‘A Compendium of Quality’

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Overview

- Range and depth of UK NEQAS services – a Compendium of Quality

- Defining and measuring quality
  - Acceptable performance specifications

- EQA errors and troubleshooting
Compendium of quality

6.1.1
PREPQ: Pre-and Post-Analytical Quality Monitoring Service Supporting End to End EQA

6.1.2
Quality Assurance Masterclasses: Practical learning, real time proficiency Supporting End-to-End EQA

6.1.3
Proficiency and Efficiency Testing: Combined technical assessment and clinical interpretation in Histocompatibility and Immunogenetics

6.2.2
Harmonising Performance Across Methods: Detection of Antibiotic Resistance International Collaborative Leadership in Quality Improvement

6.3.1
UK NEQAS: supporting National and International Initiatives on Kidney Function Supporting Continuous Quality Improvement in Networks and Laboratories
Compendium of quality

7.2
UK NEQAS online competency assessment in Blood Transfusion in a virtual laboratory environment
Innovative Interpretative EQA

7.1
Maintaining Relevance – Matching schemes to current pathogens
UK NEQAS for Molecular detection of viruses

8.1
Ensuring the quality of Whole Genome Sequencing as part of the UK '100,000 Genomes' Project
Supporting Personalised Medicine

8.4
UK NEQAS provision for Specialist Centres: International Specialist Molecular testing in haemoglobinopathies
Supporting Personalised Medicine

8.5
Testing breast cancer for selection of HER2-targeted therapy
Supporting Personalised Medicine
6 ‘Pillars’ of traceability

- Reference materials
- Reference methods
- Reference assay services
- Reference intervals and action points
- Quality assurance
- Uncertainty of measurement

6 ‘Pillars’ of traceability

- Reference materials
- Reference methods
- Reference assay services
- Reference intervals and action points
- Quality assurance – IQC and EQA
- Uncertainty of measurement

Defining quality

Quality management system
Governance and oversight
Individual competence
End-to-end quality monitoring
Monitoring Quality

Pathology Directorate

A

Pathology Provider

Internal Quality Assurance

Internal Governance

B
Professional standards units at Professional Bodies

C
Regulation (GMC, HCPC)

D
Commissioners

E
SIs SHOT MHRA

F
EQA Schemes

G
JWGQA (via NQAAPs)

H
CQC/Hospital Inspection

UK NEQAS
International Quality Expertise
Monitoring Quality

Laboratory accreditation
ISO 15189

EQA
‘Technical’
Interpretive (individual)

UK NEQAS
International Quality Expertise
Disclosure of EQA performance to UKAS

3. NQAAP will write to the participant informing them of the outcome of their assessment and any action to be taken. The EQA scheme organisers and now UKAS will be copied in to this letter.

Steps 1 and 2 are unchanged from current practice. The only change is the inclusion of UKAS in step 3. This change requires that participants provide details of their UKAS registration solely to enable correct identification of a laboratory. This information will only be used should step 3 become necessary and will not be used for any other purpose.

28th April 2017
Re: Change to the notification process for Persistent Unsatisfactory Performance
4.29 The JWGQA should harmonise the activities of the different NQAAPs by undertaking work to refresh and set consistent standards for EQA schemes and work with UKAS to enhance their application of ISO17043 for accrediting schemes.
Acceptable performance specifications

Definitions and descriptions

Models for EQA APS

‘Milan models’

- Milan model 1
  - 1a) Outcome based evaluation
  - 1b) Clinical decision applications

- Milan model 2
  - Derived from biological variation

- Milan model 3
  - Derived from the ‘state-of-the-art’, i.e. the technically achievable analytical performance
APS: Definitions & Descriptions

- The nature of the EQA material
- The procedure for defining the target value
- The data set to which the APS are applied
- The analytical quality being measured
  - Bias, imprecision, total error
- The rationale for the selection of the APS
  - Passable, satisfactory, favourable, aspirational
UK NEQAS Haematology Performance Scoring

- The Deviation Index

\[ DI = \frac{R - M}{HSD} \]

- Analytical Performance Score
  - Calculated from the DI values of the most recent 6 samples
  - DI truncated to a maximum of 3.5
  - Retrospective, long-term measure of performance
  - Action signal = score equal to or greater than 100
Troubleshooting EQA
Registration and reporting

- Are you registered in the correct instrument group?
- Have you tested the correct specimens?
- Have you reported your results in time?
- Have your results been entered correctly by the scheme (non-web entry)?
- Have you transposed specimens or results?
- Have you reported your results in the correct units?
How many instruments are in your peer group?
What is the composition of your peer group?
Do you cross-calibrate different analyser models?
Were there problems in recent surveys that might still be affecting your score?
Examples of error – ADLC

Draft results – not released!!
Statistical analysis

- How many instruments are in your peer group?
- What is the composition of your peer group?
- Do you cross-calibrate different analyser models?
- Were there problems in recent surveys that might still be affecting your score?
Examples of error – ADLC

- **Error 1**
  - **White Cell Count (x 10^9/L)**
    - Your instrument is Siemens ADVIA 120
    - Your Result: 2.96
    - Target Value: 15.78
    - DI: 22.89
    - Uncertainty of Target Value: 0.31
    - CV: 7.43
    - N: 23
    - N(trimmed): 21
    - Perf Score: 63.68

- **Error 2**
  - **Neutrophils (x 10^9/L)**
    - Your instrument is Siemens ADVIA 120
    - Your Result: 43.90
    - Target Value: 11.45
    - DI: 78.32
    - Uncertainty of Target Value: 0.24
    - CV: 6.08
    - N: 23
    - N(trimmed): 21
    - Perf Score: 57.56

- **Error 2**
  - **Lymphocytes (x 10^9/L)**
    - Your instrument is Siemens ADVIA 120
    - Your Result: 35.40
    - Target Value: 2.40
    - DI: 220.27
    - Uncertainty of Target Value: 0.06
    - CV: 9.17
    - N: 23
    - N(trimmed): 21
    - Perf Score: 51.51

- **Error 2**
  - **Monocytes (x 10^9/L)**
    - Your instrument is Siemens ADVIA 120
    - Your Result: 12.60
    - Target Value: 1.19
    - DI: 148.00
    - Uncertainty of Target Value: 0.02
    - CV: 7.99
    - N: 23
    - N(trimmed): 21
    - Perf Score: 70.96
Registration and reporting

- Are you registered in the correct instrument group?
- Have you tested the correct specimens?
- Have you reported your results in time?
- Have your results been entered correctly by the scheme (non-web entry)
- Have you transposed specimens or results?
- Have you reported your results in the correct units?
Specimen analysis

- Are the specimens in date/in good condition?
- Did you store the specimens correctly after receipt?
- Were the specimens mixed / reconstituted / handled correctly prior to analysis?
- Have you tested the specimens in the correct mode or according to the instructions?
- Should you request repeat specimens to exclude specimen quality issues?
Could there be a real problem?

- Are your IQC results satisfactory (*really*)?
- Is maintenance up-to-date?
- Was there a change (personnel, maintenance, reagents, calibration etc.) made that correlates with the change in performance?
- Have you made a calculation error?
- Could patients’ results be affected?
Examples of error – Hb

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</tbody>
</table>

POCT site

Mixing error: training issue

Maintenance issue: salt build-up on instrument probe
Specimen analysis

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- Should you request repeat specimens to exclude specimen quality issues?
Could there be a real problem?

- Are your IQC results satisfactory (*really*)?
- Is maintenance up-to-date?
- Was there a change (personnel, maintenance, reagents, calibration etc.) made that correlates with the change in performance?
- Have you made a calculation error?
- Could patients’ results be affected?
Error in Hb units -> results 10x too low
62 patients affected
43 incorrectly diagnosed as G6PD deficient
Could there be a real problem?

- Are your IQC results satisfactory (really)?
- Is maintenance up-to-date?
- Was there a change (personnel, maintenance, reagents, calibration etc.) made that correlates with the change in performance?
- Have you made a calculation error?
- Could patients’ results be affected?
Unsatisfactory sample quality

We may withdraw specimens from analysis or scoring on occasion:

- A problem with the survey material batch was detected after distribution (stability, preparation, labelling, contamination)
- A problem for a specific group of participants occurred (technology, method, region)
- Uncertainty of the target value too great
- Lack of consensus in results
- Statistical analysis – CV% too great, changes in numbers of instruments etc.
Summary

- EQA services continue to expand in terms of geography, technology and concepts
- Assessing performance assumes
  - Quality can be defined and quantified
  - Standards reflect the quality of service
- Performance standards must not lead to the lowest common denominator
- Acceptable performance standards allow effective comparison of performance
- Understand errors to investigate out-of-consensus EQA result