NQAAP best practice guidance for selecting EQA providers

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1. Introduction and purpose

External quality assessment (EQA) is the inspection of a test result by a body outside the institute conducting the test, for the purposes of ascertaining its quality and the quality of the underlying test procedure. (This may also be described as proficiency testing [PT].) EQA is defined as a system designed to objectively assess the quality of results by an external agency.

The aims of an EQA scheme were defined by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) in 1983[1] as:

- to provide a measure of the quality of a test
- to supplement internal quality control procedures
- to provide a measure of how “state of the art” a test is
- to obtain consensus values when true values are unknown
- to investigate factors in performance (methods, staff etc.).

However, over the last 2 decades the aims have evolved to also include:

- to provide pre- and post-analytical assessment
- to act as an educational stimulus to improvement in performance[2]
- to provide a post-market vigilance service[3]
- to provide evidence and monitoring of harmonisation strategies.[4]

The primary intention of the activities of an EQA provider in laboratory medicine is to monitor performance of participating laboratories and support quality improvement of the services they provide for the benefit of patients.

The purpose of this document is to outline what aspects of an EQA scheme should be considered by laboratories before deciding on the selection of the scheme and EQA provider. To make an informed selection, laboratories need to understand the scheme design i.e., the scope and purpose of that scheme. Does it cover everything the laboratory

may need; the pre-analytical, analytical and post analytical components? Is it assessing the laboratory's technical and/or clinical competence to undertake that investigation?

2. Responsibilities

A number of factors need to be considered – such as number, type and frequency of samples, range and level of analytes/investigations, commutability, quantitative or qualitative assessment, and the assessment criteria.

3. Procedures

According to Miller et al,[5] "PT/EQA programs can be classified into 6 categories according to how well they are able to evaluate performance. Evaluation capability depends on 3 characteristics: sample commutability, the process for target value assignment, and inclusion or non-inclusion of replicate samples. Category 1 is the most desirable because programs in this category use commutable samples with target values established by a reference system and can evaluate both individual laboratories and measurement procedures for reproducibility, calibration traceability, and uniformity between laboratories and between measurement procedures. Programs in category 2 have the same attributes as category 1 except that within-laboratory reproducibility cannot be evaluated because replicate samples are not used within a survey cycle. Programs in categories 3 and 4 also use commutable samples but, because the target values are not established by a reference system, the evaluation is limited to the uniformity among results (harmonization), a feature of considerable value for laboratory medicine. Programs in categories 5 and 6 use samples likely to be non-commutable, thereby limiting evaluation to peer-group comparisons and failing to provide information on bias between different measurement procedures."

Section 4.2 below is intended to provide a scoring system to allow appropriate scheme selection and is based on the article by James et al.[6] All EQA schemes should fulfil the basic requirements of peer review and assessment of the analytical quality of a laboratory service and also provide assessment of methods and inter-laboratory variation.

To gain the most value from a scheme a laboratory should ensure that the reports returned by the scheme are timely and easy to interpret while also providing educational and quality improvement benefits. Many scheme providers have online documents/presentations to aid with report interpretation and often offer educational meetings to cover this aspect of their scheme.

4. Related documents

4.1 References

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3. EN 14136 Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures, 2014. European Committee for Standardization, Brussels.
4. Miller WG, Myers GL, Gantzer ML, Kahn SE, Schonbrunner ER, Thienpont LM *et al.* Roadmap for harmonization of clinical laboratory measurement procedures. *Clin Chem* 2011;57:1108–1117.
5. Miller WG, Jones GRD, Horowitz GL, Weykamp C. Proficiency testing/external quality assessment: current challenges and future directions. *Clin Chem* 2011;57:1670–1680.
6. James D, Ames D, Lopez B, Still R, Simpson W, Twomey P. External quality assessment: best practice. *J Clin Pathol* 2014;67:651–655.
7. Sandberg S, Fraser CG, Horvath, AR, Jansen R, Jones G, Oosterhuis W *et al.* Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine. *Clin Chem Lab Med* 2015;53:833–835.

4.2 EQA provider specification and checklist

Essential

- The scheme is ISO accredited by UKAS or another national accreditation body to ISO 17043.
- Member of the EQA Governance and Assurance Framework.
- The scheme covers the range of analytes assayed by the laboratory as well as any calculated parameters associated with those analytes.
- Samples are distributed at an appropriate frequency according to clinical risk and relevance.
- Samples are distributed in a stable, homogeneous matrix that is the same as or close to that of clinical samples (demonstration of commutability).
- Samples are distributed by the scheme cover the appropriate clinical range (or measuring range if technical scheme) of the assay.
- Samples are circulated to provide clinically relevant analytical challenges at key clinical decision limits.
- Samples are circulated to probe analytical issues, such as method interferences and analytical sensitivity and specificity.
- For quantitative analysis, in the absence of a higher order target value, the scheme has sufficient participants to ensure that the calculation of the target value and the uncertainty associated therein is valid (both clinically and statistically).
- The scheme has clinically relevant performance criteria to assess participant performance such as those identified in the Milan criteria.[7]
- The scheme applies appropriate statistical analysis methods to its data (in accordance with ISO 13528).
- Feedback is timely and effective.
- The scheme has an independent Medical and Scientific Specialist Advisory Group with appropriate medical (or scientific) expertise in the respective subject area.

- Helpful and appropriate troubleshooting support.
- Participation by the EQA scheme in post-marketing vigilance of the in vitro diagnostic regulations (IVDR).

Desirable

- Clinical interpretative exercises are carried out as part of the scheme if appropriate.
- Results can be entered and reports received electronically.
- Recovery and linearity exercises are carried out at least annually for relevant technical schemes.
- Regular user group meetings.

Table 1: EQA provider checklist.

	Scheme			
Metric				
Member of the EQA Governance and Assurance Framework.				
Scheme covers range of analytes assayed by the laboratory as well as any calculated parameters associated with those analytes.				
Samples distributed at an appropriate frequency according to clinical risk and relevance.				
Samples are distributed in a stable, homogeneous matrix that is the same as or close to that of clinical samples.				
Samples distributed by the scheme cover the appropriate clinical range (or measuring range if technical scheme) of the assay.				
Samples circulated to provide clinically relevant analytical challenges at key clinical decision limits.				
Samples circulated to probe analytical issues, such as method interferences and analytical sensitivity and specificity.				

For quantitative analysis, in the absence of a higher order target value, the scheme has sufficient participants to ensure that the calculation of the target value and the uncertainty associated therein is valid.				
Availability of repeat samples.				
The scheme has clinically relevant performance criteria to assess participant performance such as those identified in the Milan criteria.				
The scheme applies appropriate statistical analysis methods to its data (ISO 13528).				
Feedback of results is timely.				
Scheme is ISO accredited by UKAS (ISO/IEC 17043).				
The scheme has an independent Medical and Scientific Specialist Advisory Group.				
Recovery and linearity exercises are carried out at least annually.				
Helpful and appropriate troubleshooting support.				
Participation by the EQA scheme in post-marketing vigilance of the IVDR.				
Clinical interpretative exercises are carried out as part of the scheme if appropriate.				
Results can be entered and reports received electronically.				
Regular user group meetings.				