The Role of EQA in Diagnostic Laboratories

Scoring doesn’t really matter
A group of separate organisations (consortium) registered as a charity in the UK and dedicated to the provision of external quality assessment in the UK and internationally.

UK NEQAS for Microbiology is hosted by Public Health England, Colindale.

In the UK and ROI, UK NEQAS (like all EQA providers) report to NQAAP regarding performance evaluation.
What is EQA?

- A means of assessing the efficiency of the quality assurance procedures by the introduction of specimens of known but undisclosed contents and assessing the results benchmarked against equivalent laboratories and methodologies.
Where does EQA fit into your quality systems?

This is a very snug fit as EQA is a small element of all the activities that you undertake to achieve a quality outcome.

BUT it is an efficient, external, unbiased and independent assessment of your processes at a single moment in time.
TQM - overview

TQM puts customers at the centre of the requirements

Customer focus

Measures
- SPC, Quality tools, Benchmarking

People
- Quality culture

Processes
- Continuous improvement

GLP
Process based (general)

Suppliers → Inputs → Sub-process → Main process → Sub-process → Outputs → Customers

- Documentation: Records; SOPs; contracts
- Quality assurance/GMP: IQC; IQA; Validation; UoM
- Quality monitoring: Audits; CAPAs; Review; KPIs; EQA
- Staff training: Records; competency (extent/challenge)
Process based (Micro laboratory)

Technical instructions
Laboratory results
Quality control results

UKAS (accreditation body);
ISO 15189; DMAIC/PDCA

Bacterial Identification
Antimicrobial susceptibility
Viral marker tests/ Immunoassays
Molecular testing

Discipline (traditional)

SPC; Validation of technologies;
equipment; kits. Determination
of uncertainty of measurement

Syndromic processing

Patients/Clinicians
Specimens, reagents, kits, media
Suppliers

Competent, empowered staff

Results

Customers
Process based (Final outcome)

Good clinical outcome
Satisfied patient
EQA is the tip of the iceberg

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What do EQA schemes do? (1)

- Detect analytical errors
  - Sample mix-up
  - Inappropriate testing done
  - Tests performed incorrectly
  - Equipment/automation failure
  - Misidentification of organisms
  - Reporting artefacts/contaminants
  - Poor laboratory technique
  - Reagent/kit issues
  - Processes that are not robust
What do EQA schemes do? (2)

- Detect post-analytical errors
  - Transcription errors
  - Issues with turn-around times
  - Misinterpretation of results
  - Failure of results reaching the clinician
What do EQA schemes do? (3)

* Promote education and encourage debate
  - Rubella IgG – who is immune/who is not - why is 10 the magic number?
* Force updates for automated equipment, e.g. Vitek, MaldiToF – only as good as the database
* Manufacturer intervention
* Provide information to evaluate issues that are of national, regional and global importance - antimicrobial susceptibility (in support of antibiotic stewardship)
* Provide evidence of a commitment to quality
* Provide evidence of processes to identify and implement corrective actions when things go wrong
What prevents EQA schemes from fulfilling their role

* Having a dedicated bench for carrying out EQA/QC samples – these should be part of the routine work
* Having dedicated staff carrying out EQA samples and not just random chance as to who would test on any one day
* Treating the sample differently from the equivalent clinical sample, e.g. several tests, different algorithms, extra/confirmatory testing
* Not reading your report carefully (even if you have a full score) and following up on EQA failures as you would any other non-conformance
What do EQA schemes not do do?

- Validate a new kit or methodology
- Provide samples for calculation of uncertainty of measurement
- Prove your laboratory is perfect
- Provide the most important mechanism for quality assurance - tip of the iceberg
- Act as in-house QC samples
In what area does traditional EQA not help? YET

Plebani 2006/2012
Virtual EQA – this will help cover the whole iceberg but not for all disciplines and not for all processes

UK NEQAS PREPQ

E.g. one of the most important skills for a haematologist or a parasitologist is to achieve a perfect stain of a blood film – virtual eqa will not assess this
EQA services provide an independent assessment at one moment in time of your analytical and post analytical processes.

EQA provides an education stimulus and promotes debate on difficult issues.

EQA provides evidence of a commitment to quality.