



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

Visit to Kazakhstan: April 19 – 20, 2019

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### 1. Introduction:

- *The Kazakhstan Association of Medical Laboratory Diagnostics (KAMLD)*, a Full Member of IFCC, is actively involved in IFCC conferences and meetings. KAMLD's current president is Prof. Mustafa Rysuly.
- Following initial discussions with Dr. Urazbayeva Dinara, at that time vice-president of KAMLD, the *Application for IFCC DQCML program* was submitted on February 19, 2019, to DQCML to organize a workshop. All initial discussions with KAMLD were language-assisted by Dr. Lina Khorovskaya of St. Petersburg, Russia, member of C-AQ.
- The goals and objectives of the workshop requested by KAMLD were described as: *“Establish professional relationships and improve their knowledge in the field of quality control of laboratory service specialists in Kazakhstan”*.
- The application was discussed and subsequently approved by the EMD EB.
- Subsequently the dates of the workshop were fixed to be held on April 19 + 20, 2019, in Almaty, Kazakhstan. The workshop was intended as a satellite event of the *7<sup>th</sup> International Laboratory Medicine Congress of the KAMLD*. This had the advantage that concerned laboratory professionals visiting the congress were able to participate in the workshop. Moreover, members of the *Kazakhstan Public Association - Federation of Laboratory Medicine (FLM; President Dr. Zhanar Nurlanovna)*, an IFCC Affiliate Member, also participated.
- As the venue for the congress and the workshop, the Best Western Atakent Park Hotel in Almaty was chosen.

- The detailed planning phase started. The visiting team comprised Egon Amann (Chair DQCML), Annette Thomas (Chair C-AQ), Alexander Haliassos (Chair C-PT), and Lina Khorovskaya (Member C-AQ).
- Two major topics were listed in this application:
  - I. Developing Quality Competence in Laboratory Medicine
  - II. Implementation of External Quality Assurance in Kazakhstan
- In order to learn more about actual situations and issues in Kazakhstan’s Clinical Chemistry labs, the visiting team initially considered to visit clinical laboratories (public hospital labs and private labs) after the workshop. However, due to time constraints of the visiting experts such lab visits had to be cancelled.
- This document is a report of that visit jointly prepared for DQCML by Egon Amann, Alexander Haliassos, Lina Khorovskaya, and Annette Thomas.

## 2. Programme for Visit:

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

- Prof. Mustafa Rysuly, President KAMLD, [mrysuly@bk.ru](mailto:mrysuly@bk.ru)
- Dr. Saken Rustemov, Executive Director KAMLD, [sa.rustem@bk.ru](mailto:sa.rustem@bk.ru)
- Madina Sapparbaeva, Secretary of KAMLD, [kamld@medexpo.kz](mailto:kamld@medexpo.kz)

## 3. Day 1: Assuring Quality in the Clinical Laboratory (April 19, 2019)

Day one was devoted for lectures and workshops (see attachment 1). Since English language proficiency appeared to be rather low, lectures were translated into Russian. Workshop group results, as summarized below, were presented in Russian and translated into English for the visitors.

For the interactive workshop “*What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory*” the approximately 42 participants were divided into six groups.

The following is a summary of most hot topics (or issues) presented by the six groups:

Group 1	Group 2	Group 3
1/ Insufficient materials, finance, untrained staff.	1/ High cost of reagents.	1/ Lack of equipment; Expensive reagents.
2/ Lack of continuous education for biologists. Low level of salary for specialists in Laboratory medicine with biological graduated level.	2/ Insufficient and problematic post-graduate education in Laboratory Medicine.	2/ Absence of reference material and reference ranges in Kazakhstan. They use the Russian reference ranges.
3/ Lack of continuous education for all specialists in Laboratory	3/ Absence of training and education for Quality Managers.	3/ Education in new Laboratory technologies and

Medicine. Specialist training is missing.		standards for specialists in Laboratory Medicine.
4/ Certification of specialist in Laboratory Medicine with background in biology.	4/ Absence of reference values for Kazakhstan population.	4/ Low level of salary for specialists in Laboratory Medicine.
	5/ No standardization of IQC	5/ Needs in Education, reference materials and software on IQC.
	6/ No established national EQA	6/ Lack of a large purchasing facility for all supplies to get better
<b>Group 4</b>	<b>Group 5</b>	<b>Group 6 (Uzbekistan)</b>
1/ Lack of postgraduate education in Laboratory Medicine including possibility of education abroad in international level.	1/ Most laboratories are not accredited according ISO 15 189: Absence of training, teachers, and education.	1/ Necessity of accreditation according ISO 15189.
2/ Lack of IQC.	2/ Lack of money. Absence of budget for reference materials for EQA.	2/ Acute needs in consulting for accreditation and other directions on Laboratory service.
3/ Insufficient IQC and EQC in relation of national level of standardization.	3/ Deficiency of qualified specialists in Laboratory Medicine especially with medical education.	
4/ Necessity of Standardization in all aspects of Lab Medicine.	4/ Deficiency of Quality Managers.	
5/ Lack of reference values in Kazakhstan.	5/ The profession of the laboratory specialist is not perceived seriously. Clinicians' consider specialist in lab medicine as to paramedics not as laboratory scientists.	

#### 4. Day 2: Quality challenges going forward: understanding the needs of Kazakhstan (April 20, 2019)

Day two was also devoted for lectures and the continuation of the workshop from Day one (see attachment 2). In particular, the identified issues from Day one were classified into main themes. These themes were discussed and possible solutions were considered.

The following main themes and issues could be identified:

- High cost of materials (i.e., standards, controls), resulting in:
- Insufficient IQC (or at least need for improvement).
- Only very few labs are accredited according to ISO 15189 (since the visitors did not visit labs, the real number or percentage of accredited labs in Kazakhstan remains unclear).
- As a result: Few (if any) labs participate in EQA and proficiency testing.
- Reference values for many tests are not well established.

- Standardization of many tests is often not established.
- Educational limitations for lab technicians exist.
- Training of quality managers insufficient.
- Recognition of Clinical Laboratory specialists by the medical profession is often not adequate.

Prof. Rysuly gave a summarizing lecture to describe the specific situation, limits and possible improvements for the situation of Clinical Chemistry Laboratories in Kazakhstan.

Some proposals to improve the general situation of Clinical Chemistry in Kazakhstan were discussed:

- Improving the materials (reagents, standards, controls, etc.) supply by establishing larger facilities for centralized purchase and delivery to Clinical Labs. This is under the control of the Ministry.
- Given the 60 : 40 % ratio of public : private labs, what are possible improvements for material supply? More centralization?
- Better understanding of the improvement needs within the Ministry responsible for Health Care must be initiated.
- The SLIPTA approach for step-wise quality improvements might be a useful approach also for Kazakhstan labs to “Move up the quality ladder” and should be considered (reference is made to the lecture “Moving along the road to accreditation”).
- Accreditation is costly and the benefit for small rural laboratories may not always be given.
- However, the need for laboratory accreditation according to ISO 15189 is understood and must be applied for more laboratories.
- Participation in EQA schemes for many tests must be implemented.
- Education of quality managers is necessary.
- Contacts to Russian accreditation bodies or Greek Accreditation Body ESYD may be expanded for planned accreditation of labs in Kazakhstan.
- Some laboratories in Astana are accredited by Greek accreditation body ESYD in 2016 and they are competent in this process.
- Those specialists in laboratory medicine who participated in this process and their labs were accredited could give assistance from KAMLD-FLM to other labs in collaboration with accreditation bodies.
- The DQCML / IFCC recommends to create a National Accreditation Body in Kazakhstan

The visitors expect that KAMLD will utilize the lessons from the workshop to improve pre-analytical, IQC and EQA quality in Kazakhstan.

## **5. Summary of possible solutions for identified issues**

### IQC & Reagents issues

- Reagent supply & cost seems to be a big issue.
- Reagent ordering route can be quite convoluted and should be shortened.
- Work on better forecasting for reagents & QC materials is needed.

#### Ministerial involvement and education

- The Ministry must understand the needs of Clinical Chemistry labs better.
- Active involvement and enhanced contacts may help.
- Try to involve the Ministry of Health actively in order to make clinical chemistry work recognized.
- Overall process monitoring by government bodies should be considered.

#### Attitude and lack of commitment of staff

- Individual facilities needs to consider workload and adequate needed staff.
- Better workload planning is required.
- Training should also include training of other personnel, i.e., phlebotomists, pre-analytical staff.
- “Quality” is responsibility of everyone – management needs to lead in this.
- Include Quality in basic training.

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

- Like in all Clinical Labs worldwide, this is the major cause of error!
- Try to optimize the processes, in particular sample handling, temperature control, and documentation.

#### EQA schemes

- Consider an EQA technical working group, maybe as a joint KAMLD-FLM effort.
- Labs need to participate in EQA schemes to improve quality and patient safety.
- Current schemes are not enough.
- Participation in international EQA schemes should enhance quality of participating labs.
- Consider creating a National EQA scheme in Kazakhstan.

## **6. Visit Summary**

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

The visitors express their thanks to the KAMLD Organising Committee, the friendly welcome and professional atmosphere of the congress and DQCML workshop.

The congress and workshop days were overshadowed by the tragic and untimely loss of IFCC president Howard Morris. This report is dedicated to his memory.

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

Signed April 30<sup>th</sup>, 2019:

Egon Amann, Alexander Haliassos, Lina Khorovskaya, and Annette Thomas

Fig. 1: Certificate ceremony of workshop participants on April 20, 2019

