International Normalized Ratio (INR): Performance of External Quality Assessment 2016 results - PNAEQ and ECAT Foundation

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Background and Aim

The International Normalized Ration (INR) is derived from the measurement of the Prothrombin Time (PT) and the International Sensitivity Index (ISI), and is a quantitative measure of the responsiveness of individual thromboplastin reagents to the different clotting factors involved in the PT measurement.
Under the INR system, all results are standardized. For example, a person taking an oral anticoagulant (ex. Coumadin) would need regularly to have a blood test to measure the INR. The INR permits patients on anticoagulants to travel and obtain comparable test results wherever they are. So it is very important to verify the laboratories performance over this test.
In 2014 the Portuguese National External Quality Assessment Program (PNAEQ) has established a consortium with ECAT Foundation for INR measurement where Portuguese laboratories are included in the statistical analysis.

The main objective of this study was to evaluate the performance for INR of PNAEQ participants that used two different thromboplastin reagents during 2016 and compared those with the results of ECAT participants.

Methods

The mean value and coefficient of variation (CV%) of 12 human citrated plasma lyophilized samples of different INR levels ([0,98- 1,08], [2,45-3,62] and [4,44-7,94]), distributed in 6 surveys during 2016, were obtained with Algorithm A application, by ECAT.

The analysis was focused on the two most used lyophilized thromboplastin by PNAEQ participants (human placenta and rabbit cerebral tissue).

A comparison between Portuguese (PNAEQ) participants and total ECAT participants was made for each of the two lyophilized thromboplastin used, by a t-student test assuming normal data, since only final values were available.

Only for Portuguese (PNAEQ) participants a comparison between the two lyophilized thromboplastin was also made, and ISI and CV% values reported for the two thromboplastins were evaluated.

The tests were performed bilaterally at a significance level of 5%, where by a p-value of less than 0,05 was considered statistically significant.

Results

There was no significant differences between the Portuguese and total ECAT participant's in INR mean values, neither with lyophilized thromboplastin of human placenta or with rabbit cerebral tissue (p-values>0,05).

Significant differences between lyophilized thromboplastins (p-value < 0,02) were observed on the 10 samples with INR>2,45 from PNAEQ participants **(Figure 1)**.

ISI values reported by PNAEQ participants ranged from 0,91 to 1,13 and 1,17 to 1,35 for human and rabbit thromboplastin, respectively.

The mean INR CV% by range in PNAEQ participants was higher for rabbit than for human Thromboplastin **(Table 1)**.

Table 1: *Mean CV% by INR range for each thromboplastin (Portuguese ECAT participants)*

INR range	Mean CV% - Human -	Mean CV% - Rabbit -
0,98 – 1,08 (n=2)	5,73	6,27
2,45 – 3,62 (n=6)	9,13	9,98
4,44 – 7,94 (n=4)	8,90	10,86

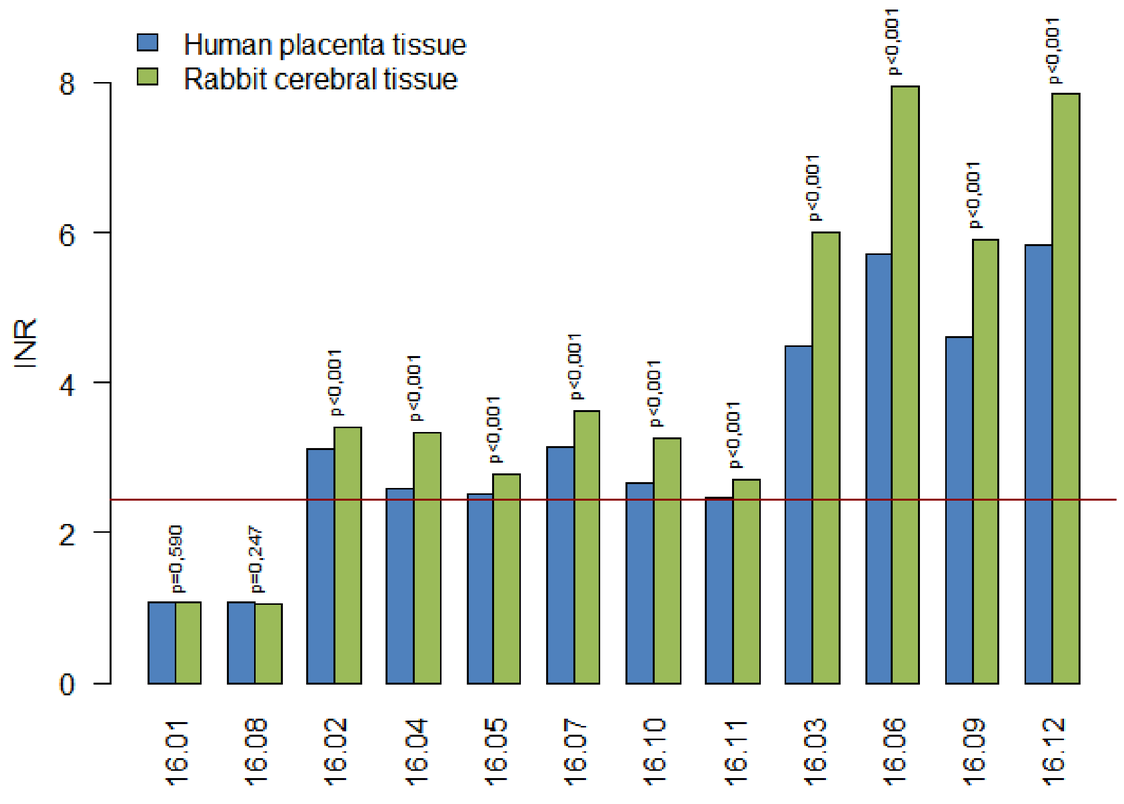

Figure 1: *Comparison between the two thromboplastin by sample (Portuguese ECAT participants)*

Conclusion

ISI values reported by PNAEQ participants are in agreement with the WHO guidelines (0,9-1,7).

As expected PNAEQ and total ECAT participants performance has no differences.

Although INR is meant to harmonise the PT measurement this is not completely achieved, as shown by the differences between different thromboplastins in PNAEQ participants.

Participation in EQA programs permit laboratories to monitor, improve and establish good laboratory practice in order to ensure accuracy, precision and quality of testing. This will provide more correct diagnosis and safer patient care by clinicians, which is the main purpose of laboratory procedures.

References
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