IFCC General Conference 2018
Laboratory medicine: Preparing for the 2020's
10th – 11th November 2018
Hotel Novotel Budapest City, Hungary

Advancing excellence in laboratory medicine for better healthcare worldwide

Egon Amann, DQCML
Developing sustainable EQA in resource-poor environments

The Quality Ladder

ISO 15189
Quality Management System
Accreditation Scheme
International Liaison
Local Liaison
External Quality Assurance
Internal Quality Control

Independently assessed to international/national standards
Ties together laboratory quality
Identifies the route to accreditation
Informs the international context
Establishes a local peer group
Improves the accuracy of results
Reduces method imprecision

Source: Mike Thomas
The **quintessential**

- To train Medical Laboratory Professionals on quality process and practice.

- Help the society plan and strategize on how to execute an EQA pilot project.
New Developments

• Current workshop scheme was developed by S. Yenice and E. Amann and initially tested at IFCC’s GM in Madrid 2016.
• Important: High degree of participant’s involvement (groups are formed working on self-chosen quality-related topics).
• Only moderate guidance given by the moderators.
• Groups present their finding which serves to define conclusions and potential programs.
• IFCC Certificates of participation are usually issued as desired.

A typical workshop program includes:

• Lectures on IQC & EQA and on accreditation experiences.
• Impulse lecture “Compliance with Quality Systems”.
• Groups are formed.
• Group discussions on the topic.
• Group presentations.
• Concluding activity: Evaluating, deciding and listing actions.
• Interactive workshop with participants & moderators.
• Developing the road map to a pilot EQA project.
Workshop topics are modified according to society-specific needs:

- “IQC building blocks of quality control”
- “Standardization of laboratory tests – Why it is needed and how to do it?”
- “How to organize a National EQA”
- “Delivering effective EQA”
- “Moving along the road to accreditation”
- “Good laboratory practice and patient safety”
- “Traceability & Uncertainty & Metrology”
Egon Amann, DQCML  
*Developing sustainable EQA in resource-poor environments*

Nepal, May 2018

Requester:  > Nepal Association of Medical Laboratory Scientists (NAMLS)  
> Nepal Association for Clinical Chemistry (NACC)

Type of Support:  > Two day workshop with 160 participants in Kathmandu; visits of 7 hospitals

Lecturers:  > E. Amann, R. Bais, A. Thomas

EQA program:  > started in October; 20 labs participate initially with 20 sets of Clinical Chemistry and 10 sets of HbA1c supplied by the RCPAQAP Pty Ltd.

Lengths:  > two years

Coordinators:  > R. Bais (AU); Binod Kumar Yadav (NP)
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Nepal 2018
Malawi, Feb. 2018

Requester: > Malawi Association of Medical Laboratory Scientists (MAMLS)

Type of Support: > Two one day workshop with 54 participants in Blantyre & Lilongwe; visits of 5 hospitals

Lecturers: > E. Amann, G. Beastall, A. Thomas

EQA program: > Pending. G. Beastall in contact with the Scottish Government to financially support an EQA program; Randox (?)

Lengths: > open

Coordinators: > G. Beastall (GB), Wakisa Kipandula (MW)
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Malawi 2018
Requester: > Association of Clinical Chemistry of Nigeria (ACCN)
Type of Support: > Lectures & Workshop at the 7th Biennial ACCN Scientific Conference
Lecturers: > E. Amann, G. Beastall, C. Sturgeon, A. Thomas; M. Ferrari
EQA program: > Pending. A request for further DQCML support as the National Member moves forward with its plans to improve the quality of laboratory services in Nigeria is expected.
Lengths: > Open
Coordinators: > G. Beastall (UK), A. Okesina (NG), M. Charles-Davies (NG)

Zambia, 2015
Requester: > Biomedical Society of Zambia (BSZ)
Type of Support: > Provision of EQA materials by Randox (1st phase) and the Australian Quality Assurance Program (2nd phase) with financial support from IFCC
Initiators: > J. Hicks, V. Steenkamp, H. Lumano, (besides others)
EQA program: > 1st phase in 2015 involving 12 labs
> 2nd phase in 2016 involving 26 labs
Lengths: > ongoing
Coordinators: > R. Bais (AU), H. Lumano (ZM), Mrs. Lucky Kalyapu (ZM)
The analytes included in the Zambia program are:

<table>
<thead>
<tr>
<th>Sodium</th>
<th>Bilirubin - Conjugated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium</td>
<td>Urea</td>
</tr>
<tr>
<td>Glucose</td>
<td>Urate</td>
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<tr>
<td>Creatinine</td>
<td>Total Protein</td>
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<tr>
<td>ALT</td>
<td>Albumin</td>
</tr>
<tr>
<td>AST</td>
<td>Cholesterol</td>
</tr>
<tr>
<td>Bilirubin - Total</td>
<td>Triglycerides</td>
</tr>
</tbody>
</table>

Source: Renze Bais
General Findings for Zambia January to July, 2016 (I)

- Laboratories have submitted results 163 out of a possible 170 times (94%). The reasons for not returning results were instrument down (3), EQA sample delivery issues (1) and no explanation (3).

- Very few times have laboratories been able to return a complete set of results for the tests they perform, the main reason being the lack of reagents. From this program it is clear, supply of reagents continues to be the biggest issue facing laboratories.

- On average, laboratories are returning only 50% of their results with the main reason given as being out of particular reagents.

Source: Renze Bais
General Findings for Zambia January to July, 2016 (II)

• Four laboratories have enrolled two different analyzers from the start of the program but have not returned results for the newer upgrade as it has not been made functional.

• Some laboratories are notorious for submitting results after the cut-off date. We have allowed this as this is an introductory program but in a fully-fledged EQA program this would not be permitted.

• Four different laboratories have, on one occasion, prepared the material incorrectly by adding all the diluent instead of the correct amount of 5 ml. This has been easy to see on submission and we have asked that they try to get material from a nearby laboratory and re-assay. Again, not normally allowed in EQA program but we have made the exception in this one.

Source: Renze Bais

Reports for Zambia (I)

• Laboratories received two types of reports on a monthly basis.

• One compared their results with the other Zambian laboratories in the survey.

• The other compared their results with those from the World-wide results for the material.

• In the World-wide survey there are at least 500 laboratories for each analyte.

• There was no separate analysis for specific instruments or reagents as there would be insufficient results for each group from the current laboratories we have in the survey in Zambia.

Source: Renze Bais
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Reports for Zambia (II)

• As expected the statistics for the Zambian laboratories are generally but no always, less precise than for the World-wide result simply due to the smaller number of points in the data.

• If there are discrepancies, laboratories should compare their results with the World-wide results.

• Zambian laboratories perform reasonably well but we intend to carry out a more detailed analysis of their results.

Source: Renze Bais

Some learnings (I):

• The project has more chance of success if it has support from a local authority such as the Department of Health.

• There needs to be a local “Champion or a number of Champions”. These people are vital as they know the local regulations, are familiar with the local environment and culture and would be responsible for the local logistics.

• An initial survey should be sent to laboratories asking various questions related to their practices and procedures. The questions are specifically designed to establish baseline data on practices and procedures rather than to assess performance.

Source: Renze Bais
Some learnings (II):

• The way the actual survey is run depends on the level of understanding and involvement in QA.

• By being the major organizer of the QA scheme, the IFCC would make a significant and lasting contribution to healthcare in the selected country. Furthermore, a successful project would enable the IFCC to use its World-wide standing in the laboratory community to encourage laboratories in other developing countries to participate in QA schemes and use this activity to drive their laboratory improvement.

• Any program should be designed so that it is eventually run locally.

Source: Renze Bais