ABSTRACT FORM ECAT SYMPOSIUM 8 – 9 NOVEMBER 2018

Name:

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Title:

Analytical variation in factor VIII one-stage and chromogenic assays: experiences from the ECAT external quality assessment program

Abstract:

Background
Both one-stage (OSA) and chromogenic substrate assays (CSA) are used to measure factor VIII (FVIII) activity. Factors explaining the analytical variation in FVIII activity levels remain to be elucidated.

Aim
The aim of this study was to quantify and understand the analytical variation in OSA and CSA.

Methods
Factors determining analytical variation were studied for FVIII activity levels in sixteen lyophilized plasma samples (FVIII activity <0.01 - 1.94 IU/ml) and distributed by the ECAT foundation external quality assessment (EQA) program. To elucidate the origin of OSA variation, we exchanged deficient plasma between three company set-ups.

Results
On average, 206 (range 164–230) laboratories used the OSA to measure FVIII activity and 30 (range 12–51) used CSA. The CV of OSA and CSA increased with lower FVIII levels (FVIII < 0.05 IU/ml). This results in misclassification of a severe haemophilia A sample into a moderate or mild haemophilia A sample in 4/30 (13.3%) of the CSA measurements, while this was 37/139 (26.6%) for the OSA. OSA measurements performed with reagents and equipment from Werfen showed slightly lower FVIII activity (median 0.93, IQR 0.88–0.98 IU/ml) compared to measurements with Stago (median 1.07, IQR 1.02–1.14 IU/ml) and Siemens (median 1.03, IQR 0.97–1.07 IU/ml). Part of the difference is explained by the value of the calibrator. For CSA, the measured FVIII levels were similar with the different kits.

Conclusions
In the lower range (<0.05 IU/mL), analytical variation of FVIII measurements is high in both OSA and CSA measurements. The variation in FVIII activity levels was largely explained by the manufacturer. Further standardization of FVIII measurements and understanding of the analytical variation are required.