

ECAT: From Analytical Performance Towards Diagnostic Performance

Meijer P

ECAT Foundation, Leiden, The Netherlands

This session will explain the traditional EQA focusing on analytical performance and case-based EQA focusing on diagnostic performance. External quality control is an important tool for the laboratory for assessing the quality of the analytical performance of laboratory tests in comparison to other laboratories. For more than ten years the ECAT Foundation has been providing an international external quality assessment (EQA) programme in the field of thrombosis and haemostasis. From a small group of about 60 participants in Europe participation has increased, and nowadays more than 750 laboratories from all over the world take part in the EQA programme of the ECAT Foundation.

Results: Up to now the programme has focussed mainly on the analytical performance of the participants. The regular reports provide the participants with information about the accuracy of the laboratories' own result in relation to the consensus value as well as the distribution of the results of all participants. Depending on the analyte and the level of the particular analyte in the sample, a wide inter-laboratory variation may be observed. An example of an analyte with relatively low inter-laboratory variation is antithrombin (7 – 13%). However protein S activity, for instance, showed an inter-laboratory variation of between 15% and 38%. At least for control samples in the abnormal range there seems to be a tendency to a decrease in the inter-laboratory variation over time. Here the effect of the improved attention of the laboratories to more precise measurements probably counts.

Conclusions: The EQA for analytical performance is very useful to the laboratory. It helps the laboratory to reveal possible analytical errors, such as calibration problems (systematic errors) and performance problems (imprecision). However, the EQA for analytical performance is mostly limited to the analytical phase of the diagnostic process. The total diagnostic process includes also the pre- and post-analytical phase. For patient care the quality of the total diagnostic process is of major importance. Although the EQA can never cover the whole diagnostic process (e.g. blood collection and handling cannot be included), an extension of the focus from analytical performance to diagnostic performance may be very useful. This can be achieved by organising case-based EQA surveys. These particular EQA surveys cover, for instance, interpretation of patient history, test selection, data interpretation and diagnosis. Here, the EQA can bridge the gap between the physician and the clinical biochemist.