What do laboratories need from an External Quality Assessment (EQA) Programme – is it time to redefine the aims of EQA?

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Introduction

EQA is defined as a system designed to objectively assess the quality of results by an external agency. The aims were defined by the IFCC in 1983 in that they should:
- provide a measure of the quality of a test
- supplement IQC procedures
- provide a measure of the “state of the art” of a test
- obtain consensus values when true values are unknown
- investigate factors in performance.

By using dedicated designs and samples, EQA can be used to provide a wealth of additional information such as assessment of trueness, inter and intra-laboratory variation, robustness of methods; sensitivity and specificities, linearity, post market vigilance, act as an educational stimulus, assess pre- and postanalytical factors as well as provide evidence for harmonisation strategies.

Expectations of EQA Provider

In most countries, outside North America, the choice of EQA provider lies with the laboratory, where a range of factors should be considered in undertaking that choice.

Figure 1 Factors influencing choice of EQA

- Accreditation status
- Clinical relevance
- Range and number of samples
- Core of clinical outcomes
- Radioanalytical performance criteria

EQA Programme Design

In the design a number of factors need to be considered such as: number, frequency and type of samples, target value, statistical analysis and the analytical performance specification (APS). The use of material as close as possible to the patient sample minimizes any matrix effect and allows the assessment of accuracy. Other factors to consider include: stability, homogeneity, clinically relevant concentrations at clinical decision limits, Figure 2, and use of challenging samples.

Clinically relevant samples

Clinical relevance

Laboratories should ensure that the quality is appropriate for the needs of the clinical service. It is therefore essential that EQA evaluation criteria should also reflect clinical need. A hierarchical strategy for APS proposed by the EFLM is suggested.

Clinically relevant APS

The primary intention of an EQA provider is to monitor the performance of laboratories and to support quality improvements for the benefit of patients. It is therefore proposed that the definition should be broadened to include education, troubleshooting support, the assessment of the pre and post analytical phase, post market vigilance, and the monitoring of harmonisation strategies.