Mind the (EQA) Gap

Barbara De la Salle
Director, UK NEQAS Haematology
UK NEQAS Haematology developments

(with apologies to Ian Mellors)
Finding the gaps

- UKAS assessors
  - ISO15189 (Laboratories)
  - ISO17043 (Scheme)
- Oversight bodies (NQAAP)
- Strategic initiatives (e.g. PQAR)

- Steering committee and SAG members
- Participants
## Automated counting provision

### Participation December 2015 (#labs)

<table>
<thead>
<tr>
<th>Scheme</th>
<th>UK</th>
<th>Non-UK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBC</td>
<td>691</td>
<td>366</td>
<td>1057</td>
</tr>
<tr>
<td>ADLC</td>
<td>647</td>
<td>280</td>
<td>927</td>
</tr>
<tr>
<td>Retics</td>
<td>281</td>
<td>168</td>
<td>449</td>
</tr>
<tr>
<td>Hb only</td>
<td>110</td>
<td>24</td>
<td>134</td>
</tr>
<tr>
<td>ESR</td>
<td>229</td>
<td>26</td>
<td>255</td>
</tr>
<tr>
<td>Plasma viscosity</td>
<td>49</td>
<td>5</td>
<td>54</td>
</tr>
</tbody>
</table>
## Automated counting provision
### Participation December 2015 (#labs)

<table>
<thead>
<tr>
<th>Scheme</th>
<th>UK</th>
<th>Non-UK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBC</td>
<td>691</td>
<td>366</td>
<td>1057</td>
</tr>
<tr>
<td>ADLC</td>
<td>647</td>
<td>280</td>
<td>927</td>
</tr>
<tr>
<td>Retics</td>
<td>281</td>
<td>168</td>
<td>449</td>
</tr>
<tr>
<td>Hb only</td>
<td>110</td>
<td>24</td>
<td>134</td>
</tr>
<tr>
<td>ESR</td>
<td>229</td>
<td>26</td>
<td>255</td>
</tr>
<tr>
<td>Plasma viscosity</td>
<td>49</td>
<td>5</td>
<td>54</td>
</tr>
</tbody>
</table>
## Special Haematology provision

Participation December 2015 (# labs)

<table>
<thead>
<tr>
<th>Scheme</th>
<th>UK</th>
<th>Non-UK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal Hbs (Full)</td>
<td>147</td>
<td>170</td>
<td>317</td>
</tr>
<tr>
<td>Sickle screen only</td>
<td>128</td>
<td>29</td>
<td>157</td>
</tr>
<tr>
<td>Newborn screening (DBS)</td>
<td>22</td>
<td>6</td>
<td>28</td>
</tr>
<tr>
<td>Liquid newborn</td>
<td>30</td>
<td>6</td>
<td>36</td>
</tr>
<tr>
<td>DNA Hbopathies</td>
<td>10</td>
<td>38</td>
<td>48</td>
</tr>
<tr>
<td>G6PD</td>
<td>136</td>
<td>100</td>
<td>236</td>
</tr>
</tbody>
</table>
### Special Haematology provision

#### Participation December 2015 (# labs)

<table>
<thead>
<tr>
<th>Scheme</th>
<th>UK</th>
<th>Non-UK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal Hbs (Full)</td>
<td>147</td>
<td>170</td>
<td>317</td>
</tr>
<tr>
<td>Sickle screen only</td>
<td>128</td>
<td>29</td>
<td>157</td>
</tr>
<tr>
<td>Newborn screening (DBS)</td>
<td>22</td>
<td>6</td>
<td>28</td>
</tr>
<tr>
<td>Liquid newborn</td>
<td>30</td>
<td>6</td>
<td>36</td>
</tr>
<tr>
<td>DNA Hbopathies</td>
<td>10</td>
<td>38</td>
<td>48</td>
</tr>
<tr>
<td>G6PD</td>
<td>136</td>
<td>100</td>
<td>236</td>
</tr>
</tbody>
</table>
### Morphology provision
Participation December 2015 (# labs)

<table>
<thead>
<tr>
<th>Scheme</th>
<th>UK</th>
<th>Non-UK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphology/Parasites</td>
<td>336</td>
<td>192</td>
<td>528</td>
</tr>
<tr>
<td>Haemosiderin</td>
<td>150</td>
<td>21</td>
<td>171</td>
</tr>
<tr>
<td>SBB/MPO</td>
<td>23</td>
<td>11</td>
<td>34</td>
</tr>
<tr>
<td>Malaria RDT</td>
<td>251</td>
<td>48</td>
<td>299</td>
</tr>
</tbody>
</table>
## Morphology provision
**Participation December 2015 (# labs)**

<table>
<thead>
<tr>
<th>Scheme</th>
<th>UK</th>
<th>Non-UK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphology/Parasites</td>
<td>336</td>
<td>192</td>
<td>528</td>
</tr>
<tr>
<td>Haemosiderin</td>
<td>150</td>
<td>21</td>
<td>171</td>
</tr>
<tr>
<td>SBB/MPO</td>
<td>23</td>
<td>11</td>
<td>34</td>
</tr>
<tr>
<td>Malaria RDT</td>
<td>251</td>
<td>48</td>
<td>299</td>
</tr>
</tbody>
</table>
Plus another 3000 individual registrants in Digital Morphology for CPD programme (2015)

30%↑ since 2013
## Total participations

<table>
<thead>
<tr>
<th></th>
<th>UK</th>
<th>Non-UK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total participations</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dec 2015</td>
<td>3381</td>
<td>1518</td>
<td>4899</td>
</tr>
<tr>
<td>Dec 2014</td>
<td>3301</td>
<td>1465</td>
<td>4766</td>
</tr>
<tr>
<td>Dec 2013</td>
<td>3168</td>
<td>1482</td>
<td>4650</td>
</tr>
</tbody>
</table>
ESR scheme

- Full scheme from April 2016, submitted for ISO17043 accreditation August 2016
- On-line operation
- 4 distributions / year
- 2 modules:
  - ES – all methods except Alifax (2 specimens/survey)
  - ESX – Alifax methods (3 specimens/survey)
- Able to register as many instruments as required from 2017
- 350 labs registered (October 2016) – note the jump from December 2015
SAG Proposals for Development

Automated counting
- nRBC pilot scheme – currently a pilot
- RDW (MPV)
- Optical platelet counts
- Monocyte counts in ADLC
- Reticulocyte Haemoglobin
- Automated body fluid counting
- Glandular Fever screening
“Laboratory Diagnosis of Anaemia” questionnaire

- In collaboration with NHSBT – the ‘anaemia’ part will be distributed more widely and reported separately

- Questionnaire also included a section on new developments in automated counting EQA
Questionnaire 2016 feedback

- 220 responses
- Rank proposed developments by priority

<table>
<thead>
<tr>
<th></th>
<th>HIGH</th>
<th>MEDIUM</th>
<th>LOW</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>BodyFluid</td>
<td>16%</td>
<td>11%</td>
<td>14%</td>
<td>59%</td>
</tr>
<tr>
<td>GF Sc</td>
<td>43%</td>
<td>8%</td>
<td>8%</td>
<td>41%</td>
</tr>
<tr>
<td>IG</td>
<td>15%</td>
<td>25%</td>
<td>5%</td>
<td>55%</td>
</tr>
<tr>
<td>MPV</td>
<td>10%</td>
<td>30%</td>
<td>5%</td>
<td>54%</td>
</tr>
<tr>
<td>RDW</td>
<td>29%</td>
<td>24%</td>
<td>3%</td>
<td>45%</td>
</tr>
<tr>
<td>Ret Hb</td>
<td>13%</td>
<td>26%</td>
<td>6%</td>
<td>55%</td>
</tr>
<tr>
<td>ZPP</td>
<td>4%</td>
<td>5%</td>
<td>20%</td>
<td>70%</td>
</tr>
</tbody>
</table>
Also asked to identify reportable parameters

[Bar chart showing development priorities with categories such as RDW, GFSC, MPV, BodyFluid, RetHb, IGG, ZPP, and their respective proportions for clinical application report and priority high.]
Other work

- Performance assessment in development
  - Blood Film Morphology
  - Interpretive comments in haemoglobinopathies
  - Liquid newborn haemoglobinopathy screening
  - Malaria RDTs

- Corrective & Preventative Action forms

- EQA for specialist testing
  - Pyruvate kinase activity

SAG proposal
Most errors are not in the analytical phase

The Iceberg of Laboratory Errors

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
It’s not just about the Quality of the test

A UK NEQAS Pre & Post Analytical Quality Monitoring Service
Minding the gaps

- Expectations
- Limitations
Con founding factors – understanding the limitations

- Survey material
  - Availability
  - Commutability
  - Stability

- Statistical robustness
  - Sufficient participant numbers

- Instrument grouping
  - Re–badged instruments
  - Different software versions

- ‘Special’ attention to EQA samples
UK NEQAS (H) Participants
EDTA blood (clinical material)

- Clinically relevant
- Commutable
- Affordable

- Impractical
- Unsustainable
- Insufficient volume
- Very limited stability

Local interlaboratory specimen exchange networks

UK NEQAS
International Quality Expertise
Extended life material

- Sufficient volume
- Sustainable
- Reasonably affordable
- Practical, adaptable
- Clinically relevant if manipulated
- Reasonably stable

- Limited commutability
- Requires skill
- Stability may limit distribution range and methods
- Clinical relevance requires access to a range of blood products

Major national and international EQA providers, e.g. UK NEQAS, Spain
EQA providers in resource poor regions
UK NEQAS Extended Life Material: Stability in transit
UK NEQAS Extended Life Material: Commutability

- Same material used across all instrument groups
- Hb comparable across all groups
- MCV – affected by stabilisation
- WBC
  - Affected by stabilisation
  - Not suitable for differential WBC
- Platelet count
  - Affected by stabilisation
  - Suitable for impedance and immunological methods
Commutability: Hb

Reference Standard and Method Available
Commutability: MCV

Mean Cell Volume
Your analytical performance score is 97.3

Mean Cell Volume (fl)
Your instrument is Sysmex SF3000
Your Result: 97.1
Target Value: 90.43
DI: 2.85
CV: 2.53
N: 28
N(trimmed): 26
Perf Score: 97.3

Mean Cell Volume (fl)
Your instrument is Sysmex XT1800i
Your Result: 97.1
Target Value: 97.51
DI: -0.23
CV: 1.91
N: 105
N(trimmed): 95
Perf Score: 11.5

UK NEQAS
International Quality Expertise
ISO Accreditation

- EQA participation for every analyte, where available
  - ISO15189
  - Alternative procedures if no EQA available

- Every method to be registered?
  - Conflict with scheme design

- Every member of staff responsible for reporting?
  - EQA as competency assessment, e.g. individual consultant registration in Blood Films
Steering Committee / SAG members

- Advise & Guide
  - Design/Fit for purpose /Relevancy /Scope
    - Format/Performance Scoring
    - Initiatives
    - Trends-Analytical and groups

- Where Poor performance indicates scheme operational failure
- Mechanics of operation
- Horizon scanning

UK NEQAS
International Quality Expertise
Summary

- UK NEQAS Haematology continues to develop and diversify to support participants’ needs

- ISO accreditation has proved a stimulus and a challenge to UK NEQAS Haematology as well as laboratories

- We couldn’t do it without your input!