Haematology EQA: Current concepts

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Quality Control in Haematology: Report of Interlaboratory Trials in Britain

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Quality Improvement

**Professional**
- Quality management
- Accreditation
- Education & training
- Competency
- Standardisation
- New diagnostic pathways

**Technological**
- ‘Black box’ technology
- New tests/parameters
- Laboratory integration
- Use of IT to monitor quality
- Calibration
- Traceability

**Political**
- Funding
- Demographics
- Service reviews
- Public opinion
- Governance
- Transparency

**Professional**

UK NEQAS
International Quality Expertise
Monitoring Quality

Laboratory accreditation
ISO 15189

EQA
‘Technical’
Interpretive (individual)

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50 years of UK NEQAS Haematology

1970-80
- FBC
- Blood Films
- Abnormal Hbs
- G6PD
- Coagulation
- Blood Transfusion

1980-90
- Retics
- Cytochemistry
- Schilling test
- Red cell mass
- Auto diff count
- Immunophenotyping
- FMH

1990-2000
- 2000-2010
- Newborn
- sickle
- Digital
- morphology

2010-
- Molecular
- Hbopathies
- Plasma
- viscosity
- Malaria RDTs
- ESR
- NRBC
- POCT EQA
- PK assay

18/01/2019 6
New parameters in automated counting EQA

- Mean platelet volume (MPV)
- Red cell distribution width (RDW)
- Immature granulocyte count (Igs)
- Immature platelet fraction
- Functional iron deficiency parameters
- Body fluid counting
New PK scheme proposal: International EQA

- European collaboration: essential because of small numbers of laboratories in each country
- Performance assessment for quantitative assay initially
- Develop to include NGS methods
- Phased development
- Frequency of distribution – decide with labs
- Objectives and purpose:
  - EQA not just PT – strong educational emphasis
  - Performance assessment – Outcome orientated
“Proficiency test items should **match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing or calibration**”

Holy grails:
Homogeneity, stability
Commutability, traceability
Challenge at clinical decision-making points
FBC survey material: the options

- EDTA blood
- CPD/ACD blood
- Partially stabilised whole blood
- Commercial material
Conditions in transit

- Average transit time is 2 to 4 days
- Courier or first class post
- Temperature trackers sent to selected destinations
- Package temperatures may exceed 30 degrees Celsius:
  - Periods of up to 24 hours
  - July – September
  - Middle East, Eastern Mediterranean, Africa
Instrument grouping

- Allows peer performance assessment where there is a lack of commutability, e.g. using stabilised material
- Reflects participants’ and manufacturers’ preferences
- Avoids consensus trimmed mean target favouring the instrument with the largest numbers
11 instrument groups (including miscellaneous)

200+ different models of instruments registered in the past 10 years

Current registrations include 86 different instrument models

Numbers of each model range from 1 to more than 350
Fresh blood material is commutable for almost all instruments for Hb.
HemoCue 301+ and some other POCT analysers have proved the exception.
Approximate 8 g/L difference in Hb.
The same difference in results is seen with stored EDTA samples.
Instruments are designed for capillary blood.
MetHb may be the cause.
UK NEQAS Haematology has developed a new platform for presentation of digital services

EQATE

*External Quality Assessment,*

*Training & Education*
Quality beyond the laboratory

- End to end quality monitoring
- Defining reference intervals
- Standards in POCT
Most errors are not in the analytical phase

The Iceberg of Laboratory Errors

Plebani M et al
Clinical Chemistry and Laboratory Medicine (CCLM). Volume 53, Issue 3, Pages 357–370, ISSN (Online) 1437-4331, ISSN (Print) 1434-6621, DOI: 10.1515/cclm-2014-1051, December 2014
THE QUALITY INDICATORS PARADOX

- Increasing interest of Scientific Societies, International Federations and laboratory professionals
- Availability of a list of harmonized QIs, a specifically developed website, and numerous scientific articles
- Few laboratories are making regular comprehensive data collection

DOI 10.1515/cclm-2015-1080

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International Quality Expertise
Assessment beyond the analytical phase in UK NEQAS Haematology

- Monitoring the laboratory
  - Interpretation of EQA results
  - As part of an analytical scheme, e.g. haemoglobinopathy and morphology schemes

- Monitoring the individual
  - Using stand-alone case studies
  - CPD
  - Demonstration of competence

- Pre and post-analytical monitoring
Where are we at with POCT in haematology?
Briggs (2012), BJHaem 158:679–690

- Use of POCT will increase
- Studies on clinical impact required

- Performance of POCT may be hampered by:
  - Lack of training
  - Poor standardisation in obtaining blood samples
  - Insufficient IQC and EQA
The UK situation 2014

- 30% of laboratories do not monitor pre-analytical indicators routinely
- Only 2 indicators are measured by more than 50% of laboratories
  - Booking in errors
  - Mislabelling
- Approximate 50:50 split in whether specimens are counted by request or by tube
- Wide range of LIMS in use
- Errors are recorded manually (67.5%) and electronically (32.5%)

Cornes M et al
Summary

- Haematology EQA services continue to expand in terms of geography, technology and concepts
- Commutability and traceability of survey materials remain major issues
- Assessing performance assumes
  - Quality can be defined
  - Quality can be quantified
  - Standards reflect the quality of service
Thank you for your attention!