



IFCC Developing Quality Competence in Medical Laboratories (DQCML)

Visit to Nepal: May 28 – 30, 2018

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1. Introduction:

- The Nepal Association of Medical Laboratory Scientists (NAMLS) has been a Full Member of IFCC since 2010 and actively involved in IFCC conferences and meetings. NAMLS's current president is Mr. Binod Kumar Yadav. NAMLS expressed a wish for support from IFCC to help develop the quality of laboratory medicine in Nepal.
- Following discussions with NAMLS, the "*1st application*" (see below for explanation) was submitted to DQCML to fund a workshop 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 Vietnam and Zambia. Both EQA schemes were organized and implemented by Dr. Renze Bais, previous secretary of the IFCC, with special help (e.g., material supply) by Dr. Tony Badrick, CEO of the Royal College of Pathologists of Australasia (RCPA).
- The Nepal Association for Clinical Chemistry (NACC) was established in 2014 and became an Affiliate IFCC member in 2015. NACC's current president is Prof. Bharat Jha and current general secretary is Mr. Ram Vinod Mahato. DQCML suggested to jointly apply (NAMLS *and* NACC) for the workshop in order to optimize its use and to reach a maximal number of clinical chemists in Nepal.
- Complying with this suggestion, a joint DQCML project application (the "*2nd application*"), signed by both Mr. Binod Kumar Yadav and Mr. Ram Vinod Mahato, was issued to IFCC on December 17, 2017. The application was discussed and subsequently approved by the EMD EB.
- The detailed planning phase started. The visiting team comprised Egon Amann (Chair DQCML), Renze Bais (Past IFCC secretary), and Annette Thomas (Chair C-

AQ). The dates of the workshop were fixed to be held on May 28 -29, 2018 in Kathmandu.

- Two major topics were listed in this application:
 - I. To train Medical laboratory professionals on quality process and practice.
 - II. Help the societies plan and strategize on how to execute an EQA pilot project in Nepal.

- In order to learn more about actual situations and issues in Nepal's Clinical Chemistry labs, the visiting team requested to visit clinical laboratories (hospital labs and private labs) after the workshop. The afternoon of May 29 and May 30 were reserved for these visits.

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

2. Programme for Visit:

The programme for the visit was discussed in advance with the following people who would host the visit:

- Mr. Binod Kumar Yadav, President NAMLS, yadavbinod4u@gmail.com
- Mr. Ram Vinod Mahato, General Secretary NACC, ramvinodmahato42@gmail.com
- Dr. Binod Kumar Yadav, Ex-President of NAMLS, binod3aug@gmail.com
- At a later stage in the workshop planning, additional people from several Workshop Organizing Committees were involved (see Attachment 1).

3. Day 1: Workshop on developing quality competence in medical laboratories (May 28, 2018):

Day one was devoted for presentations and workshops, divided into three Sessions (see Attachments 1 and 2 for the programme). Two additional presentations were put up, one by Mr. Shyam Kumar Mishra on "*Diagnostic Stewardship – A Step to Quality Reporting in Microbiology*" and one by Prof. Dr. Madhab Lamsal on "*Internal and External Quality Control*".

Approximately 150 participants were present in the workshop.

The Opening Ceremony ("*Chairing and Inauguration*") was highly impressive: Besides five welcome addresses (including Egon Amann's one on behalf of IFCC and its President Howard Morris), the organizers had managed to host as the Chief Guest Hon. Dr. Ram Baran Yadav, Nepal's first President elected in 2008. Dr. Ram Baran Yadav is a medical doctors and also served the country as minister of health. He appeared very knowledgeable in Clinical Chemistry.

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

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

Group 1	Group 2	Group 3	Group 4
Establishment of Quality System by government.	Need compulsory policy on IQC / EQA participation.	Lack of trained manpower (don't have enough knowledge on QC!).	Difficulty of interpreting control values, differences between analyzers.
QC materials must not be expensive.	High cost for Quality Management. High cost for QC and EQA. Competition of price vs. quality.	Finance is always an issue! Everything is expensive, e.g., training. Not given sufficient wages.	Lack of reagents, storage. Short supply of reagents and low quality.
Sample transportation act needs monitoring by government.	No Government policy regarding sample, reagent, and transportation.	Lack of reliable, regular and effective monitoring system.	Lack of training regarding quality control.
Good policy on biohazard issues, waste products, how to dispose required.	Lack of Practical implication of corrective actions when e.g., EQA fails.		
Commission to the medical doctors is a big challenge.	Lack of practical training on CAPA.		
Group 5	Group 6	Group 7	Group 8
Training in pre-analytical phase not available. Involves non-technical personnel with no training.	Practice based on commission system rather than quality system.	Corrective action not followed. Qualified and trained human resource missing.	Pre analytical sample prep is problematic.
Use old equipment not calibrated.	Lack of lab work harmonization, e.g. sample tracking system, inadequate acquisition forms, infrequent availability of EQA samples,	Instrument and reagent, calibration, validation and certification inadequate.	Post analytical – waste disposal and interpretation.
Lack of waste management.	Unskilled personnel working in clinical labs, lack of audit.	Lack of government policy on QC implementation.	Lack of moral values amongst practicing clinicians, lack of manpower.
Lack of understanding of ISO standards	High turnover of staff due to poor environmental working conditions and low wages.		Implementation of quality control act. Financial cost high. Address policy maker.
Handling of specimen. Training limited to professionals only.	Lack of recognition of profession.		



Figure 1: Opening Ceremony Participants of the Kathmandu workshop on May 28, 2018 (from left to right: Dr. Renze Bais; Mr. Binod Kumar Yadav, President NAMLS; Hon. Dr. Ram Baran Yadav, Nepal's first President; Prof. Bharat Jha, President NACCC; Prof. Egon Amann, Dr. Annette Thomas, and Dr. Binod Kumar Yadav, Ex-President NAMLS).



Figure 2: Workshop Group Work with eight group comprising approx. 150 participants

4. Day 2: Working out the details of the Nepal EQA scheme (May 29, 2018):

In preparation of this workshop, Renze Bais had send out questionnaires (Attachment 3) to interested Nepal laboratories asking for the assays carried out in their labs.

The morning was devoted to discuss the EQA schemes with the approximately 20 labs in Nepal planning to participate and of which some had responded to the questionnaire.

This second day was thus limited to approximately 40 participants. Renze Bais laid the groundwork in his lecture “*Developing an EQA program in emerging countries*”. He reported on the experiences form a similar program he orchestrated in Zambia, which were very positive. Renze proposed an EQA program for Nepal labs and highlighted that participating labs will gain confidence in their ability to produce reproducible and reliable results.

This lecture was followed by a vivid discussion on doing EQA for the many varying assays, hormones, proteins, general serum chemistry, etc.

The visitors expect that Nepal will take this opportunity to develop a national EQA scheme in Nepal.



Figure 3: Farewell picture at the end of Day 1 (only a fraction of participants are shown).



Figure 4: Farewell picture at the end of Day 2 (only a fraction of participants are shown)

5. Day 2 (May 29, 2018) and Day 3 (May 30): Laboratory visits

The IFCC visitors had the chance to see seven clinical laboratories during these two days. Our hosts arranged for the pre-announced visits. The visitors enjoyed very warm welcomes in all the labs and were shown patient reception & phlebotomy rooms, patient documentation procedures and instruments. Questions were answered openly. The IFCC visitors want to express their gratitude to all management and personnel in these seven visited laboratories.

- 5.1. Nepal National Hospital, Kalanki, Kathmandu
- 5.2. Nepal Cleft and Burn Center, Pushpalal Medical College & Teaching Hospital (pfect Nepal), Kirtipur, Kathmandu
- 5.3. Samyak Diagnostic Pvt.Ltd (private lab – Nepal's first ISO 15189:2012 Certified Pathology Laboratory
- 5.4. Patan Private Hospital – Clinical Laboratory
- 5.5. Kathmandu Model Hospital, Bhrikutimandap, Kathmandu
- 5.6. Tribhuvan University Teaching Hospital – Institute of Medicine – Maharajgunj Medical Campus
- 5.7. Shahid Gangalal National Heart Center, Basbarai, Kathmandu.

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 (usually in smaller percentage) out-patients.
- Phlebotomy areas were very small and not always in good shape and hygienic standards. General Practitioners don't collect blood from their patients but rather send patients direct to the clinic for phlebotomy – we have seen huge queues lining up!
- Only one lab (Samyak Diagnostic) 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 use the patient's name in combination with a numbering system as ID.
- Out-patients are asked to carry the test result form to their doctors.
- Instrument maintenance and servicing is not always optimal.
- Labs seem to cope well with occasional power outages. Some have Diesel generators as back-up and one had battery backup.
- Each lab performs blood sugar test.
- No glomerular filtration rates are measured.
- Most labs struggle with budget restrictions.
- Labs sometimes complained about budget restrictions and lack of governmental and public health support.
- Many labs don't participate in EQA schemes.
- Often QC/EQA could not be done since QC materials did not arrive on time.
- The only private lab visited (Samyak Diagnostic) showed remarkable differences to the public sector labs in:
 - Much higher variety of test performed, e.g., in haematology, tumour markers, serology, diabetes (e.g., HbA1c), tropical diseases.
 - Higher test volumes
 - More space (although still storage space is lacking)
 - Better décor and laboratory furniture.
 - More and better equipment.
 - Skilled, better trained staff.
 - Obviously, better attitude of staff (based on better pay?).
 - Re-Accreditation to ISO 15189 just received.

6. Summary of possible solutions for identified issues

QC & Reagents issues

- QC issues – use patient samples as back up short term!
- Reagent supply & cost seems to be a big issue.
- Ordering route can be quite convoluted and should be shortened.
- Labs order the reagents late so there is also an issue with this (?)
- Work on better forecasting for reagents & QC materials.

Attitude and lack of commitment of staff

- Individual facility needs to look at workload and what staff is needed.
- Try to involve Ministry of Health more intensively in order to get recognition for clinical chemistry work.

- Better workload planning is required.
- Training should also include training of others, i.e., pre-analytical staff.
- “Quality” is responsibility of everyone – management needs to lead in this.
- Include Quality in basic training.
- Can be done within the laboratory, keep up to date.

Sample transportation & waste disposal

- Sample transportation needs improvement (but how?)
- Overall process monitoring by government needs implementation.
- Policies on biohazard issues & waste disposal need to be improved.

EQA schemes

- Labs need to participate in EQA schemes to improve quality and patient safety.
- Current schemes are not enough
- Participation in the offered RCPAQAP program will enhance in a pilot study quality of participating labs.

7. Visit Summary

This visit of IFCC officers by request of NAMLS and NACC was extremely useful. Both national organisations 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 tests being performed in Nepal. NAMLS and NACC should intensify their activities to the Department of Health Services 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 NAMLS and NACC members accordingly.
- Raise attention to the EQA schemes by workshops or seminars.
- NAMLS and NACC must influence the education curriculum by highlighting the meaning of IQC and EQA.
- NAMLS and NACC should moreover influence the education curriculum by raising attention to risk management tool, e.g. FMEA.
- NAMLS and NACC should develop programs to enable labs to “move up the Quality ladder” by applying SLIPTA and SLMTA schemes (see presentations).
- The final goal must be to achieve accreditation according to ISO 15189 for all labs.

The IFCC visitors would like to express their thanks to NAMLS and NACC and in particular to Mr. Binod Kumar Yadav (current NAMLS president), to Dr. Binod Kumar Yadav (Ex-president NAMLS), and to Mr. Ram Vinod Mahato (General Secretary of NACC) for this invitation to come to Nepal. We wish you all the best in working towards (and reaching) these ambitious goals in the medium term.

Signed June 11, 2018:

Egon Amann, Renze Bais, and Annette Thomas