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## IFCC Guidelines for compliance with applicable codes of ethical business practice

*by James C. Wesenberg*  
*Chair, IFCC Committee*  
*on Congresses and Conferences*

### **Introduction**

National and international agencies have established codes of ethical business practice that are applicable to the *in vitro* diagnostics (IVD) industry and third party educational event organisers such as the IFCC and national societies.

The IFCC endorses these codes of ethical business practice and supports compliance for all educational events developed and/or supported by the IFCC.

A code with significant impact to the IFCC is the “MedTech Europe Code of Ethical Business Practice” since this code is applicable from an IFCC perspective to all third party educational events held in Europe or anywhere in the world if the delegates are from two or more “European” countries. Therefore, this code is applicable to all WorldLab and EuroMedLab Congresses. Similarly, this code or other comparable national or international codes may be applicable to educational events for which IFCC auspices may be requested.

The MedTech Europe Code of Ethical Business Practice is available for download (MedTech Europe Code of Conduct.pdf) from the MedTech Europe website: <http://www.medtecheurope.org/node/715>.

To alleviate the complex administrative burden of determining compliance and to harmonize interpretation of the code, “EthicalMedTech” hosts a platform referred to as the “Conference Vetting System” that enables third party educational event organisers to ensure compliance with the MedTech Europe Code of Ethical Business Practice:

<http://www.ethicalmedtech.eu/conference-vetting-system/objective>.

The IFCC requires use of the EthicalMedTech - Conference Vetting System to ensure code compliance for all applicable third party educational events. For third party educational events for which the MedTech

Europe Code of Ethical Business Practice is not applicable, the IFCC recommends a method of self-assessment to ensure compliance with any other applicable code(s) of ethical business practice.

An informational document has been posted to the IFCC website – Congresses and Conferences – Auspices and Congress Guidelines – IFCC Guidelines for Compliance with Applicable Codes of Ethical Business Practice, which can be accessed at: <http://www.ifcc.org/media/467898/guidelines-for-compliance-with-applicable-codes-of-ethical-business-practice-rev1-june-2017.pdf>.

### **MedTech Europe Code of Ethical Business Practice**

[www.medtecheurope.org](http://www.medtecheurope.org)

MedTech Europe is the European Trade association representing the medical technology industries - Diagnostics and Medical Devices. The MedTech Europe Code of Ethical Business Practice regulates all aspects of the industry’s relationship with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), to ensure that all interactions are ethical and professional at all times and to maintain the trust of regulators and – most importantly – patients. The MedTech Europe Code of Ethical Business Practice became binding and applicable globally for MedTech Europe corporate members on January 1, 2017.

A new directive effective January 1, 2018 particularly affects the sponsorship of congresses, conferences and events organized by third parties. From that date, direct sponsorship of healthcare professionals was discontinued. MedTech Europe corporate members will no longer be able to directly cover the costs related to the enrollment and/or participation in an event of a single healthcare professional. The training supports must be provided to healthcare organizations or professional conference organizers.

*Article continued on next page*

There are comparable national codes for the different European countries.

Similarly, there are comparable national and international organisations elsewhere in the world, e.g., AdvaMed and Mecomed.

### **Advanced Medical Technology Association (AdvaMed)**

[www.advamed.org](http://www.advamed.org)

AdvaMed is an American medical device trade association. AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.

### **Mecomed**

[www.mecomed.com](http://www.mecomed.com)

Mecomed is the medical devices, imaging and diagnostics trade association; serving as the voice of international medical technology manufacturers (MedTech) for 21 countries across the Middle East and North Africa. The current Mecomed guidelines are in tone with those adopted by other trade associations in North America and Europe.

### **Ethical MedTech – MedTech Europe Compliance Portal**

[www.ethicalmedtech.eu](http://www.ethicalmedtech.eu)

EthicalMedTech is a platform, supported by MedTech Europe, dedicated to ethics and compliance projects in the MedTech industry.

The three current initiatives are as follows:

- The Conference Vetting System: A unique initiative that assesses the conformity of third-party educational events with the MedTech Europe Code,
- Transparent MedTech: A European centralised platform for MedTech companies to disclose publicly the financial support they provide to independent medical education,
- The Ethical Charter: A voluntary certification initiative that ensures commitment of third party educational event organisers on the

application on the MedTech Europe Code provisions to the educational events for which they seek industry's financial support.

MZ Congressi, the partner Professional Conference Organizer of the IFCC was certified as an EthicalMed-Tech Trusted Partner on February 10, 2018.

### **Ethical MedTech – Conference Vetting System**

[www.ethicalmedtech.eu/conference-vetting-system](http://www.ethicalmedtech.eu/conference-vetting-system)

The Conference Vetting System (CVS) is a unique initiative in the healthcare industry. It is a centralised decision-making system that encourages transparency and consistency in medical education events and alleviates the complex administrative burden previously faced by MedTech Europe and Mecomed members, who were constrained to make their own determinations on whether or not a third-party educational event they wished to provide support to was compliant with the associations' respective Codes.

CVS is an independently managed system which reviews the compliance of third-party educational events with MedTech Europe Code of Ethical Business Practice and Mecomed Code of Business Practice (the "Codes") to determine the appropriateness for companies which are members of MedTech Europe and Mecomed to provide financial support to such events in the form of educational grants or commercial activities, e.g., booths, advertising, and satellite symposia.

Members of MedTech Europe and Mecomed cannot provide support to an event that has not received positive assessment by CVS. Furthermore, the decisions rendered by the Compliance Officer are binding on MedTech Europe and Mecomed members which means that these members cannot provide support to an event which is found to be not compliant.

The review process is based on a set of 6 criteria that have each the same weight in the evaluation: the scientific programme, the geographic location, the conference venue, the hospitality, the registration packages benefits and the communication.

## IFCC WG-PCT: towards standardization of procalcitonin assays

*by Vincent Delatour  
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Early identification diagnosis and appropriate therapy of severe sepsis remains a real challenge in intensive care units. Despite new therapies and guidelines developed over the past decade, sepsis incidence and mortality remain high.

Severe sepsis is the first cause of death in the non-coronary intensive care unit where the mortality rate generally ranges from 30% to 60%. Every year in the US, severe sepsis strikes about 750,000 people resulting in 100,000 deaths, making it the tenth-leading cause of death in the US.

Due to the aging of the population, the increasing number of immunocompromised patients, the use of invasive procedures and the use of antibiotics which encourages the growth of drug resistant microorganisms, the incidence of severe sepsis in the US is expected to rise and reach close to one million in the upcoming years. Thus, early recognition of sepsis and timely initiation of appropriate therapy are key steps for survival faced with these potentially devastating conditions. In addition to the medical consequences on patient, it also places an enormous strain on the healthcare system.

The annual cost of treating sepsis is a staggering \$16.7 billion in the US and 5 billion Euros in Germany (Angus et al. *Crit Care Med.* 2001;29(7):1303-10). Therefore, both the medical and the health-economic problems of sepsis are in the focus of the medical community. The intensive care specialists took the challenge to overcome the current situation and to reduce significantly sepsis mortality by implementing evidence-based clinical standards for diagnosis and treatment of sepsis worldwide.

Subsequently, Procalcitonin (PCT) has demonstrated its major utility in medical and emergency medicine practice (Assicot et al. *Lancet.* 1993;341(8844):515-8). According to its selectivity and specificity of severe

bacterial/parasitic infections (sensitivity 93%, specificity 96%), PCT is increasingly recognized as the most promising early biomarker for risk stratification of progression to severe sepsis or septic shock. Since PCT concentration does not increase during non-infectious inflammatory reactions contrary to C-reactive protein (CRP), its diagnostic relevance is superior to that of CRP. Indeed, high PCT levels allow the early identification of patients prone to develop severe sepsis or septic shock.

The medical area application of PCT is rather broad as its measurement not only includes discrimination between inflammatory disease and infectious complication or between bacterial/parasitic and viral infection, but also allows assessing antibiotic treatment efficiency. Based on more than 500 trials, PCT obtained a valuation according to the criteria of evidence-based medicine.

Particularly, some interventional trials showed the possibility of guiding antibiotic treatment with PCT measurements in patients with infections of the lower respiratory tract. Lower respiratory tract infections account for almost 10% of the worldwide burden of morbidity and mortality.

About 75% of all antibiotic doses are prescribed for acute respiratory-tract infections, despite their mainly viral cause (Macfarlane et al *Lancet.* 1993;341(8844):511-4.). This inappropriate use of antibiotics is believed to be a main cause of the spread of antibiotic-resistant bacteria (Wenzel et al. *Clin Infect Dis.* 1999;28(5):1126-7).

Thus, PCT measurements have a key role to play in the reduction of the excessive use of antibiotics and is essential to combat the increase of antibiotic-resistant microorganisms (*JAMA.* 1999; 28;281(16):1512-9, *Clin Infect Dis.* 2001;33(4):542-7). In 2004, a clinical trial involving more than 200 patients with suspected

infections of the lower respiratory tract (e.g. pneumonia, chronic obstructive pulmonary disease, Bronchitis) and utilizing PCT as a decision biomarker allowed to reduce by 50% the antibiotic prescriptions (Christ-Crain et al. Lancet. 2004;363(9409):600-7).

In another interventional trial including more than 200 patients with community acquired pneumonia (CAP) and guiding the antibiotic treatment with PCT measurements allowed to shorten the duration of antibiotic treatment from 13 days to 5 days (Christ-Crain et al. Am J Respir Crit Care Med. 2006;174(1):84-93).

Since the cost of daily PCT measurement is about 10 times lower than that of a broad-spectrum antibiotherapy (10€ vs. 115€), the use of PCT obviously leads to substantial savings. When an antibiotic-based treatment is needed, PCT demonstrated its interest to monitor its efficiency and adapt posology since sepsis-related raised PCT levels are closely linked to the magnitude of host systemic inflammatory response to microbial invasion.

A 50% reduction of PCT concentration per day over several days has been shown to be an indication for success of therapeutic intervention (surgery, antibiotic treatment). Persisting high or further increasing PCT levels, indication for non-controlled infectious process, justify a re-assessment of therapeutic strategy.

Overall, having reliable PCT measurements is of major interest for the accurate identification of bacterial infections in patients presenting at the emergency department to allow early and rational antibiotic treatment.

The first PCT assays were based on manual immunochemistry methods (Brahms PCT LIA). These assays have been replaced by fully automated immunochemistry methods (Brahms Kryptor, Diasorin Liaison, Biorad Vidas, Siemens Advia, Roche Cobas, Abbott Architect, Beckman AU, Radiometer AQT90 FLEX). Although results provided by most of these methods are traceable to the Kryptor designated reference method, results of different EQA schemes suggest that method comparability is quite poor (eg. 2015 French Mandatory EQAS in which a 17-20% between-methods RSD was observed).

In the absence of any higher order reference method or reference material for PCT measurements, this situation can only worsen with the inevitable onset of new techniques in response to the increasing demand for PCT testing in the intensive care unit environment. However, other studies come to the opposite conclusion (Dipalo et al. Pract Lab Med. 2015;2:22-28), suggesting that commutability of EQA materials could be questionable.

To address this issue, IFCC WG-PCT will address the following objectives:

- Develop and validate a reference measurement procedure for PCT absolute quantification by isotope dilution mass spectrometry (IDMS) in order to establish metrological traceability of results to the SI Units:
  - Agreement on measurand(s)
  - Produce and characterize a primary calibrator for PCT;
  - Develop separation methods to purify PCT in biological samples;
  - Assess recombinant PCT and/or synthetic peptides as possible primary calibrators
  - Develop and validate a candidate reference measurement procedure for absolute quantification of PCT by IDMS;
- Document and understand the variability of results provided by the different commercially available PCT assays :
  - Produce candidate EQA materials consisting in various matrices;
  - Organize a commutability study aiming at assessing suitability of various EQA materials to assess comparability of results provided by the different PCT assays;
  - Organize an EQA scheme relying on commutable EQA materials to document the state of the art on the results provided from the different PCT assays used in clinical practice;
  - Investigate the sources of variability between PCT assays;
  - Make a decision whether standardization is needed or not;

- Evaluate the feasibility for standardization of PCT assays through common calibration with commutable calibrators value assigned with the SIDMS reference measurement procedure;
- If standardization of PCT assays appears desirable and feasible:
  - Produce commutable calibrators value assigned with the IDMS reference measurement procedure;
  - In cooperation with assays manufacturers, effectively recalibrate PCT assays;

- Using commutable EQA materials, assess accuracy and comparability of PCT assays before and after recalibration with commutable calibrators;
- Evaluate the impact of assays recalibration and the need to revise clinical decision limits that are currently used in clinical practice.

(<http://www.ifcc.org/ifcc-scientific-division/sd-working-groups/wg-pct/>)



Education and Management Division

## DEVELOPING QUALITY COMPETENCE IN MEDICAL LABORATORIES

Visit to Nepal: 28-30 May 2018

**by Egon Amann**

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**Renze Bais**

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**Annette Thomas**

*University of Wales, College of Medicine, Cardiff, UK*

### 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 "1<sup>st</sup> 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 "2<sup>nd</sup> application"), signed by both Mr. Binod Kumar Yadav and Mr. Ram Vinod Mahato, was issued to IFCC on 17 December 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 28-29 May 2018 in Kathmandu.

➤ Two major topics were listed in this application:

- To train Medical laboratory professionals on quality process and practice.
- 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 29 May and 30 May were reserved for these visits.



Opening Ceremony Participants of the Kathmandu workshop on May 28, 2018

L to R: Dr. Renze Bais; Mr. Binod Kumar Yadav, President NAMLS; Hon. Dr. Ram Baran Yadav, Nepal's first President; Prof. Bharat Jha, President NACC; Prof. Egon Amann, Dr. Annette Thomas and Dr. Binod Kumar Yadav, Ex-President NAMLS



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

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

## 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 another 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 the one of Egon Amann, 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 doctor 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.

**Table 1** 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 (do not have enough knowledge of 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.  | -   | -   |
| <b>Group 5</b>  | <b>Group 6</b>   | <b>Group 7</b>  | <b>Group 8</b>  |
| 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.   | -   | -   |



Workshop group work - with eight groups comprising approx. 150 participants



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

## 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.

## DAY 2 (29 MAY 2018) AND DAY 3 (30 MAY): 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.

1. Nepal National Hospital, Kalanki, Kathmandu
2. Nepal Cleft and Burn Center, Pushpalal Medical College & Teaching Hospital (pfect Nepal), Kirtipur, Kathmandu



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

3. Samyak Diagnostic Pvt.Ltd (private lab – Nepal’s first ISO 15189:2012 Certified Pathology Laboratory)
4. Patan Private Hospital – Clinical Laboratory
5. Kathmandu Model Hospital, Bhrikutimandap, Kathmandu
6. Tribhuvan University Teaching Hospital – Institute of Medicine – Maharajgunj Medical Campus
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 do not 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 patient 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 do not 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.

## 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.

## 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 all 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.

## *Clinical Chemistry Trainee Council: Journal Club*



*by Nader Rifai*  
*Founder of CCTC programme*  
**Ann Gronowski**  
*Co-Chair, CCTC programme*

This is the fifth in a series of articles about the free multi-lingual online educational program for laboratory medicine trainees and their mentors ([www.traineecouncil.org](http://www.traineecouncil.org)), the *Clinical Chemistry Trainee Council* (CCTC). Over 12,000 registrants, from 157 countries, are currently benefiting from the use of this program; 40% of CCTC users are from emerging and developing countries.

The CCTC website houses a variety of educational materials and activities including Journal Club (JC). Every month, the Editors of *Clinical Chemistry* identify an article that is deemed suitable for discussion in a journal club setting and work with the authors on developing a set of slides to accompany it. The editors try to alternate between analytical and clinical articles and aim to cover a broad spectrum of topics. In addition to information describing the rationale for the study, findings, and conclusions, the slides contain questions throughout the presentation to help the presenters in their effort. Both the PDF of the article and the set of slides are available to CCTC participants. At the present time, 107 JC are available on the website, with one new article added each month. In order to participate in this activity and receive the monthly notification about the JC, send a request to Ms. Erin Roberts ([eroberts@aacc.org](mailto:eroberts@aacc.org)).

Currently, almost 20,000 individuals from 157 countries participate in this activity. Although this feature is primarily available in English, several JC articles and slides have been translated to Spanish, Portuguese, French, and Japanese.

The Journal Club articles are popular among laboratory medicine professionals and on average are downloaded 30% more than regular original reports. The JC feature has been downloaded almost 1.3 Million times. The top ten most popular ones are listed in the table below (Table 1).

We encourage all trainees in laboratory medicine and their mentors to take advantage of this free resource and register to gain access to these materials by going to [www.traineecouncil.org](http://www.traineecouncil.org). It takes less than a minute!

Enjoy the JC.

*Article continued on next page*

**Table 1** The top ten most popular articles

| Title  | Downloads |
|--|-----------|
| Diagnostic Accuracy of Point-of-Care Fecal Calprotectin and Immunochemical Occult Blood Tests for Diagnosis of Organic Bowel Disease in Primary Care: The Cost-Effectiveness of a Decision Rule for Abdominal Complaints in Primary Care (CEDAR) Study | 35,385    |
| Cancer Genome Scanning in Plasma: Detection of Tumor-Associated Copy Number Aberrations, Single-Nucleotide Variants, and Tumoral Heterogeneity by Massively Parallel Sequencing  | 34,911    |
| Accuracy of 6 Routine 25-Hydroxyvitamin D Assays: Influence of Vitamin D Binding Protein Concentration   | 27,273    |
| Prevalence of Blood Doping in Samples Collected from Elite Track and Field Athletes  | 30,297    |
| Seven Direct Methods for Measuring HDL and LDL Cholesterol Compared with Ultracentrifugation Reference Measurement Procedures  | 25,762    |
| Magnetically Promoted Rapid Immunoreactions Using Functionalized Fluorescent Magnetic Beads: A Proof of Principle  | 22,407    |
| False-Negative Results in Point-of-Care Qualitative Human Chorionic Gonadotropin (hCG) Devices Due to Excess hCG $\beta$ Core Fragment   | 22,545    |
| Cystic Fibrosis Carrier Testing in an Ethnically Diverse US Population   | 24,111    |
| Low 25-Hydroxyvitamin D and Risk of Type 2 Diabetes: A Prospective Cohort Study and Metaanalysis   | 21,259    |
| Inappropriate Requesting of Glycated Hemoglobin (Hb A1c) Is Widespread: Assessment of Prevalence, Impact of National Guidance, and Practice-to-Practice Variability  | 18,440    |

## News from the IFCC Website

### eJIFCC Vol 29 n<sup>o</sup>2 - July 2018



#### Laboratory Investigation of Vitamin D and Bone Metabolism Markers

The second issue of eJIFCC for 2018 is now available. Guest edited by Dr Harjit Pal Bhattoa (Department of Laboratory Medicine, University of Debrecen, Hungary), it focuses on Laboratory Investigation of Vitamin D and Bone Metabolism Markers. Given the pandemic of vitamin D insufficiency experienced on a global scale it is important to understand the laboratory implications pertaining to the determination of this not so easily measured analyte. The articles in the current issue consider the many aspects related to Vitamin D. Three further articles complete the edition.

[Read more](#)

## What kind of world do we want for tomorrow?

**by Bernard Gouget**

*SFBC-International Committee*

*Counselor for Public Health-FHF*

*Chair-Human Health Care Committee-COFRAC*

*IFCC past Chair-Nominations Committee*

*General Secretary of the International Francophone Federation  
of Clinical Biology and Laboratory Medicine (FIFBCML)*



Bernard Gouget

Advances in biology and medicine pose a certain number of moral problems to reconcile the respect due to human beings with scientific progress. There are two conflicting conceptions of bioethics. For some, it is a framework that moves to adapt to scientific advances according to the expectations of society. For others, it is the application of intangible benchmarks to new situations.

Reflecting on the model for the society we want to have tomorrow is the question which has guided the French National Consultative Ethics Committee which, after several months of civic debate, is preparing a synthesis before the promulgation of the new bioethics law.

The programme is very broad, with nine societal themes or themes dictated by scientific progress: medically-assisted reproduction (MAR) and gestational surrogacy, end of life, research in the fields of reproduction, genetics, organ donation, health data, artificial intelligence, neuroscience and health/environment relationship.

MAR is at the forefront of controversial subjects. It has given rise to the hope of having a child in many people who cannot procreate naturally, posing a major question for society. Can MAR be considered as a new method of reproduction, alleviating the inability to procreate in the broad sense for infertile couples, same-sex couples and single women?

The techniques used are: artificial insemination, including via a donor, considered the simplest, which aims to remedy certain types of sterility, male or female, often associated with ovarian stimulation, and *in vitro* fertilization including assisted fertilization or via a donor.

In France, it is currently reserved for heterosexual couples in the event of male or female infertility, or both, or where there is a risk of transmission of a serious disease to the spouse or child. The beneficiaries of medically-assisted reproduction (MAR) must be of childbearing age. MAR also covers practices such as storage of gametes, germinal tissues and embryos. Some practices can be implemented when the future fertility of a person (child, adolescent or adult) is at risk of being impaired after a treatment or disease.

In MAR internationally, policies differ from one country to another. Also, some women choose to go to another country since MAR is not always allowed for lesbian couples and single women.

Other methods such as surrogacy, post-mortem MAR and double gamete donation and preservation of oocytes with no medical indication, prohibited in France, are allowed in other countries. Surrogacy, an agreement according to which a woman agrees to become pregnant by artificial insemination or embryo transfer

*Article continued on next page*



and to give birth to a child that she gives up at birth, and in exchange for payment, to its “contractual parents” is prohibited by bioethics law and the French penal code. But it is allowed partly abroad and in several European countries (BE, PT, NL, IE, UK, PL, SK, RO,...).

While some would like to allow surrogacy under strict conditions, for women who lack a uterus for medical reasons, for example, others are against it, in the name of the interest of the unborn child and the risk of instrumentalisation of women’s bodies, highlighting legal and ethical difficulties.

In a context relating to “*children’s rights*”, we need to consider the future of the unborn child when applying certain medical technologies. Numerous questions are raised: related to descent, the gratuitousness and anonymity of gamete donations, the opening of MAR to lesbian couples and single women, to surrogacy itself which attributes a market value to the child and to the organic life of the surrogate mother.

The anonymity and gratuity of donations is a principle set down in French law that is common to all elements issued from the human body: the donor cannot know the identity of the receiver, nor the receiver that of the donor. Gametes, as cells issuing from the human body, are subject to these same provisions. However, regulations applying to gamete donation vary greatly within the EU. Should we reconsider or update this principle of anonymity?

Associations of people born from MAR with donation claim their right to know their origins. Today, major technological advances, which have led to the appearance of vast genetic databases, risk undermining this principle of anonymity insofar as these data may become accessible to everyone.

Debate around surrogacy is lively; infertility treatment associations believe that we can no longer ignore children born from surrogacy. Should the possibility of gestation in a non-commercial context be open to women with serious uterine anomalies?

Male couples also wish to use surrogacy to become parents. Should access to gestation be allowed for others outside a therapeutic indication?

The question is even more pressing, since there are currently some major nations, including India, Russia, and parts of the US that allow surrogacy. Other countries such as Sweden are banning all surrogacy, commercial as well as altruistic because the social acceptance of this practice will perpetuate the notion that the wombs of women can be used as a service.

It has become the subject of a growing globalized reproductive market which includes the sale of sperm and oocytes. However, since the commercial surrogacy industry kicked off, it has been awash with scandals, exploitation and abuses.

The ethics of outsourcing pregnancy is an issue that deeply divides citizens. According to Prof. René Frydman, father of the first test-tube baby, *“Today people are rising up to denounce violence against women and tackle gender stereotypes, and the claim to gender equality has taken center stage. Now should be the time to mobilize public opinion and the media about the use made of women’s bodies in the reproductive industry”*.

National and international legislative decisions in this area are of great importance, faced with the pressure of those who have financial interests in the business, as well as those who want a child at any cost.

Society must mobilize via an international agreement to resist commodification of bodies on an international scale and effectively condemn any attacks on fundamental human rights, the only way of combating situations where the dignity of women and the safety of children are not respected.

The ethical issues related to the life and health sciences pose questions that transcend borders with a need to be shared internationally.

We must ceaselessly ask ourselves whether what is “technically” possible is desirable. This is the evolution from the medical to the societal that we are living through.



# The 15<sup>th</sup> Iranian National Congress of Biochemistry & 6<sup>th</sup> International Congress of Biochemistry & Molecular Biology

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## European trial assesses HbA1c testing in more than 2,000 labs across 17 countries: an interview with Cas Weykamp

by Renee Caruthers  
Staff reporter, 360Dx

NEW YORK – The following interview has been published on 360Dx (<https://www.360dx.com/clinical-lab-management/european-trial-assesses-hba1c-testing-2200-labs-17-countries#.Wz81C9IzY2y>). The interview was initiated on behalf of the IFCC Committee C-EUBD, which organised the project.

The quality of haemoglobin A1c diabetes testing varies not just from laboratory to laboratory, but from country to country and test manufacturer to test manufacturer, according to findings of a massive multicountry trial conducted by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

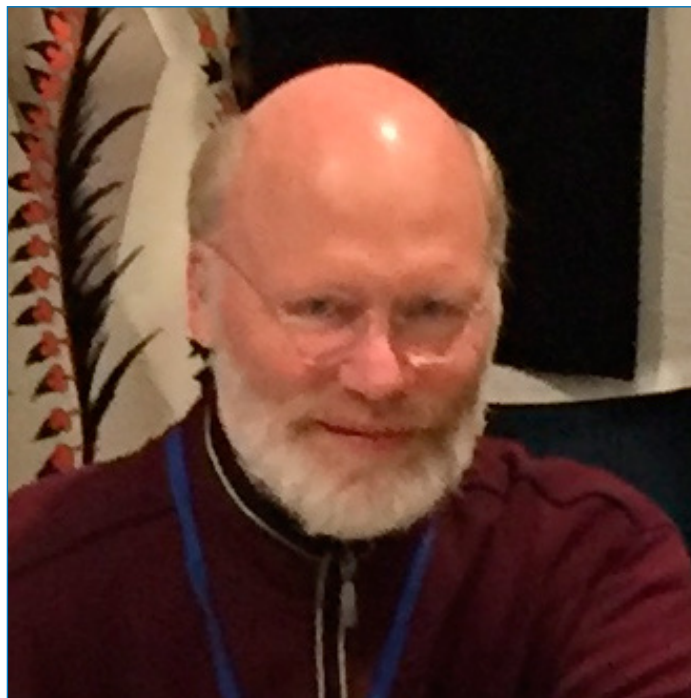
The trial involved HbA1c proficiency testing in 2,166 laboratories, across 17 countries and 24 testing manufacturers. One in 20 of the laboratories tested did not meet the IFCC HbA1c testing criterion, according to the study, which was published in the June issue of *Clinical Chemistry*.

The trial represents a latest step in a multiyear effort by IFCC HbA1c focus groups to standardize HbA1c diabetes testing in laboratories, according to Cas Weykamp, a clinical chemist with Queen Beatrix Hospital in the Netherlands, and the network coordinator for the IFCC HbA1c laboratory network.

Those efforts included the development of a reference system for HbA1c testing in 2008, followed by the establishment of quality targets three years ago, he said.

*“We had created a reference system; we had created a model for quality targets; and now we wanted to see how well laboratories perform in daily life in the field. That can be best tested by sending out the same sample to as many laboratories as possible to see how well they work,”* Weykamp said.

The study looks at lab performance by manufacturer, lab performance by country, and manufacturer performance by country. Half of the labs were evaluated using fresh whole blood and the other half were tested using



Cas Weykamp, member of the IFCC Committee C-EUBD

lyophilized haemolysates, depending on the preference of the external quality assessment organizations participating in the study. Seventeen external quality assessment organizations, which are the equivalent of US proficiency testing organizations, participated in the trial.

For many manufacturers, trial data indicated that their tests performed similarly across different countries. There were occasional exceptions, however. A Roche test performed very well in Sweden, the Netherlands, and the United Kingdom, but performed poorly in Switzerland and Turkey, according to the report. The specific Roche test was not identified.

*“That can trigger Roche to investigate. They see it can be done well, but why doesn’t it work in Switzerland and Turkey?”* Weykamp said.

Although the trial is intended to evaluate lab quality, publication of these types of trials can often prompt corrective actions within the industry, Weykamp noted.

Article continued on next page

*“In general with trials like these, and also with [the College of American Pathologists] in the US, manufacturers that have a poor performance are triggered to improve their products,” Weykamp said. “Also, customers of laboratories that can see they are using a test kit that in general has a poor performance will either contact the manufacturer and ask to improve, or will simply choose the best test kit of a competitor.”*

Among countries as well as among manufacturers, the major contribution to total error derived from between-laboratory variation, meaning the mean calibration of laboratories appeared to be fine, but the differences between laboratories were substantial and should be the focus of further improvement, according to Weykamp.

At the country level, with fresh whole-blood testing, six countries met the IFCC criterion, while two did not, and two were borderline. With lyophilized haemolysates, five countries met the criterion, two did not, and three were borderline. In whole blood testing, Ireland had the best performance testing, while Turkey and Switzerland did not meet the IFCC criterion. In lyophilized haemolysate testing, Italy performed best, while Greece and Austria were outside the criterion.

While the study did not examine any reasons for disparities in performance, it is possible that different countries might have different quality standards, such as narrower acceptance limits for external quality

assessment, Weykamp speculated. Some countries might also use better quality testing equipment than others, he noted.

Among manufacturers, using fresh whole blood, thirteen manufacturers met the criterion, whereas eight did not, and three were borderline. Using lyophilized haemolysates, seven manufacturers met the criterion, six did not, and three were borderline. With fresh whole blood, Abbott’s Architect Enzymatic test performed best. With lyophilized haemolysates testing, Bio-Rad Laboratories’ D100 system was the top performer.

The trial is scheduled to be repeated annually, according to Weykamp. The second study has already been completed, and proficiency testing for the third study is scheduled to begin in October. The study is growing both in the number of labs participating and in the number of countries represented, Weykamp noted, adding the third study will include labs in Africa and Latin America.

*“The number of labs, especially from Africa, will be low, but it’s important to make a start,” he said. “There are many diabetics in the western world, but many, many more in developing countries. HbA1c will be used more and more in those countries, and being aware of quality and trying to achieve good quality and monitor quality is important there as well.”*

## News from the IFCC Website

### IFCC-Roche Travel Scholarship awarded in Rome Tor Vergata (Italy)



IFCC and Roche are pleased to announce the IFCC-Roche Travel Scholarship Awardees. They were selected to attend the 1st IFCC, EFLM, AFCB Conference "Laboratory Medicine: Meeting the needs of Mediterranean Nations", held in Rome Tor Vergata (IT).

Congratulations to: Khalil Ramy Samir Helmy Assaad (EG Aff), Ana Sofía Duarte Acuña (GT), Ashish Kumar Mohanbhai Agravatt (IN Aff), Swarnima Singh (IN Full), Dwy Yuniati Daulay (ID), Kamal Abu-Eisheh (JO), Caroline Wanjiku Njeru (KE), Nerxhivane Gerguri-Ratkoceri(XK), Sebbar El-houcine (MO), Mithileshwar Raut (NP Full), Adaeze Njideka Nwabuogo Onyekwena (NG), Suhanyah Mahathevan (LK), Manel Chaabane Ep Doghri (TU), Yevgenija Kryvenko (UA), Itai James Blessing Chitungo (ZW).



Group photo of the IFCC Roche Travel Scholarship Recipients in Rome, Tor Vergata University, together with IFCC President, Prof. Howard Morris, IFCC Past President, Prof. Maurizio Ferrari, and Task Force for Young Scientists Chair, Dr. Pradeep Dabla.

IFCC Roche Travel Scholarship programme enables Young Scientists from emerging countries to attend major conferences of clinical chemistry and laboratory medicine.

## Results of an international survey of the reporting of protein electrophoresis and serum free light chains, and quantification of small monoclonal proteins

*by Jill Tate*

*Chemical Pathology, Pathology Queensland | Health Support Queensland  
Royal Brisbane & Women's Hospital (AU)  
on behalf of the IFCC WG Harmonisation of Interpretive Commenting  
EQA (WG-ICQA) subgroup*

### INTRODUCTION

Clinical laboratory testing plays an important role in the diagnosis, monitoring and prognostication of monoclonal gammopathies. Analytical methods using serum and urine protein electrophoresis (SPEP, UPEP), immunofixation electrophoresis (IFE) and immunosubtraction (IS), serum free light chains (FLC), immunoglobulin (Ig) and heavy/light chain (HLC) immunoassay, and more recently mass spectrometry, identify and are used to quantify monoclonal proteins.

While international clinical guidelines for myeloma, AL amyloidosis, and Waldenström macroglobulinemia advise on the required M-protein testing for these monoclonal gammopathies, they do not recommend the exact methodology that clinical laboratories should use for the quantification and reporting of M-proteins.

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) subgroup of the Working Group on the Harmonisation of Interpretive Commenting in EQA (WG-ICQA) developed a survey to determine how clinical laboratories that perform routine

protein testing for monoclonal gammopathy quantify, interpret, and comment on M-proteins when reporting results.

The survey was conducted between January and April 2017 and contained 30 questions that addressed specific aspects of the Pre-analytical, Analytical and Post-analytical phases, as well as laboratory demographics of each responding laboratory. Complete responses to all questions were received from 31 countries and included 245 laboratories.

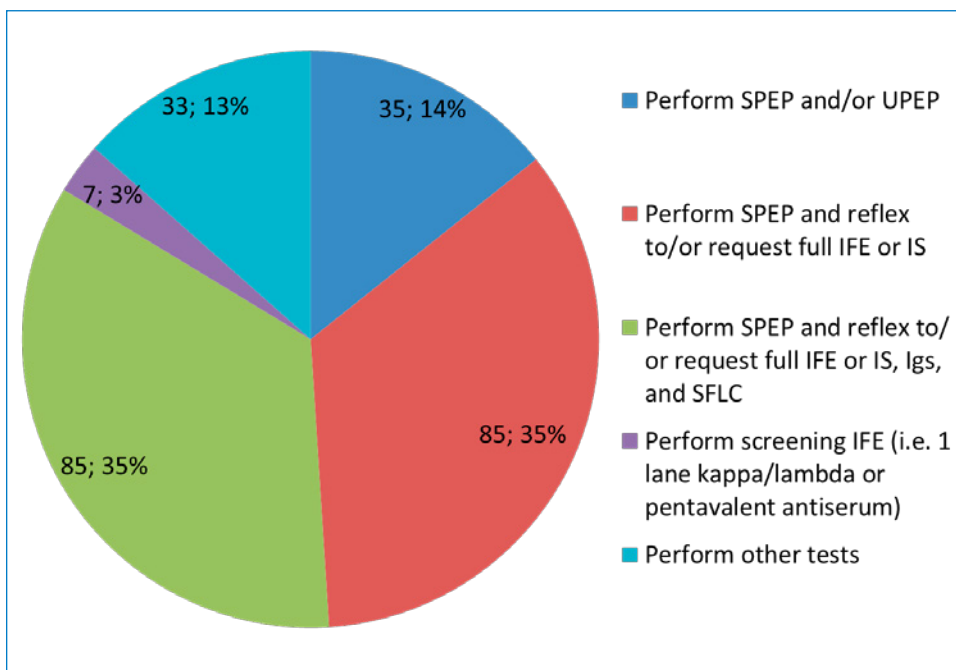
As it was uncertain if some laboratories participated more than once, only completed survey responses have been included in this report.

### RESULTS AND CONCLUSIONS

An example of adherence to clinical guidelines is shown for Question 1 which asked: "If you screen for a monoclonal gammopathy, which of the following describe best your laboratory procedure?" According to the survey the clinical guidelines are generally followed when screening for a monoclonal gammopathy, with 70% of laboratories either reflexing to, or recommending

*Article continued on next page*

**Figure 1** Question 1 responses (number; %)



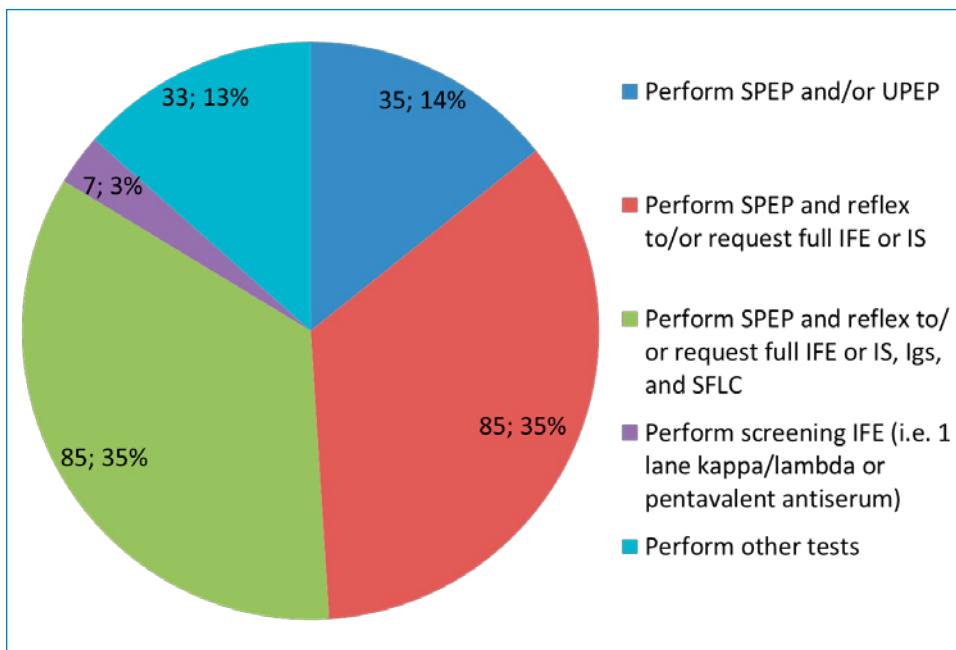
follow-up tests when an M-protein is found on SPEP (Fig. 1).

However, if a light chain (kappa or lambda) is identified for the first time on serum IFE or IS, without a corresponding heavy chain, 19% of labs would not have tested for IgD but would report either a monoclonal light chain or reflex to serum FLC (Question 7).

In response to: “How do you currently quantitate the M-protein migrating in the gamma fraction?” the perpendicular drop (orthogonal, top to bottom) method of gating is the most popular method for quantification of M-proteins in the gamma region on SPEP (Question 11). For monoclonal proteins in the beta and alpha-2 regions, 35% of labs quantitate the M-protein by perpendicular drop (28%) or tangent skimming (7%) whereas 32% report the “Total beta/alpha-2 + M-protein” (Question 16).

Several questions addressed the reporting and interpretative commenting of small bands on SPEP. For example: “How do you report a new, small abnormal band with different electrophoretic mobility from the original M-protein in a patient with a known M-protein?” (Question 24). Only 35% of responses recommended adding a comment when a small band of different electrophoretic mobility

**Figure 2** Question 11 responses (number; %)



from the original M-protein was present. In the case of the band identified as IgG kappa, this may represent the presence of a monoclonal antibody (mAb) and 31% of responses would include the comment: “A new small monoclonal IgG kappa band has been found in the gamma fraction on immunofixation. This could represent a new clone or the presence of a therapeutic monoclonal antibody. Clinical correlation is required”. Currently only 4% of labs perform routine testing to distinguish between an endogenous M-protein and a therapeutic mAb (Question 8) and there is no clear consensus of the preferred method to detect mAb interference (Question 9).

A report and accompanying slides regarding the survey results are now available on the IFCC website at: <http://www.ifcc.org/ifcc-education-division/working-groups-special-projects/wg-icqa/>.

The survey provides a baseline of information from 31 countries doing protein electrophoresis. The quantification and reporting of M-proteins is heterogeneous across laboratories. It is recommended that Laboratory Medicine societies in individual countries work with their clinical haematologists and immunologists to achieve greater harmonisation of methodology and results.

**IFCC WG Harmonisation of Interpretive Commenting EQA (WG-ICQA) subgroup:**

*Jill Tate (AU), Maria Stella Graziani (IT), Maria Willrich (US), Hans Jacobs (NL), Mike Moss (CA)*

## NEWS FROM REGIONAL FEDERATIONS AND MEMBER SOCIETIES



### Certificate workshop on 'Enhancing Quality Control Skills'

by Department of Pathology and Laboratory Medicine  
Karachi, Pakistan



by **Hafsa Majid**  
Chemical Pathology, AKU  
Karachi, Pakistan

Seventy percent of the medical decisions are made based on laboratory results, making it imperative to achieve the highest level of accuracy and reliability of test results. It is essential that laboratorians have good understanding of processes and procedures involved in the laboratory internal quality control. To achieve this, section of Chemical Pathology, Department of

Pathology and Laboratory Medicine at Aga Khan University, Karachi Pakistan conducted a half day workshop on 'Enhancing Quality control Skills' arranged under the auspices of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the Pakistan Society of Chemical Pathologist (PSCP) on May 14th 2018.



Group Photo of Workshop facilitators and organizers

The workshop focused on the understanding of internal quality control (IQC), proficiency testing (PT), identification of errors and running root cause analysis (RCA) for different types of errors. The workshop started with the introduction of all participants followed by a talk by Dr. Farooq Ghani, Service line chief Clinical Laboratory on 'Quality Management in Clinical Laboratory'.

This was followed by interactive lectures by Drs. Hafsa Majid, Senior Instructor Chemical Pathology and Imran Siddiqui, Professor Chemical Pathology, on basic statistics, application of Westgard rules to identify errors and causes of these errors.

Article continued on next page

Dr. Sibtain Ahmed, Consultant Chemical Pathology, facilitated a group activity to enhance and self-assess the understanding gained by participants during a previous exercise of Levey Jennings Chart interpretation.

The second part of the workshop was based on evaluation of PT reports. Framing this part was a talk given by Dr. Lena Jafri, Assistant Professor Chemical Pathology on basic statistics of evaluating a PT surveys, appreciating different patterns consistent with errors, identified in PT reports and RCA to reach the cause. This was followed by another group activity in which participants were given different case studies to assess their understanding, facilitated by Dr. Aysha Habib Khan, Associate Professor and Section head Chemical Pathology.

This workshop was well attended by wide range of enthusiastic participants from more than ten institutes and laboratories of Karachi. Participants included residents, technologists, quality managers, supervisors and pathologists from different subspecialties of Pathology.

Apart from these, auditors involved in performing audits of clinical laboratories also attended this workshop. The participants found the workshop very insightful and comprehensive.

They welcomed these opportunities for more in-depth exploration of quality topics and peer interaction and thanked the organizers for sharing their rich and educational experience.



Group Photo of Workshop organizers and participants

## News from the IFCC Website



### IFCC TF-YS Webinar "Method Verification and Validation in Clinical Laboratories"

The IFCC Task Force for Young Scientists invites you to join in for the sixth Complimentary Educational Webinar: Method Verification and Validation in Clinical Laboratories. Brought to you by the IFCC Task Force Young Scientists, this educational program focuses on good practices around method validation and verification in laboratories. The Calendar is already available.

[Read more](#)





## News from the Romanian Association of Laboratory Medicine (RALM)

2nd Congress of RALM  
9-12 May 2018 – Bucharest, Romania

by Ioana Brudașcă  
RALM President



The 2nd Romanian Association of Laboratory Medicine (RALM) Congress was held between on 9-12 May 2018 in Bucharest. The congress was organized under the auspices of IFCC and EFLM and in collaboration with the Romanian Society of Microbiology, the Romanian Society of Hematology and the Universities of Medicine and Pharmacy of Bucharest, Târgu Mureș, Cluj-Napoca, Iași, Timișoara.

The congress was attended by over 650 participants (medical doctors, scientists and lab technicians working in medical laboratories). Four speakers from abroad were invited to the congress: Prof. Mauro Panteghini (Italy), Prof. Evi Lianidou (Greece), Prof. Janos Kappelmayer (Hungary) and Prof. William Au (China). Most of the Romanian



Clockwise from top: Prof. Evi Lianidou, Prof. Janos Kappelmayer, Assoc. Prof. Ioana Brudașcă - RALM president, Prof. Mauro Panteghini

speakers were teachers at the medical faculties of Bucharest, Cluj Napoca, Târgu Mureş, Timișoara, Iași. The lectures of the keynote speakers provided up-to-date information about various aspects (high sensitivity troponin, liquid biopsy, laboratory monitoring of direct oral anticoagulants, clinical value of genetic testing, inflammatory cytokines, etc.).

As in Romania laboratory medicine encompasses a large area of subspecialties, the scientific programme covered themes in clinical chemistry, microbiology, haematology, genetics, molecular biology, immunology, presented in 41 posters, 17 short oral communications and 22 plenary reports. The posters and the slides for the oral presentations were written in English.

Many of the presentations focused on continuous professional development for laboratory professionals, quality assessment, standardization, technology, instrumentation and method evaluation, performance

criteria of laboratory tests, showing the interest of the participants in the improvement of our professional activity.

During the discussions that followed the presentations, the participants had the opportunity to share their experience and to identify solutions for the scientific or technical issues they are confronted to in their everyday practice.

As our RALM is very interested in motivating young laboratory professionals, many communications and posters were presented by young colleagues, most of them PhD fellows. Two awards were granted, one for the best poster, and one for professional activity.

RALM also initiated this year an internal grant competition for young scientists, consisting in 3000 euros. Four applications were submitted, which were evaluated by experts, and the winner of the competition (Dr. Adina Huțanu from the University of Medicine



Congress participants

and Pharmacy of Târgu Mureş) was announced at the General Assembly.

Conference abstracts were published in a supplement of the Romanian Journal of Laboratory Medicine.

As our profession is in a permanent partnership with the clinical diagnostic industry, during the congress an exhibition of equipment, reagents, supplies, software was organized by 20 companies.

There were also 13 workshops organized by IVD providers, which were an excellent opportunity for the development and transfer of technical innovations to clinical laboratory professionals.

The scientific quality and the diversity of the presentations, the excellent organization, as well as the attracting social programme fully contributed to the success of this scientific and professional event.

## IFCC PROFESSIONAL SCIENTIFIC EXCHANGE PROGRAMME (PSEP)



### My experience at the Hospital Bicêtre

*by Alba Alonso Llorente  
Spain*

Thanks to the IFCC professional scientific exchange programme, and also thanks to the SEQC-ML and Jose Luis Castaño foundation I was able to stay at the molecular genetics, pharmacogenetics and hormonology laboratory of Hospital Bicêtre in Le-Kremlin Bicêtre (France) from March to May with Doctor Céline Verstuyft. This lab is accredited by COFRAC (ISO 15189), number 8-1128 ([site www.cofrac.fr](http://www.cofrac.fr)) since 2012.

I chose this service for my external rotation because of the interesting research projects they were developing regarding psychiatric drugs, but also because of their experience in pharmacogenetics tests performed on the clinical level.

During my rotation, I was able to learn and perform the different methods used in the laboratory for pharmacogenetics tests, such long PCR or allelic discrimination, and also to interpret these results and to give useful information to clinician or researchers that would result in a benefit for the patient.

In the clinical part I was able to learn more about cancerous therapies and their possible fatal effects in patients carriers of deficient variants of the genes TPMT, DPYD or UGT1A1, while the research part was more

related to CYP2D6, CYP2C19 and CYP1A2 variants and their effect in the toxicity in patients treated with psychiatric drugs and possible phenoconversion when taking concomitant drugs.

During my stay, Dr. Verstuyft also proposed me to assist different conferences related to pharmacology to obtain a more open view of the whole support given to the patient, and also the opportunity to visit other hospitals in the region of Ile de France who used different approaches to evaluate the response of patients to drugs.

All in all, it has been a great experience that has allowed me to learn a different way of working in a laboratory, but also the opportunity to achieve an academic knowledge in a field that I was interested in.

I would like to, once again, thank the IFCC for the funds and the creation of this exchange programme, to Céline Verstuyft for all her support, and also to Allison Cardoso and Élodie Dupuis (technicians) for their patience and explanations about the whole technical procedure, and to Dr. Caroline Vigneau-Vitorri, pharmacologist post-doc, without her backing our research project would have been more complicated.

## News from the IFCC Website



### IFCC Handbook 2018 - 2020

We are happy to announce that the 2018 - 2020 edition of the IFCC Handbook is now available. A valuable resource, the Handbook contains comprehensive information about the function and operation of IFCC including: IFCC Regional Organizations, Divisions, Committees and Working Groups; Full Members, Corporate Members and Affiliate Members; contact details; and Statutes and Rules of the IFCC.

Read all the updated information about the function and operation of IFCC in a single online publication!

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## IFCC's Calendar of Congresses, Conferences & Events

### Calendar of IFCC Congresses/Conferences and Regional Federations' Congresses

|                   |  |  |               |
|-------------------|--|--|---------------|
| May 19 - 23, 2019 |  | XXIII IFCC - EFLM EuroMedLab<br><i>Barcelona 2019</i>  | Barcelona, ES |
| Sep 11 - 13, 2019 |  | COLABIOCLI<br><i>COLABIOCLI Regional Congress 2019</i> | Panama, PA    |

*Calendar continued on next page*

|                   |   |  |            |
|-------------------|---|--|------------|
| Nov 17 - 20, 2019 |  | <i>APFCB Regional Congress 2019</i>                      | Jaipur, IN |
| May 24 - 28, 2020 |  | <i>XXIV IFCC WorldLab - Seoul 2020</i>                   | Seoul, KR  |
| May 16 - 20, 2021 |  | <i>XXIV IFCC - EFLM EuroMedLab - Munich 2021</i>         | Munich, DE |
| May 21 - 25, 2023 |  | <i>XXV IFCC - EFLM WorldLab - EuroMedLab - Rome 2023</i> | Rome, IT   |

### Calendar of events with IFCC auspices

|                       |  |                 |
|-----------------------|--|-----------------|
| May 28 - Oct 11, 2018 | <i>Virtual Postgraduate Course in Control of Analytical Quality in the Clinical Laboratory - MODULE I - VIII</i>                           | Online          |
| Aug 4 - 5, 2018       | <i>Course of complete blood count in the diagnosis of anemia</i>   | Mexico City, MX |
| Aug 25 - 28, 2018     | <i>15th Iranian National Congress of Biochemistry and the 6th International Congress of Biochemistry and Molecular Biology</i>             | Isfahan, IR     |
| Sept 3 - 5, 2018      | <i>AACB AIMS 2018 Combined Scientific Meeting</i>  | Sydney, AU      |
| Sept 6 - 7, 2018      | <i>6th Chromatography Mass Spectrometry Satellite Meeting and Inaugural Chromatography Mass Spectrometry Educational Workshop</i>          | Sydney, AU      |
| Sept 6 - 8, 2018      | <i>The 15th Asian Society of Clinical Pathology and Laboratory Medicine</i>  | Ulaanbaatar, MN |
| Sep 13 - 16, 2018     | <i>First Congress of Kosovo Association of Clinical Chemistry</i>  | Prishtina, XK   |
| Sep 26 - 29, 2018     | <i>15th Annual Meeting of the German Society for Clinical Chemistry and Laboratory Medicine - The foundation for diagnosis and therapy</i> | Mannheim, DE    |
| Sep 30 - Oct 3, 2018  | <i>Santorini Conference "Systems medicine and personalised health &amp; therapy" - "The odyssey from hope to practice"</i>                 | Santorini, GR   |
| Oct 3 - 5, 2018       | <i>26th BCLF Meeting and 6th National Congress of MSMBLM</i>   | Skopje, MK      |

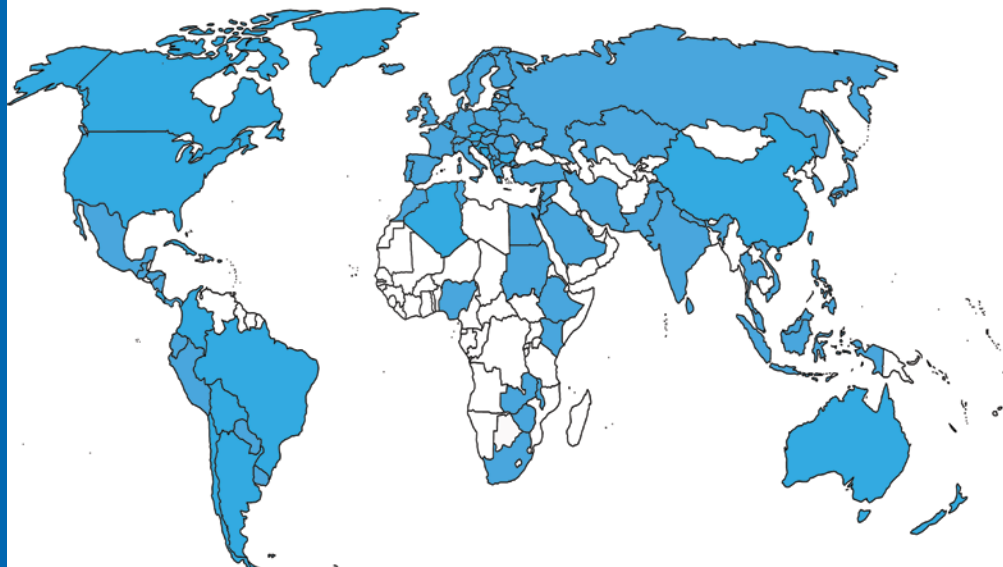
Calendar continued on next page

|                      |   |                    |
|----------------------|---|--------------------|
| Oct 3 - 5, 2018      | <i>IV Russian Congress of Laboratory Medicine</i>   | Moscow, RU         |
| Oct 10 - 13, 2018    | <i>5th EFLM UEMS European Congress in Laboratory Medicine</i>   | Antalya, TR        |
| Oct 11 - 13, 2018    | <i>16th National Congress of Clinical Chemistry</i>   | Alexandroupoli, GR |
| Oct 15 - 20, 2018    | <i>Conference of the Association of Clinical Chemists of Nigeria (ACCN)</i>   | Lagos, NG          |
| Oct 16 - 17, 2018    | <i>2èmes Journées Francophones de Biologie Médicale</i>   | Paris, FR          |
| Oct 17 - 20, 2018    | <i>XIII Ecuadorian Congress of Clinical Biochemistry and IX International Congress of Clinical Biochemistry</i>   | Riobamba, EC       |
| Oct 18 - 19, 2018    | <i>Journées de l'innovation en biologie (JIB 2018)</i>  | Paris, FR          |
| Oct 23 - 25, 2018    | <i>Patologia e Medicina di Laboratorio 4.0</i>  | Acicastello, IT    |
| Oct 24 -26, 2018     | <i>XII National Congress of Clinical Laboratory</i>   | Bilbao, ES         |
| Oct 26 - 30, 2018    | <i>TBS International Biochemistry Congress 2018 / 29th National Biochemistry Congress</i>   | Bodrum, TR         |
| Oct 29 - 30, 018     | <i>5th Congress on eCardiology and eHealth</i>  | Moscow, RU         |
| Oct 30, 2018         | <i>International Conference on Laboratory Medicine "Laboratory Medicine: 25 Years On"</i>   | Padova, IT         |
| Nov 1 - 3, 2018      | <i>LMCE 2018 and KSLM 59th Annual Meeting</i>   | Seoul, KR          |
| Nov 1 - 4, 2018      | <i>2nd International Cell Death Research Congress</i>   | Izmir, TR          |
| Nov 9 - 12, 2018     | <i>18º Congreso Internacional del Colegio Nacional de Bacteriología</i>   | Barranquilla, CO   |
| Nov 13, 2018         | <i>Workshop on Alzheimer's disease "Making the point"</i>   | Prague, CZ         |
| Nov 28 - Dec 1, 2018 | <i>II International Conference of the Bolivian Society of Clinical Biochemistry</i>   | La Paz, BO         |
| Nov 29, 2018         | <i>International Scientific Meeting of the Centre of Metrological Traceability in Laboratory Medicine (CIRME) "Standardization in Laboratory Medicine and Patient Safety"</i> | Milan, IT          |
| Nov 5 - 6, 2018      | <i>4th Annual Meeting, Saudi Society for Clinical Chemistry</i>   | Riyadh, SA         |
| Dec 7 - 8, 2018      | <i>52e Journée de Biologie Praticienne</i>  | Paris, FR          |
| Feb 7 - 8, 2019      | <i>International Congress on Quality in Laboratory Medicine</i>   | Helsinki, FI       |
| Apr 4 - 5, 2019      | <i>10th European Symposium on Clinical Laboratory and In Vitro Diagnostic Industry: 'THE CLINICAL LABORATORY IN THE PREGNANCY MONITORING'</i>                                 | Barcelona, ES      |
| Jun 9 - 12, 2020     | <i>XXXVII Nordic Congress in Medical Biochemistry</i>   | Trondheim, NO      |

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|   |
|---|
| Arab Federation of Clinical Biology (AFCB)  |
| African Federation of Clinical Chemistry (AFCC)                                   |
| Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB) |
| European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)          |
| Latin America Confederation of Clinical Biochemistry (COLABIOCLI)                 |
| North American Federation of Clinical Chemistry and Laboratory Medicine (NAFCC)   |

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**N° 5 – June:** *by mid May*

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**N° 9 – October:** *by mid September*

**N° 10 – November:** *by mid October*

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