



IFCC Developing Quality Competence in Medical Laboratories (DQCML)

Visit to Malawi: February 26 – March 1, 2018

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1. Introduction:

- The Malawi Association of Medical Laboratory Scientists (MAMLS) became a Full Member of IFCC during 2015. Shortly after joining IFCC, MAMLS expressed a wish for support from IFCC to help develop the quality of laboratory medicine in Malawi. Following discussions an application was submitted to DQCML to fund a scoping visit by IFCC representatives to assess how best IFCC may assist MAMLS. Particular mention was made in the application of possible support for a pilot external quality assessment (EQA) scheme similar to that supported by IFCC in neighbouring Zambia. This scoping visit took place on January 18 and 19, 2016. The IFCC visiting team comprised Graham Beastall (Past President) and Hilary Lumano (National lead for the pilot EQA Scheme in Zambia).
- A report on this scoping visit was issued by Graham Beastall. Reference to this report is made herewith. The findings and conclusions of the scoping visit report serves as input to the current visit and this report.
- On 10th November 2017, after additional discussions at the occasion of the IFCC WORLTLAB Conference in Durban in October 2017 with concerned people, the request for an IFCC DQCML workshop was received. Two major topics were listed in this application:
 - I. To train Medical laboratory professionals on quality process and practice.
 - II. Help the society plan and strategize on how to execute an EQA pilot project in Malawi.
- This request was discussed at and approved by the EMD EB. The detailed planning phase started: The visiting team comprised Egon Amann (Chair DQCML), Graham Beastall (Past President), and Annette Thomas (Chair C-AQ). Visiting days were fixed with the MAMLS (February 26-28, 2018).

- It was decided to conduct two workshops of identical content, the first on Monday, February 26, at the University of Malawi, College of Medicine in Blantyre, and the second on Wednesday, February 28, at the College of Medicine in Lilongwe.
- On Tuesday, February 27, on the way from Blantyre to Lilongwe by car, five public sector clinical laboratories under the auspices of the Malawi Ministry of Health were visited in order to get a first-hand impression of local standards and processes.

This document is a report of that visit jointly prepared for DQCML by Egon Amann, Annette Thomas, and Graham Beastall.

2. Programme for Visit:

The programme for the visit was discussed in advance with the three members of MAMLS who would host the visit:

- Victor GL Makwinja Interim President, vgmakwinja@gmail.com
- Elias Chipofya, National Representative, eliaschipofya@gmail.com
- Humphries Malata, Training and Education Technical Advisor to MAMLS council, hmalata@medcol.mw
- Wakisa Kipandula, MAMLS project coordinator, wkipandula@medcol.mw

Humphries Malata is Deputy the Head of Medical Laboratory Sciences at the University of Malawi, College of Medicine was involved in the preparation of the visit and accompanied the IFCC visitors during the entire three days of the visit. He was instrumental in arranging the five laboratory visits on February 27 (see below).

3. Day 1: EQA and QC Workshop in Blantyre (February 26, 2018):

Day one was devoted for presentations and workshops, divided into three Sessions (see Appendix 1 for the programme and participation list). It is worthy of note that the programme included a presentation from Ronald Khunga who completed an IFCC-funded PMEP at the EQA scheme run by neighbouring Zimbabwe (ZINQAP).

For the interactive workshop “*What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory*” 38 participants were divided into four groups.

The following is a summary of most burning issues presented by the four groups:

Group 1	Group 2	Group 3	Group 4
Quality monitoring inadequate	Insufficient inventory management	Internal quality control not always correctly applied	Knowledge gap from policy makers to labs workers
Too intensive Governmental control of labs	Documentation and document control	EQA materials supply logistics inadequate	Insufficient supply of reagents and QC
Missing freedom to act	Equipment maintenance not done properly	Trained staff have high workload and must do everything	Too ambitious government body plans – reality miss

Even National Labs not being accredited	EQA National labs: not trustworthy	No CAPA system in place	No real interest and push for EQA from government
Insufficient training of personnel		Missing instrument maintenance & servicing	Bad commitment from lab staff / no reward system

Figure 1: Participants at the College of Medicine, Blantyre, 26 February 2018



4. Day 2: Travel by car from Blantyre to Lilongwe (February 27, 2018):

The IFCC visitors were picked up by their hosts in the morning. A bus from the College of Medicine with a driver served as the vehicle. We were accompanied by eight (!) hosts on this “Laboratory visit tour”. Pre-announced (brief) visits of five different District Hospital Laboratories took place during the drive from Blantyre to Lilongwe, covering the whole day. These visits were very “telling” and confirmed many of the afore-mentioned expressed issue during the workshop in Blantyre. The following public, District Hospital Laboratories were visited:

- Zomba
- Machinga
- Balaka
- Ntcheu
- Dedza

We were welcomed in all laboratories and shown around. Questions were openly answered. Instead of describing the impressions of each laboratory separately, the common themes and situations are summarized as follows:

- Laboratories are very small in size, variety and number of assays and endowment.
- Personnel number is small and varies between 5-8 staff.
- Laboratories primarily serve the hospitals in-patients, and also (in smaller percentage) out-patients.
- Phlebotomy areas were very small and not always in good shape and hygienic standards.
- Only one lab (Zomba) had a barcode system in place.
- No laboratory displayed a fully developed LIMS system.
- Some labs used a four-digit system to assign and identify patients' samples.
- Most labs just used the patient's name as ID.
- All labs used uniform Ministry of Health forms to capture test results.
- Out-patients are asked to carry the test result form to their doctors.
- Out-patients from Mozambique are accepted in border-close cities.
- Instrument maintenance and servicing is poor: we saw often signs reading "Out of order since..."
- Blood-group matching (in transfusion medicine) could often not be done, because fridges and freezers were not in operation.
- The labs experience often power outages. Few have generators, and in case they have, Diesel may not be available.
- Some Labs have large battery packs, which allow to bridge power outages for concerned instruments of approximately four hours.
- Tests of major public health importance are: Malaria, HIV, and TB. The three major test (some of which are POC tests / Test strips) are sponsored by international organisations, like US Aid, the Bill Gates foundation, the CDC, amongst others. For those tests, some labs employ EQA schemes.
- Only one Lab performed blood glucose tests (by POCT).
- No blood sugar tests are performed.
- No glomerular filtration rates are measured.
- Labs complained about budget restrictions and lack of governmental and public health support.
- Often QC/EQA could not be done since QC materials did not arrive on time.

Figure 2: Visit to Zomba District Hospital Laboratory



Figure 3: Visit to Machinga City Hospital Laboratory



Figure 4: Visit to Balaka District Hospital Laboratory



Figure 5: Visit to Ntcheu District Hospital Laboratory



Figure 6: Visit to Dedza District Hospital Laboratory



5. Day 3: EQA and QC Workshop in Lilongwe (February 28, 2018)

On day 3, the presentations and workshop from day 1 in Blantyre was repeated for a new audience at the Kamazu College of Nursing, part of the Medical Department, in Lilongwe (see Appendix 2 for the programme and participation list).

For the interactive workshop “*What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory*” 16 participants were divided into three groups.

The following is a summary of most burning issues presented by the four groups:

Group 1	Group 2	Group 3
EQA is expensive.	Lack of commitment of staff. No sharing of QMS.	Some facilities not enrolled in EQA or SLIPTA.
It takes 3 to 4 months to get the reports.	Instrument service contracts not available. Engineer takes time to respond.	QC not consistently provided. Expiry date a problem.
Power outages! Can't store reagents; can't do tests!	QC and tests not available in EQA so don't know our performance.	Stock out is an issue.
Reagents aren't available. Therefore:	Frequently reagent stock unavailable.	Reagents from suppliers not good

IQC with short shelf live. Expiry next week.	Lab dept. not being recognized by Hospital Management.	SOPs not followed esp. outside lab.
	Poor lab infrastructure.	Attitude of staff.

6. Summary of possible solutions for identified issues for both workshops (Blantyre and Lilongwe)

Power outage

- Some but not all hospitals have back up power.
- Laboratories are not considered as important main priority is theatres.
- Outage can be up to 48 hours.
- Some solar panels have been installed but expensive to install, but long term gain.
- Existing backup Generator may not have any diesel (coming directly from Government).
- Private labs have backup generators and are generally better equipped than the public sector.
- Need to highlight to Management – laboratories role not recognised.
- Need to improve lab profile with management and central government.
- Do hospital management ask labs for their risk analysis? No.
- The tool of risk management / FMEA should be applied.
- There seems to be a lack of risk analysis / management / FMEA at the educational level. This needs to be taken up into curriculum at teaching schools, but also as part of continuous education at work place. Graham Beastall agreed to provide a simple example.

Reagents issues

- QC issues – use patient samples as back up short term!
- Central supplies (Central medical stores) seems to be a big issue.
- It is now electronic but not all are using this.
- Central stores supply everything, lab reagents are just a small component.
- Who is in charge of central stores?
- There is now a lab representative however this is a new post, based in HQ in Lilongwe.
- Ordering route can be quite convoluted also currently pharmacist may be reprioritising.
- Labs order the reagents late so there is also an issue with this (?).
- Is there a procedure for ordering from central stores – lead time etc.?
- This is available. Orders placed 5th of each month.
- Forecasting needs to be improved.
- Shortfall of funds even when orders are placed.

Attitude and lack of commitment of staff

- Individual facility needs to look at workload and what staff is needed.
- Needs to be determined by lab manager rather than Ministry of Health.
- Workload planning is not easy.
- Trained staff in SLIPTA are moved to another laboratory which causes frustration.
- Facility should own the programme rather than individuals.

- Training should also include training of others.
- “Quality” is responsibility of everyone – management needs to lead in this.
- Include Quality in basic training.
- CPD is available but it not as organised as it could be.
- Professional bodies will take a lead on this.
- Training institutes now include SLIPTA as part of the curriculum.
- Can be done within the laboratory, keep up to date.

7. Visit to a Private Lab: Partners in Hope Medical Center Laboratory in Lilongwe on March 1, 2018

At the Lilongwe workshop, the IFCC staff received an invitation for visiting a private lab at the “Partners in Hope Medical Center” in Lilongwe in the morning of departure day. This was gladly accepted, since this was in contrast to the previous visits of the labs in the public sector.

This Lab showed remarkable differences to the previous labs, some of them are listed below:

- Much higher variety of test performed, e.g., in haematology, tumour markers (including CA 19.9, CA 125, CEA, PSA), serology, diabetes (e.g., HbA1c), tropical diseases.
- Higher test volumes (also for out-patient samples at a low percentage)
- More space (although still storage space is lacking – packages of reagents everywhere).
- Better décor and laboratory furniture.
- More and better equipment.
- Skilled, better trained staff.
- Obviously, better attitude of staff (based on better pay?).
- Up-to-date Roche and Abbot PCR instrumentation for HIV viral load testing (being sponsored by US aid, other philanthropic societies).
- Issues remain: Documentation, SOP and document control still inadequate.
- Accreditation still pending.

Figure 7: Visit to Partners in Hope Medical Center Laboratory in Lilongwe (Private Laboratory)



8. Visit Summary

This visit of IFCC officers by request of MAMLS was extremely useful. MAMLS expressed their thanks and explained that the two workshops have raised their attention towards improved IQC and, even more importantly, towards implementing EQA schemes for all tests being performed in Malawi. So far, EQA is done by the National EQA institute only for Malaria, HIV and TB. MAMLS should intensify their activities to the Ministry of Health towards country-wide, general EQA schemes. In brief, such activities should include, but are not limited to the following strategic plan:

- Develop an EQA establishment work place.
- Establish an EQA technical Working Group.
- Inform (and involve where necessary and appropriate) all labs and MAMLS members accordingly.
- Raise attention to the EQA schemes by workshops or seminars.
- MAMLS must influence the education curriculum by highlighting the meaning of IQC and EQA.
- MAMLS should influence the education curriculum by raising attention to risk management tool, e.g. FMEA.
- MAMLS should develop programs to enable labs to “move up the Quality ladder” by applying SLIPTA, SLMTA schemes.
- The final goal must be to achieve accreditation according to ISO 15189.

The IFCC visitors would like to express their thanks to MAMLS (in particular, Humphries Malata, Elias Chipofya, Wakisa Kipandula, and Ronald Khunga) for this invitation to come to Malawi. We wish you all the best in working towards (and reaching) these ambitious goals in the medium term.

Signed:

Egon Amann
Annette Thomas
Graham Beastall

March 26, 2018