Barbara De la Salle
Deputy Director and Manager
UK National External Quality Assessment Scheme for General Haematology
www.ukneqash.org
Maintaining Quality: the Challenge of Changing Service Provision

PAST, PRESENT, FUTURE.............
- 1960 – CAP proficiency testing programme
- 1966 – INSTAND (Germany)
- 1960s –
  - Professor Tom Whitehead
  - UK NEQAS Clinical Chemistry
  - Dr Mitchell Lewis
  - UK NEQAS Haematology
Fig. 5—Trial 1. Results of haemoglobin measurements on lysate.
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.
THE NUFFIELD PROVINCIAL HOSPITALS TRUST
PATRON: H.M. QUEEN ELIZABETH THE QUEEN MOTHER

3 PRINCE ALBERT ROAD
LONDON, N.W.1

15th November, 1968

I am glad to tell you that at their meeting yesterday the trustees approved the offer of a grant of £3,000 a year for three years for the study set out in the memorandum sent with your letter to me dated 11th October. I would like to know how the proposed grant should be administered and by which authority, as soon as you can. Our normal process is to pay six monthly instalments in advance.

Kind regards,

Dr. M. Lewis,
Department of Haematology,
Postgraduate Medical School,
Ducane Road,
UK NEQAS now comprises a network of **144 schemes** operating from **24 centres** based at major hospitals, research institutions and universities throughout the UK

30 November, 2012
UK NEQAS Haematology Division

Watford General Hospital
- General Haematology
- Blood Transfusion Laboratory Practice
- Feto-Maternal Haemorrhage

Sheffield Hallamshire Hospital
- Blood Coagulation
- Leucocyte Immunophenotyping

Good Hope Hospital, Birmingham
- Haematinics
UK NEQAS Objectives

- Highlight the need for improvement
- Demonstrate the benefits of best practice
- Provide information on causes of laboratory error
- Provide education and support
- Independent of manufacturers
- Not for profit

To improve participant performance through education
 Improvements in performance

UK Improvement in Haemoglobinometry

With thanks to Dr SM Lewis
General Haematology schemes

- 12 times per annum:
  FBC
  Newborn Sickle Screening

- 8 times per annum:
  Blood Film Morphology

- 6 times per annum:
  ADLC Retics
  G6PD Abnormal Hb

- 4 times per annum:
  Cytochemistry Blood Parasites
  Manual WBC differential

And gone –
  Neutrophil Alkaline Phosphatase
  Vitamin B12 Absorption
  Red Cell Volume?
Annual service provision from UK NEQAS (H)

75,000 specimens

15,000 packages

1000 laboratories

50 countries
New schemes, Pilots and Projects

- Molecular Haemoglobinopathies
- Rapid Malaria Diagnostic Testing
- Blood Component Quality Monitoring Pilot
- New Pilot Schemes 2012
  - Nucleated RBC
  - ESR
- Development Projects
  - BCSH Functional Iron Deficiency Guideline
  - MPV and RDW
  - Survey material stabilisation
  - E-learning
- Secure, individual participation
- Immediate access to annotated slide once results submitted
- Once a survey is closed for submission, participants get access to diagnostic commentary and annotations, even if they did not submit answers
- Cases are analysed by and a final diagnosis is provided to participants
- Recognised for CPD
Post-analytical haematology pilot

NN
Username: NN
E-mail: NN
Type of instrument: SYSMEX

Bergen, 19 December 2010

Case history: A 46-year-old man with no previous chronic illnesses is admitted to the hospital for the first time due to fever and low Total white blood count (WBC=1.9x10^9/L) analyzed by his general physician. Complete Blood Count (CBC) is requested by the hospital emergency department.
Examples of Current Work
Laboratory A

Haemoglobin A2: Your Performance Score is 110.7

Analytical Performance Score

-5  25  55  85  115  145  175

1005 1006 1101 1102 1103 1104 1105 1106 1201 1202

UK NEQAS
Laboratory A – using HPLC analyser incorrectly

<table>
<thead>
<tr>
<th>Haemoglobin A2 (%)</th>
<th>n</th>
<th>Mean</th>
<th>GCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>All methods</td>
<td>279</td>
<td>2.5</td>
<td>6.3</td>
</tr>
<tr>
<td>Capillary Electrophoresis</td>
<td>35</td>
<td>2.5</td>
<td>3.4</td>
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<tr>
<td>Sebia Capillars</td>
<td>29</td>
<td>2.5</td>
<td>3.8</td>
</tr>
<tr>
<td>HPLC</td>
<td>236</td>
<td>2.5</td>
<td>6.4</td>
</tr>
<tr>
<td>BioRad Variant Classic</td>
<td>15</td>
<td>2.5</td>
<td>3.5</td>
</tr>
<tr>
<td>BioRad Variant II; Beta-thal</td>
<td>54</td>
<td>2.6</td>
<td>3.4</td>
</tr>
<tr>
<td>Menarini HA8160</td>
<td>53</td>
<td>2.5</td>
<td>10.3</td>
</tr>
<tr>
<td>TOSOH G7</td>
<td>31</td>
<td>2.5</td>
<td>7.6</td>
</tr>
<tr>
<td>TOSOH G8</td>
<td>17</td>
<td>2.4</td>
<td>6.1</td>
</tr>
<tr>
<td>BioRad Variant II; Dual Kit</td>
<td>22</td>
<td>2.5</td>
<td>4.8</td>
</tr>
<tr>
<td>BioRad D10, Dual Program Kit</td>
<td>28</td>
<td>2.5</td>
<td>5.8</td>
</tr>
</tbody>
</table>

**DI Values:**

1202  0.39/0.49  1104  Non-return  1006  -1.76/-3.89
1201 -0.32/1.29  1103  Nil HbA2   1005  -0.53/0.20
1106 -11.43/1.66 1102  -4.84/-4.66 1004  -0.34/0.02
1105  4.12/3.29  1101  -0.53/0.21 1003  -0.17/0.20

Your registered method is HPLC
Your result:  2.6
Your DI:  0.39
Your Score: 110.7
Reported Range (Overall)
Minimum:  0
Maximum:  3.3
Assessment vs your Ref Range
You reported: Normal
Overall Assessment (%)
Low:  0.4
Normal:  98.9
High:  0.4
Uncertain:  0.4

UK NEQAS
Laboratory B – in need of maintenance

- **White Cell Count**
  - Your analytical performance score is 51.8
  - Performance Score vs. Distribution

- **Red Cell Count**
  - Your analytical performance score is 104.0
  - Performance Score vs. Distribution

- **Haemoglobin**
  - Your analytical performance score is 93.8
  - Performance Score vs. Distribution

- **Packed cell volume**
  - Your analytical performance score is 85.2
  - Performance Score vs. Distribution

UK NEQAS
Laboratory B – post correction

- **White Cell Count**
  - Your analytical performance score is 14.9

- **Red Cell Count**
  - Your analytical performance score is 70.4

- **Haemoglobin**
  - Your analytical performance score is 64.3

- **Packed cell volume**
  - Your analytical performance score is 58.4
Hb A2 Performance – 1980s
Performance at the levels of clinical decision making Hb A₂

Figure 1. 0604AH4: Distribution of UK Hb A₂ Results
Performance at the levels of clinical decision making – Platelet counting

American Journal of Clinical Pathology
ajcp.ascpjournals.org

doi: 10.1309/AJCP86JMBFUCFCX4

The Accuracy of Platelet Counting in Thrombocytopenic Blood Samples Distributed by the UK National External Quality Assessment Scheme for General Haematology

Barbara J. De la Salle, FIBMS 1, Paul N. McTaggart, FIBMS 1, Carol Briggs, FIBMS 1, Paul Harrison, FRCPath 1, Caroline J Doré 2, Ian Longair 2, Samuel J. Machin, FRCPath 1 and Keith Hyde, FRCPath 1
Discrepancies with EQA MCV values was raised by participants:

- **RPU**
- **Cellpack® (pre-diluted reagent)**

Discussed at SAG and with Sysmex.

Sysmex has implemented a solution.

A water calibration procedure is now being rolled out to all users.
Hb in Acute Hospital POCT Settings

2011: UK NEQAS (H) survey on the performance of Hb

- Blood Gas Analysers
- HemoCue Analysers
- Automated Haematology Analysers
- ICSH Reference Hb Method
Drivers for change in pathology

- Finance
  - Costs ↓

- Technology
  - Automation ↑
  - Skill ↓

- Legislation
  - EU WTD
  - Quality ↑

- Workforce
  - Age
  - Skill mix
  - Recruitment
  - Training
UK Reviews of Pathology

- **Recognised**
  - NHS Pathology as good value
  - Quality systems/clinical skills

- **Noted**
  - Excess in capacity
  - Duplication of services
  - Excessive volume of requests
  - Variable costs
Reconfiguring pathology

- Integrated Blood Sciences
- Networked laboratories
- Hub and spoke provision
- Separation of acute and community services
- Point of care testing
- Public and private pathology providers
- Commissioning on quality
- Pre/Post Analytical Phase – responsibility for end to end service
POCT – challenges for quality

- Diversity of service provision
  - Hospital, Community, Home
- Training and Competency
  - Non-laboratory personnel
- Oversight
  - Accreditation
  - Professional accountability
  - Responsibility for corrective actions
Potential for failure

- Financial pressures
- Inadequate training
- Inadequate supervision
- Inadequate/no SOPs
- Incorrect use of equipment and reagents
- High workload
Quality vs Cost?

- Educated and trained staff
  - Appropriate skills at all levels
  - Demonstration of competency
- Quality management systems
  - Process and outcome
  - End to end service – pre & post analytical phases
- Test selection
  - Evidence based
- Scientific accuracy
  - EQA
UK Pathology taken for granted
3rd World Pathology not missed
Pathology operates in a “black box”
Pathology poorly understood
Potential to be ignored or degraded

*From Dr Archie Prentice, President RCPath, 12 October 2012*
Demonstrating Quality in Pathology

- **COLLECTIVE – Quality Systems**
  - Accreditation
  - EQA
  - Guidelines (compliance)
  - Harmonisation – units, reference intervals
  - Mandatory?

- **INDIVIDUAL**
  - Examination Qualifications Registration
  - Training
  - CPD, Appraisal
  - Competency
  - EQA
  - Revalidation?
UK NEQAS: Future Challenges

- Meeting the needs of ‘new’ participants
  - Reports, delivery, specimens
- Collective and personal EQA
  - E–learning
  - Individual competency
- New technology
  - Molecular diagnosis
  - Non–invasive technology
  - New parameters (e.g. Immature cell types)
  - ‘Lab on a chip’
UK NEQAS: Future Challenges

- Remaining fit for purpose
  - ISO 17043 accreditation
  - Refining scoring systems
- Maintaining professional oversight of all providers
- Anonymity
  - Disclosure of EQA performance
- Harmonisation – reflecting laboratory practice