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A critical analysis of our experience as participants in an external quality assessment scheme for blood coagulation

Vanessa Oliveira¹, Maria Manuel Campos², Maria José Marques², Ana Isabel Fernandes², Ana Maria Lopes², Maria Helena Alves², Deonilde Espírito Santo²

¹Department of Transfusion Medicine of Hospital Prof. Dr. Fernando da Fonseca, EPE (HFF) – Amadora, Portugal; ²Department of Immunohaemotherapy of Centro Hospitalar Lisboa Central, EPE (CHLC) – Lisboa, Portugal

Introduction: In clinical practice, patient’s diagnosis and therapeutic decisions are often dependent on the outcome of laboratory results which should be highly accurate and reliable. Laboratories should be obliged to participate in international external quality assessment schemes (EQAS) as an essential feature to evaluate laboratory performance and quality control. The aim of this study was to perform a critical analysis of the last 6 and half years of UK National EQAS for blood coagulation in the Department of Immunohaemotherapy of CHLC.

Methods: In this study we compiled the analysis of all UK NEQAS blood coagulation samples received from April 2011 to December 2017 comprising a total of 399 samples and including: Laboratory Programme (Level 1: Screening Tests; Level 2: Assays), Additional/Supplementary Exercises and DOAC (Direct Oral Anticoagulant) Assay Programme. In the case of FXIII samples and DOACs, results are from 2013 to 2017 and 2015 to 2017, respectively. The number of samples per year varied according to the test being performed. Total number of samples per test from 2011-2017 varied from 37 (PT/INR) to 6 (Heparin Dosage and VWF:RCo) and 5 (direct oral anticoagulants). All the results obtained were included in this study.

Results: From the total number of samples analyzed (399) we obtained 95.5% of results within consensus (**Figure 1**). PT/INR and APTT were the tests with the highest number of samples 37 and 36, respectively (**Figure 2A**). On the contrary, tests like Heparin Dosage, VWF:RCo and DOACs are represented by a total of 6, 6 and 5 samples, respectively (**Figure 2A**).

Results outwith consensus were observed in 8 tests, namely in 32% and 11% of results for tests Prot C:Act and FVIII:C, respectively (**Figure 2B**). Whenever a value was outwith consensus, a thorough review of the test was performed to find the problem, so that solutions could be applied accordingly. As described in **Table 1** most actions involved using new sets of reagents or calibration curves and sometimes even review the hole methodology.

When applicable, we analyzed the results in each quantile (in a total of 260 samples) and observed that 7.7% and 8.5% of all samples were in quantile D/d and E/e, respectively, whereas the vast majority of samples could be found in quantiles A/a (53%) and B/b (19%) (**Figure 3**).

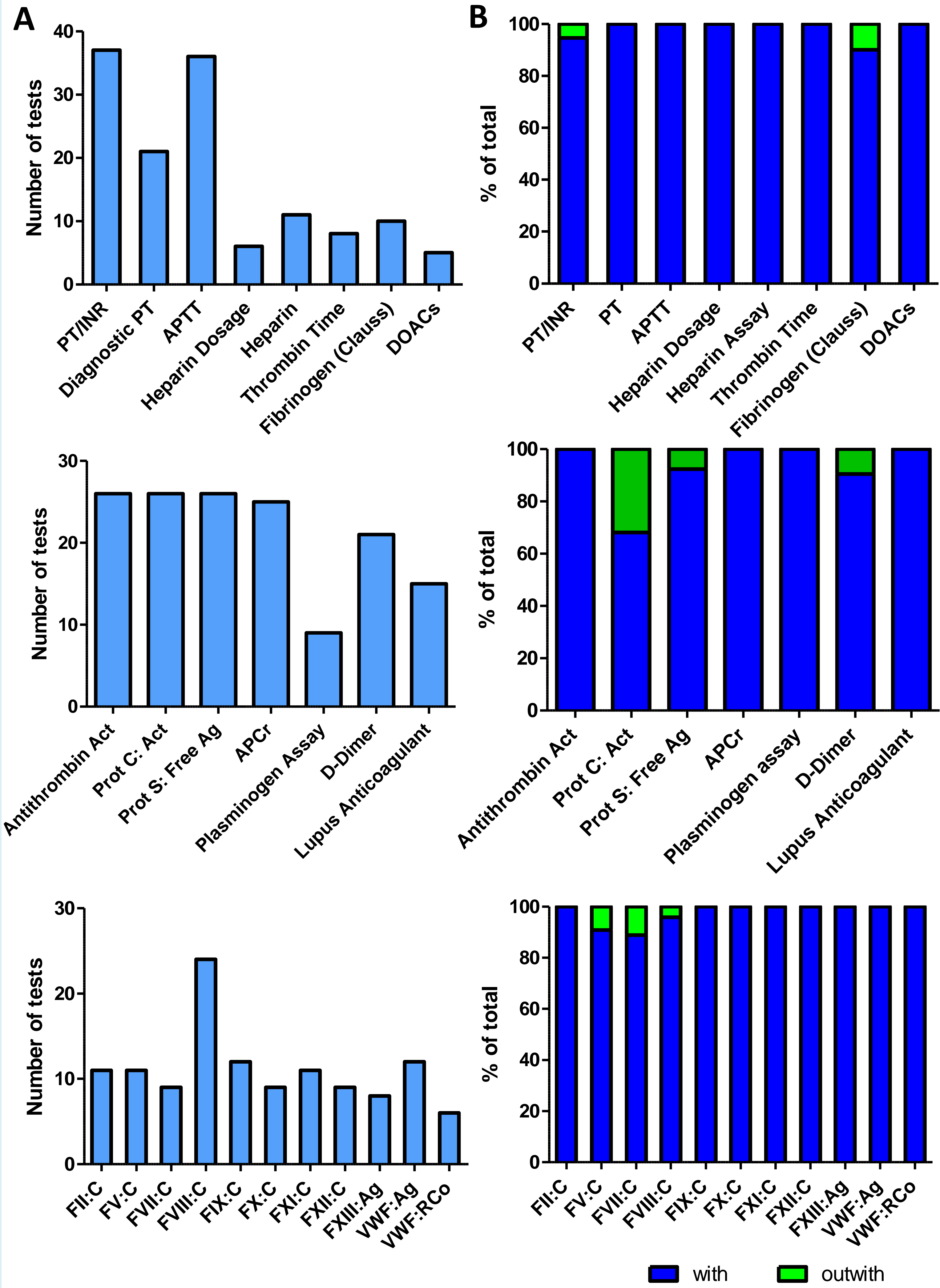


Figure 2 – A) Total number of samples performed per test. **B)** Representation of values within and outwith consensus for each assay

Table 1- Examples of tests outwith consensus and some of the solutions applied to solve them

Test	Resolution
Prot C: Act	New calibration curve, reviewed methodology, ACL TOP maintenance
D-Dimer	Results were biased for portuguese samples
Clauss Fibrinogen	New methodology, namely freezing and thawing procedures
FVIII:C	New reagents, new calibration curve, substitution of factor diluent
FV:C	Reviewed methodology, substitution of factor diluent

Conclusion: EQAS are essential tools for the continuous improvement in quality standards of patient care. These periodical assesments allow interlaboratory comparison but, more importantly, they function as a survey for procedures performed daily in laboratories allowing the detection of systematic errors that might, otherwise, go unnoticed.

In this study we analysed our results from 2011-2017 and, when applicable, outwith consensus samples were resolved promptly and adequately. We can conclude that our overall performance for the last 6 and half years was very good.