Analytical Specifications for Haemostasis Assays

Meijer P

ECAT Foundation, Leiden, The Netherlands

This session will explain the use of analytical quality specifications for haemostasis assays based on results of an external quality assessment programme. Analytical quality is the net result of the process of quality management, including the assessment of analytical quality specifications, quality creation and quality monitoring. Analytical quality specifications (AQS) are meant as criteria to control the quality of the analytical process. Quality monitoring can be done by both internal quality control (IQC) and external quality assessment (EQA). In this session we focus on the role of EQA. There are several approaches for the assessment of analytical quality specifications. In 1996 it was decided by an international working group of EQA organizers that AQS for EQA programmes should be based on the biological variation of the analytes under investigation. This concept will be discussed.
Results and Conclusions: In summary, for monitoring patients the imprecision should be equal to or less than 0.5 times the within-subject biological variation and bias should be equal to or less than 0.33 times the within-subject biological variation. For diagnostic testing the imprecision should be equal to or less than 0.58 times the total biological variation and bias should be equal to or less than 0.25 times the total biological variation. To assess imprecision and bias for a particular test performed by an individual laboratory based on the data of an EQA programme the ECAT Foundation has designed a special evaluation model. This model allows us to assess the long-term within-laboratory analytical coefficient of variation (LCVa), which here represents imprecision, as well as bias and total analytical error. This model will be discussed. The model was applied to the data for the assay of antithrombin (activity), protein C (activity and antigen) and protein S (activity, total and free antigen). These data will be discussed. The data for imprecision and bias will be compared to the analytical quality specifications for monitoring and diagnostic testing.