



## IFCC Developing Quality Competence in Medical Laboratories (DQCML)

Visit to Lahore, Pakistan: January 10 – 11, 2020

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### 1. Introduction:

- The Pakistan Society of Chemical Pathologists (PSCP), a Full Member of IFCC, is actively involved in IFCC conferences and meetings. PSCP's current president is Prof. Dr. Aamir Ijaz.
- After initial E-Mail contacts, PSCP submitted the *Application for IFCC DQCML program* on September 27, 2019, to DQCML to organize a workshop. Requested topic was described as "*Developing Quality Competence in Medical Laboratories*". The goal and objectives of the visit was described as "*To have interaction of freshly qualified Chemical Pathologists and Medical Technologists with foreign experts in this field. This will make their vision broader about the most important aspect of Chemical Pathology*".
- Prof. Ken Sikaris (Australia) and Prof. Paivi Laitinen (Finland) were nominated as speakers. Both nominees, however, rejected the nomination due to health and time constraints. Subsequently, several alternative speakers were contacted. Finally, Dr. Annette Thomas (Chair C-AQ) and Prof. Egon Amann (Chair DQCML) were confirmed as speakers.
- The application was discussed and subsequently approved by the EMD EB.
- Subsequently the dates of the workshop were fixed to be held on January 10 + 11, 2020, in Lahore, at the University of Health Sciences and EXPO Center. The workshop was intended as a satellite event of the *4<sup>th</sup> Pak Health International Expo & Pakistan Society of Chemical Pathologists (PSCP) Conference*. This expo provides a platform for the world's leading manufacture & distributors to meet the medical & scientific companies. This is the largest gathering of Healthcare, Diagnostic and Trade professionals in Lahore, Pakistan. This conference will also have gathering of renowned Chemical Pathologists, Pathologists and Medical Technologists for attending workshop & Conference in subject of Quality Assurance for Pathology Laboratories.

- The detailed planning phase started and the final 2-day workshop program was fixed.
- Three major topics were listed in this application:
  - I. Quality Assurance (IQC & EQA)
  - II. Lab Management
  - III. Clinical Interpretation
- In order to learn more about actual situations and issues in Pakistan's Clinical Chemistry labs, the visiting team considered to visit clinical laboratories (public hospital labs and private labs) after the workshop.
- Egon Amann was denied to enter the country upon arrival in Lahore. He expected to receive the VISA for Pakistan upon arrival, due to information on the embassy's website that German residence are exempt from pre-VISA requirements. That appeared not to be the case. As a consequence, Annette Thomas delivered the presentations and facilitated the workshop with the support of Professor Asim Mumtaz. (Egon Amann's presentation slides had been provided beforehand to Prof Azim).
- This document is a report of that visit jointly prepared for DQCML by Egon Amann and Annette Thomas.

## **2. Programme for Visit:**

The programme for the visit was discussed in advance with the host of the visit:

- Prof. Asim Mumtaz, drasim123@yahoo.com

## **3. Day 1: Assuring Quality in the Clinical Laboratory (Friday, January 10, 2020)**

Day one was devoted for lectures and workshops (see attachment 1). Fifty-two participants attended, with a mix of primarily Chemical Pathologist and Laboratory Managers.

For the interactive workshop "*What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory*" the 52 participants were divided into five groups and asked to provide the 3 most important issues that impacted on quality in their laboratory.

Each of the groups nominated a speaker and an interactive question and answer session with the audience and Annette Thomas ensued. The following is a summary of the hot topics (or issues) presented by the five groups:

<b>Group 1</b>	<b>Group 2</b>	<b>Group 3</b>
1/ Purchasing cost for low budget lab also the cost and frequency of using IQC. <i>Q: How many QC tests should be undertaken by laboratories with low workload (&lt; 30 month)</i> <i>A: Base frequency on risk.</i>	1/ No EQA for some laboratories. Not using trending for IQC and not using any Westgard rules. Frequency of QC not defined.	1/ Different issues arise depending on size of laboratory and whether public or private. / Larger laboratories tend to need assistance in providing the right documentation to comply with accreditation requirements whilst smaller laboratories tend to have more pre-analytical issues.
2/ Pre - analytical issues – incomplete information, unlabeled samples, haemolyzed sample. <i>Q and A in Group 5</i>	2/ Procurement – no regular supply chain. On & off supply. Instrument maintenance – vendors not responsive. Reagent rental not as problematic as capital purchase. Public sector problems rather than private sector.	2/ Large labs have bar coded samples minimizing transcription errors compared with the smaller laboratories.
3/ Liquid control from suppliers is unreliable <i>Q. How to ensure stability.</i> <i>A: Suggest that this should be part of manufacturers responsibility. Include in the contract to provide temp control markers on the reagents and controls. Color changing ones cost £, more sophisticated USB devices £30 but that would provide full audit trail. Set this as KPI to supplier.</i>	3/ Inventory management - 99% goods imported. No support from the supplier but also issues with end user in managing the inventory.	3 Calculation of CV is an issue.
4/ Interpretation of capillary samples. <i>Q. There is an issue on how to report them. A: need to undertake verification of capillary samples against venous samples re: reference range.</i>		
<b>Group 4</b>	<b>Group 5</b>	
1/ Pre-analytical errors as above. <i>Q and A in Group 5</i>	1/ Pre-analytical phase – hemolyzed samples, EDTA contaminated samples, drip arm samples. <i>Q How to minimize these errors? A: zero tolerance to incomplete forms or hemolyzed samples, need to audit incidence of issues.</i>	
2/ Verification of ref ranges and Troubleshooting the system.	2/ Problem is with new medical staff rotation every 3 months – training is an issue. Errors are being monitored in some labs. One	

	lab has recently published a paper on this.	
3/ Cost in remote area is an issue as well as short samples. Need further training. <i>A: Education is the answer to most of the pre-analytical issues</i>		
4/ How to enforce IQC - education needed.		

The following main themes and issues could be identified:

- High cost of materials (i.e., standards, controls and reagents) is an issue for some small laboratories.:
- No regular supply chain or inventory management and little support from the distributor or manufacturer to assist.
- Insufficient IQC or a lack of understanding as to when and how to undertake IQC.
- Only very few labs are accredited according to ISO 15189 or CAP.
- Not all laboratories participate in EQA.
- Reference values for many tests are not well established.
- Pre-analytical issues relating to sample draw, sample handling, or mislabelling due to lack of trained staff. There is no dedicated phlebotomy service in most areas and samples are usually taken by junior medical staff.

Some proposals to improve the general situation of Clinical Chemistry in Pakistan were discussed in the Q and A session:

#### IQC & Reagents issues

- Work on better forecasting for reagents & QC materials is needed. Additional inventory management tools and assistance from the distributors and manufacturers.
- Tighter specifications relating to the quality, stability and delivery of reagents and consumables.
- Set KPIs for manufacturers to provide quality reagents and maintenance.

#### Training of staff

- Training on inventory management and workload planning is required.
- Training of pre-analytical issues should also include training of other personnel, i.e., phlebotomists, junior medical staff.
- Training of IQC principles and planning relating to frequency, statistical analysis, trending, troubleshooting.
- Risk management awareness training

#### Pre-analytical and Post-analytical work

- Try to optimize the processes, in particular sample handling, temperature control, and documentation.

#### EQA schemes

- Emphasise that Laboratories need to participate in EQA schemes to improve quality and patient safety.
- Participation in international EQA schemes should enhance quality of participating labs.

- Consider creating a simple pilot programme in Lahore for laboratories that do not currently participate in any EQA Scheme.

#### **4. Day 2: Symposium on Developing Quality Competence in Clinical Labs (Saturday 12, 2020)**

Day two was devoted to formal lectures and the continuation of the workshop discussions from Day one (see attachment 2). 140 delegates attended, in addition to those from day 1 and additional cohort of medical technologists and trainees attended.

The IFCC officers expect that PSCP will utilize the lessons from the workshop to improve pre-analytical, IQC, EQA and contract management in Pakistan.

#### **5 Day 3: Laboratory visits.**

Annette Thomas visited 3 very different laboratories in relation to size, complexity, specialism and the range of facilities available. Two were private laboratories and one a public hospital laboratory. The larger private laboratory had significantly better facilities and equipment, had a robust but developing quality management system and had recently applied for CAP accreditation. She also observed (but did not visit) a large number of single room laboratories offering services to the nearby Hospitals.

#### **5. Visit Summary**

This visit of IFCC officers by request of PSCP was considered useful, both by PSCP and by the visitors.

Annette Thomas expresses her thanks to the PSCP Organising Committee, the friendly welcome and professional atmosphere of the congress and DQCML workshop.

We wish PSCP all the best in working towards (and reaching) these ambitious goals.

Signed February 9, 2020

Egon Amann, Annette Thomas

Fig. 1: Organizers and Speakers



Fig 2 Q and A session on Day 1



Fig. 3: Participants on Day 1



Fig 4 Participants on Day 2



Fig 5 Laboratory visit Day 3 – Pride Lab Clinical Laboratories



Fig 6 Laboratory visits Day 3 – Pathology Laboratory, Punjab Institute of Cardiology





Figure 7 Laboratory Visits - Chughtai Lab



Figure 8 Day 3 Laboratory visits – Laboratories opposite Services Hospital, Jail Road, Lahore

