EXTERNAL QUALITY ASSESSMENT – A CONTINUOUS AUDIT PROCESS IN CLINICAL BIOCHEMISTRY
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Introduction
About 80% of medical diagnoses can only be made following some degree of laboratory input and a significant number of pathologies require laboratory input for their resolution. It is essential, therefore, that the laboratory delivers a high quality service and that clinicians, as well as laboratory staff, have confidence in the results produced. The continuous monitoring of analytical quality is achieved by implementation of internal quality control and external quality assessment procedures. Internal quality control monitors analytical performance on a day to day basis and allows any slight deterioration to be detected and rectified at an early stage. Quality control samples, with known analyte concentrations, are analysed with patient samples, and providing the results obtained from the internal quality control samples fall within predetermined statistical limits, the patient results can be released.

External quality assessment gives a retrospective picture of analytical performance and is, by its nature, a continuous audit process.

External Quality Assessment - EQA
a system of objectively checking laboratory results by means of an external agency.

WHO External Assessment of Health Laboratories (1981)
Approved EQA schemes are run by a number of organisations in the UK and although participation is voluntary, it is an essential requirement for a laboratory to obtain Clinical Pathology Accreditation (CPA) (Table 1).

The EQA Audit Process
Standards of acceptable analytical performance are set by scheme organisers in liaison with their Steering Committee and the National Quality Assurance Advisory Panel (NQAAP) for Chemical Pathology.

The EQA scheme organisers distribute a series of samples with unknown analyte concentrations, at regular intervals to participating laboratories. The laboratories analyse the samples as if they were patient samples and return the results to the scheme organisers for statistical analysis. Laboratories are sometimes asked to add interpretative comments to the EQA results that they produce. A performance report is issued to the laboratory. Any poor performance highlighted in the report is investigated by the laboratory and problems are rectified or improvements made. The laboratory receives another batch of EQA samples and its performance is re-audited (Figure 1).

Unsatisfactory Laboratory Performance
The object of EQA is not to name and shame poorly performing laboratories, but to help them maintain high standards of analytical performance. Any occasional problems highlighted in EQA scheme reports are often quickly resolved internally. However, EQA organisers will contact any laboratory that consistently fails to meet standards of acceptable performance, to ensure that the problem is being rectified and to offer help. If still no progress is made in improving performance, the NQAAP and the Joint Working Group on Quality Assurance (JWG QA) may be asked to intervene and ultimately the Medical Director of the Laboratory’s Trust may be informed.

The EQA Scheme Report
The report details the accuracy (correctness) of a laboratory result by comparing it to a target value. This value is usually a consensus mean (eg the mean of all the results submitted by the various laboratories for a particular sample, once outlying results have been removed). Accuracy is often expressed as percentage bias (Figure 2). The bias may be transformed to give an Accuracy Index which can be compared to a performance rating scale to determine whether the bias, and therefore the accuracy is acceptable. Accuracy can also be expressed by calculating the number of standard deviations the result is away from the consensus mean – the standard deviation index (Figure 3). Some schemes that distribute samples whose analyte concentrations span the analytical range, also provide in the report, information as to a laboratory’s analytical precision (reproducibility).

All scheme reports compare analytical performance between laboratories and many compare current with previous performance so any deterioration can be monitored.

Reviewing the EQA Scheme Reports
All reports are reviewed by the Quality Control Officer and are made available to departmental staff. Poor performance is actively investigated and formally documented. If necessary, the department works with the EQA scheme organisers to resolve problems. Problems are also communicated to analyser manufacturers and the suppliers of reagents and internal quality control material as appropriate.

Table 1: The EQA organisations with whom the Clinical Biochemistry laboratory is registered
All the organisations have been approved by external regulatory bodies (eg CPA)
- UK NEQAS
  - UK National External Quality Assessment Schemes
- WEGAS
  - Welsh External Quality Assessment Schemes
- RIOQS
  - Randox International Quality Assessment Scheme
- YEQAS
  - Quality Assessment Scheme

Summary
- Internal quality control and external quality assessment procedures are used in the clinical biochemistry laboratory to maintain high standards of analytical performance.
- EQA is a continuous audit process co-ordinated by independent external organisations.
- Professional bodies have agreed the standards against which analytical performance is monitored.
- EQA schemes improve and maintain analytical agreement between laboratories, identify poor analytical performance and help with analytical problem solving

Figure 1: The EQA Audit Cycle
(1) Samples are dispatched to the user laboratories
(2) Samples are received and analysed by the user laboratories
(3) Results from the user laboratories are sent to the EQA organisers
(4) Each user laboratory receives its performance in relation to the performance of all other participating laboratories and is informed of any problems
(5) Results from the user laboratories are analysed and a report prepared comparing each laboratory’s performance to that of other participating laboratories
(6) Each user laboratory reviews its performance in relation to that of all other participating laboratories

Figure 2: An extract from a UK NEQAS report for the salicylate EQA scheme

Figure 3: An extract from a WEGAS report for the CK-MB EQA scheme

Acknowledgements
Thanks to Finlay MacKenzie (UK NEQAS) and Annette Thomas (WEQAS) for allowing examples of their scheme reports to be reproduced.