantitative quality control results from 2018 of RNA viral load HIV-1 from two laboratories from Maputo.

Material and Methods

The quantification of RNA viral load HIV-1 was made by Polymerase Chain Reaction – Real Time (PCR-RT) in two different equipments, Abbott m2000 (Dream) and Cobas Ampliprep TaqMan96 (INS). Two different levels of commercial CQI samples, each from one batch, were analysed (positive low, positive high) during the routine work. The EQA program used by the two laboratories was from the Centre for Disease Control (CDC). Seven EQAs samples, including low and high levels, were analized. The CV% , Bias and MU for the quantification of RNA viral load HIV-1 were calculated using the following formulas:

Coefficient of variation

$$C.V.(\%) = \frac{SD \times 100}{\bar{X}}$$

Bias

The root mean square of the individual bias values

$$RMS_{bias} = \sqrt{\frac{\sum(bias_i)^2}{n}}$$

Combined Uncertainty

uncertainty component for imprecision $u(CV\%)^2$ and uncertainty component for Bias (*RMS* Bias %)

$$u_c = \sqrt{u(C.V.)^2 + (uRMS_{bias})^2}$$

Expanded Uncertainty

$$U = k \times u_c$$

K=2, for an 95% approximate level of confidence

Results

The CV values of RNA viral load HIV-1 CQI samples from Dream and INS laboratories were: sample control positive low 4.5% and 4.4%, respectively and sample control positive high, 2.9% and 2.3%, respectively (Table1). The bias values from EQA obtained from Dream and INS laboratories were: 11.7% and 4.1%, respectively (Table 2).

The uncertainty values for Dream and INS laboratories were: low level- consensus mean= 2.6; MU=0.7 log cps/mL and consensus mean=3.0; MU= 0.4 log cps/mL, respectively and high level- consensus mean= 4.3; MU= 1.0 log cps/mL and consensus mean= 4.5; MU= 0.4 log cps/mL, respectively (Table 3).

Table 1: CV values of RNA viral load HIV-1 quantification from CQI samples for Dream and INS laboratories

Laboratories	Dream		INS	
	Low level	High level	Low level	High level
N	25	25	72	72
Mean	3.0	4.9	2.8	5.6
Standard deviation (Sd)	0.1	0.1	0.1	0.1
CV%	4.5	2.9	4.4	2.3

Table 2: Bias values of RNA viral load HIV-1 quantification from EQA obtained for Dream and INS laboratories

Laboratories	Dream	INS
Unit- log cps/mL	consensus mean (2.3-4.7)	consensus mean (2.7-4.9)
Number of schemes	7	7
RMS Bias (%)	11.7	4.1

Table 3: Uncertainty (MU) values of RNA viral load HIV-1 quantification for Dream and INS laboratories

Laboratories	Dream		INS	
	Low level	High level	Low level	High level
Consensus mean (Unit- log cps/mL)	2.6 (n=4)	4.3 (n=3)	3.0 (n=4)	4.5 (n=3)
RMS Bias (%)	12.0	11.2	4.6	3.2
U % (expanded uncertainty)	26	23	13	9
U x10^9/L (expanded uncertainty)	0.7	1.0	0.4	0.4
Mean ± U (10^9/L)	2.6 ± 0.7	4.3 ± 1.0	3.0 ± 0.4	4.5 ± 0.4

Conclusion

The concepts and tools presented in quality control courses were applied to quality control results of two laboratories in Maputo (Mozambique) for the measure of imprecision, bias and measurement uncertainty. The courses and the work sessions have proved to be very effective in transferring knowledge and skills and therefore should be continued with other laboratories.
The results of the bias and measurement uncertainty show that the INS laboratory (Cobas Ampliprep TaqMan96) had a better performance in comparison to the Dream laboratory (Abbott m2000).
Effort must be made to continue the education program, namely the interpretation of the quality control results to achieve an improvement of the evaluation of patient results.

Bibliografia:
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