Quality Assessment & Patient Care

3rd Pan-European Conference on Haemoglobinopathies & Rare Anaemias
Limassol, 24 – 26 October 2012

Barbara De la Salle
UK National External Quality Assessment Service
Laboratory Medicine: a key role

- 70% of diagnoses depend upon the results of laboratory investigations
- Laboratory medicine is largely taken for granted
- Laboratories are good at quality
- Laboratory failure happens
How do I know it’s a good service?

“Lab tests? I just want to know what’s wrong with me”

“It takes forever to get a result from the lab!”

“Accreditation? Quality control? Competence? What does that mean?”

“Surely the machines always give the right answer?”
Quality Management

Internal Quality Control:
- Are today’s results the same as yesterday’s?

External Quality Assessment:
- Are my results the same as other laboratories?
Reprinted from the British Medical Journal
1 November 1969, 4, 253–256

Quality Control in Haematology: Report of Interlaboratory Trials in Britain

S. M. Lewis,* M.D., B.Sc., M.C.Path.
B. J. Burgess,† F.I.M.L.T.
Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures

External quality assessment using proficiency testing

International Council for Standardization in Haematology

International Journal of Hematology

1998, 68: 45-52
Drivers for EQA participation

ACCREDITATION:

ISO15189:2007

5.6 Assuring the quality of examination procedures
UK NHS Sickle and Thalassaemia Screening Programme

Programme Standards

The laboratory must participate in an accredited External Quality Assessment Scheme (EQAS), appropriate for antenatal sickle cell and thalassaemia screening, eg. UKNEQAS, and must be able to able to demonstrate satisfactory performance as defined by the criteria specified by the EQA scheme organisers.
What does EQA do?

EQA measures the standard of results produced by each laboratory and its performance relative to others

- Allows inter-laboratory comparison of results
- Provides ‘state of the art’ assessment for laboratory practice, methods, instruments and reagents/kits
- Shares problems and best practice through education

Demonstrates competence to third parties
ENERCA Work Package 2: Quality of Patient Care

- Core list of laboratory tests for RA
- Questionnaire ENQUE-H1
  - On the use of the core laboratory tests by labs
- Questionnaire ENQUE-H2
  - On the availability of EQA for the core laboratory tests among members of EQALM
- Educational EQAS
Core List of Tests

- Rare anaemia groups – ENERCA website
- Rationalised into disorders using same types of diagnostic testing
- Background research
  - Literature search for tests used
  - Abstracts
<table>
<thead>
<tr>
<th>General Laboratory Tests</th>
<th>Hb disorders</th>
<th>Red cell enzyme disorders</th>
<th>RBC membrane disorders</th>
<th>PNH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood film morphology</td>
<td>Hb variant detection</td>
<td>Glucose-6-phosphate dehydrogenase deficiency</td>
<td>Demonstration of red cell membrane proteins by sodium dodecyl sulfate</td>
<td>Bram test (acidified serumysis test)</td>
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</table>

**General Laboratory Tests**

**Blood film morphology**

**Hb disorders**

**Hb variant detection**

**Red cell enzyme disorders**

**Glucose-6-phosphate dehydrogenase deficiency**

**RBC membrane disorders**

**Demonstration of red cell membrane proteins by sodium dodecyl sulfate**

**PNH**

**Haptoglobin (acidified serumysis test)**

**Please list any additional tests here - applicable to rare and congenital anaemia diagnosis**

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**UK NEQAS**
Questionnaire ENQUE-H1: How do laboratories use the tests?

Distributed on-line to laboratories

For each test:
- How frequently it is performed?
- How clinically relevant is it?
- What quality control is used?

Do you participate in EQA?
- If not, would you take part in EQA if available?
Questionnaire ENQUE-H1

- 70 laboratories responded
  - Not all tests commented on
  - All tests commented on at least partially relevant
- No EQA participation in 154 instances
  - 102 (66%) would take part if available
- Top tests wishlist for EQA:
  - Enzyme disorders: PK assay
  - HbO disorders: Inclusion bodies
  - Membrane disorders: EMA binding test
  - General investigations: BM examination
Questionnaire ENQUE-H2:
What EQA is available?

TO EQA PROVIDERS

- Analytes
- Frequency
- Type of survey material
- Number of participants
- Performance monitoring
- EQAS ‘wishlist’
- Potential for collaboration
- Accreditation status
EQAS Available for General Laboratory Tests

- Vitamin B12
- Bilirubin
- CBC
- Serum Fe
- Folate
- Ferritin
- Haptoglobins
- Urinary haemosiderin
- Bone marrow Fe

- LDL
- LDH
- Blood morphology
- Post analytical CBC interpretation
- Reticulocytes
- Transferrin
- TIBC
EQAS Available for Hb Disorders

- Sickle cell solubility
- Hb variant identification
  - Hb A₂ %
  - Hb F %
  - Hb S %
- Hb H bodies
- Newborn sickle screening
- Molecular Haemoglobinopathies (DNA)
What’s not provided?

- Urine ferrioxamine iron
- Serum Transferrin Receptor
- Liver iron
- Myocardial iron
- Zinc protoporphyrin
What’s not provided?

- Unstable haemoglobins
- Heinz bodies
- p50 for altered oxygen affinity
- Globin chain synthesis
What’s not provided?

- Red cell enzyme disorders
  - Glucose 6-phosphate
- RBC membrane disorders
  - Demonstration of red cell membrane
- PNH

EQAS NOT PROVIDED FOR MOST TESTS

.........Except: Hb F by flow, Kleihauer, G6PD, Methaemoglobin, Haemoglobinuria, PNH by flow

UK NEQAS
Barriers to EQAS provision

- Survey material
  - Availability
  - Stability
- Insufficient demand in a single country
- Restriction of services to own country only
  - Funding restrictions
- Cost of transportation
- Customs difficulties
- Local medical practice
- Language
Do you accept participants from outside your own country?

**ALSO** - 11 out of 15 EQAS providers would be prepared to offer new specialist services in collaboration
EQA Wishlist

Available within EQALM
- Hb Variant detection
- Hb A2, Hb F, Hb S
- G6PD
- Kleihauer
- Flow cytometry for Hb F
- Retics
- Red cell folate
- Serum folate
- Cobalamin
- Serum ferritin
- Serum Haptoglobin
- Blood Film Morphology

Not available within EQALM
- Unstable Hbs
- Heinz bodies
- Serum transferrin receptor
- PK activity

QUESTION
Of the tests that you do NOT provide EQAS for, list the 5 that you think would benefit most from EQAS provision?
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Effective EQA: the challenge for RA

- Accredited – e.g. ILAC G13, ISO 17043
- Frequent distributions
- Stable specimens, similar to patients’ samples
- Reliable, valid target values
- Rapid feedback of initial performance information following analysis
- Robust, transparent performance assessment
- Structured, informative and intelligible reports
EQA and the patient
Patients, clinicians, governments expect:

- Right result
- Right patient
- Right interpretation
- Right time

Otherwise, laboratory tests have no benefit, only cost
UK NEQAS Haemoglobinopathy EQA:

- **MOTHER / PARTNER**
  - Antenatal or pre-conception screening for carrier status:
    - Haemoglobinopathy and thalassaemia screening
    - Molecular haemoglobinopathies

- **INFANT**
  - Pre-natal diagnosis
    - Molecular haemoglobinopathies
    - Newborn Sickle Screening

- **AFFECTED FAMILY MEMBERS**
  - Monitoring treatment throughout life
    - Haematology, Chemistry, Blood transfusion, Micro
### State of the Art: Hb A₂ (2010)

<table>
<thead>
<tr>
<th>SPECIMEN</th>
<th>1004AH1</th>
<th>1004AH2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Hb A₂ (%)</td>
<td>4.7</td>
<td>2.3</td>
</tr>
<tr>
<td>Estimated SD</td>
<td>0.37</td>
<td>0.15</td>
</tr>
<tr>
<td>-2SD</td>
<td>3.96</td>
<td>2.00</td>
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<tr>
<td>+2SD</td>
<td>5.44</td>
<td>2.60</td>
</tr>
<tr>
<td>Minimum reported Hb A₂ (%)</td>
<td>3.3</td>
<td>1.6</td>
</tr>
<tr>
<td>Maximum reported Hb A₂ (%)</td>
<td>6.4</td>
<td>2.9</td>
</tr>
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</table>

Bias demonstrated between different instrument types.
Borderline Hb A2 sample: instrument bias
Batterbee (2010); UK NEQAS report, www.ukneqash.org
Hb A₂ Standardisation

- IFCC Working Group on Standardisation of HbA₂ established 2004

- ICSH guideline
Encourage registration of EQA providers as ENERCA expert centres
Links to EQA provider websites
Maintain a catalogue of specialist EQA
Links with EPTIS
Sustainable
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