Editor: Edgard Delvin Ph.D
CHU Sainte-Justine
Centre de Recherche
3175 Côte-Ste-Catherine
Montréal, Québec
H3T 1C5, Canada
e-mail: edgard.delvin@recherche-ste-justine.qc.ca

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News from Regional Federations and National Associations – Welcome to ALAM

Contributed by Edgard Delvin, Editor

I have the pleasure to announce that The National Association of Medical Analysis Laboratories – ALAM is now the 84th Full Member within the IFCC (IFCC numbering system 02.01.93) has recently joined the ranks of IFCC as full member. The contact person is Professor Smail Belazzoug.

Highlights of the APFCB's Activities in 2009

Contributed by Joseph Lopez, President, APFCB

Membership: The APFCB membership comprises ordinary and 14 corporate members with one affiliate member.

2009-2010 Travelling Lectureship: Dr Samuel Vasikaran of Perth, Australia the Travelling Lecturer has offered the following topics for this Lectureship:

- bone markers and osteoporosis
- eGFR and markers of renal disease
- interpretative commentary of laboratory results.

Dr Vasikaran delivered the Travelling Lecture in November 2009 at the ACBI annual conference in Kochi, India. For 2010, lectures have been planned for delivery in Hong Kong, Mainland China, Indonesia, Singapore and Korea (at the 12th APCCB).

2011-2012 Traveling Lectureship: Dr Angela Wang, a nephrologist from Hong Kong has accepted an invitation to be the APFCB Traveling Lecturer on the topic, "New Inflammatory makers in CKD".

IFCC Visiting Lectureship:The 2008-2009 Visiting Lecturer to the APFCB region, Professor Mauro Panteghini, brought his Lectureship to a close with lectures in Chengdu and Beijing in Mainland China, in November.

APFCB-Beckman Coulter Educational Symposium: Professor Gunther Weiss of Innsbruck, Austria, visited Beijing, Hong Kong, Manila and Ho Chi Minh

City to speak on the topic, "Diagnostic Challenges in Chronic Anaemia's", between June 22-27.

Interpretative Comments Educational Program Report, 2009: Five case reports were circulated. A 3-person review panel assessed the responses. The programme had 46 registrants and a response rate was about 50%. These analyses of results will be undertaken in 2010.

The **IFCC-APFCB-ACBSL Workshop on Laboratory Quality** was held in Colombo, Sri Lanka in April. A one-day workshop on the interpretative commentary of laboratory results was conducted in conjunction with the QA workshop.

The **3rd Asian Project on Reference Intervals Project** organised by Professor Kiyoshi Ichihara, the APFCB Scientific Committee Chair and involving Japan, the APFCB and the IFCC that was initiated in 2008 continued into 2009. A total of more than 3400 individuals from Japan and 9 cities in Asia-Pacific region took part in the study. The analyses of the samples were completed at the end of July. A meeting of project participants to present preliminary results was held in Osaka on 25th September. Publications from the project are expected in 2010.

Membership: PAMET (Philippines) was admitted as a member of the IFCC in November 2009.

APFCB-AACB Scholarship: One scholarship was awarded from the APFCB's Philanthropic Fund to Dr H V Singh from India for the attendance of the Australasian ACB's Annual Scientific Meeting.

APFCB Publications: The 2008 issue of the APFCB News was published and distributed within and outside the APFCB region.

There following scientific publications in 2009 emerged from the APFCB's projects:

1. Shiesh S-C, Hsiao-Mei Wiedmeyer, Kao Jau-Tsuen, Vasikaran SD, Lopez JB and the Laboratory Management Committee for the Asian-Pacific Federation of Clinical Biochemistry. Proficiency Testing of

HbA1c: A 4-year experience in Asian and Pacific Region. Clin Chem 2009; 55: 1876-80.
2. Vasikaran SD, Lai LC, Sethi S, Lopez JB, Sikaris KA. Quality of interpretative commenting on common clinical chemistry results in the Asia-Pacific region. Clin Chem Lab Med 2009; 47: 963-70.

Laboratory Automation Meeting: The AACC-APFCB-Malaysian ACB Workshop on Laboratory Automation was held in Kuala Lumpur on 22nd and 23rd October. The meeting had 6 corporate sponsors and about more than 150 participants.

12th Asian-Pacific Congress of Clinical Biochemistry (12th APCCB), Seoul, Korea, 3-8 Oct 2010: Preparations for the congress are well in progress. Corporate sponsorship is within expectation and the scientific programme was almost completed by the end of the year. The APFCB will host the following scientific sessions that will be organized by Professor Kiyoshi Ichihara:

1. A 120-minute symposium on the "The Asian Project for Joint Derivation of Reference Intervals and Exploration of Diagnostic Evidence for Laboratory Medicine".
2. Co-host a 4 hour workshop entitled, "Educational Course: Multivariate analyses for laboratory scientists".

The IFCC will host the following symposia as part of the main scientific programme:

1. IFCC CPD: Electronic Communication and Distance Learning
2. IFCC SD: Standardization Activities in Endocrinology
3. IFCC EMD: Predictive Medicine: A New Goal For Laboratory Medicine

IFCC-APFCB Draft Agreement: The draft of an agreement between the APFCB and IFCC was actively discussed before being forwarded to the IFCC for its consideration.

APFCB Strategic Plan: Following a suggestion made at the Council Meeting held in Beijing in October 2007, a Task Force was formed to draw up a Strategic Plan for the APFCB with the President as the Chair. The Task Force will hold its first meeting in Perth, Australia, on 30th January 2010.

APFCB Corporate Members provided the following sponsorships during the year 2009:

No.	Company	Activity
1.	BD Diagnostics	IFCC-APFCB-ACBSL Workshop on QA, Sri Lanka Reference Intervals project
2.	Bio-Rad	IFCC-APFCB-ACBSL Workshop on QA, Sri Lanka
3.	Beckman-Coulter	APFCB-Beckman Coulter Educational Symposium

IFCC Grant: As in previous years, the APFCB received a grant of CHF10, 000 from the IFCC for its activities.

Management: The AFPCB is domiciled in Singapore and its office in Singapore handles the management of its financial and regulatory affairs. Despite the increasing level of activity, the APFCB's finances remain healthy. The start of financial year was changed from 1st August to 1st January to coincide the financial year with the start of the annual activity cycle.

"European Education in Laboratory Medicine and Recognition of Professional Qualifications" was held on March 25-27th in the Ministry of Health, Warsaw, Poland. The Conference, under the auspices of IFCC, was organized by the Polish Chamber of Diagnosticians under the leadership of its President Dr Henryk Owczarek, and the Polish Ministry of Health. We had an honor and pleasure to host almost 150 participants from all over the world, mostly from Poland but some from Czech Republic, UK, Montenegro, Austria and Africa.

News from the Netherlands

Contributed by Christine Ruiter, Beleidsmedewerker NVKC Office

In December 2009 the Dutch medical (VAL) and scientific (NVKC) specialists in clinical chemistry and laboratory medicine decided to join forces by signing a partnership agreement. It has been decided to operate under a common name and that all matters in the field of science, quality management, training and education, representation etc. will be dealt with in common effort.

News from the Canadian Society

News from the Canadian Society for Clinical Chemists

Clinical Laboratory Accreditation by Accreditation Canada

The First Two Years of the Programme From a Personal Perspective Part Two: Visit summaries, application of Canadian standards to foreign countries

Contributed by Dr. Maurice Dupras. Translated by Dr. Mary-Ann Kallai-Sanfaçon Editor-in-Chief, CSCC News, First published in the CSCC Newsletter

Visit summaries, application of Canadian standards to foreign countries In the June issue of CSCC News I presented a brief overview of the process of clinical laboratory accreditation. In this issue I will try to summarize my observations and impressions after the first round of visits. These are naturally presented from my point of view. However, since I have participated in twenty of these visits over the last two years, I believe that my observations are based on a fairly broad experience as I have visited laboratories ranging from the very small in local community hospitals to large regional centres in three provinces and two countries.

First observation: despite the reservations that I have expressed in Part 1 concerning the political aspects of the accreditation dossier, I was delighted to observe that both the laboratory directors and managers as well as the personnel are convinced of the importance of quality assurance programmes and are resolved to apply them as fast as possible to the extent that they are given the necessary resources. At the end of each of my visits I asked the personnel the following question: "Do you believe that the accreditation process is really useful or do you think that it is a gigantic and useless accumulation of paperwork?" In fact I never received a negative response concerning its usefulness. This means that the initial step of sensitization to the process was a success. It would therefore be a pity to not take advantage of this and to lose the momentum thus created.

It should also not be forgotten that all the laboratories that we visited were being evaluated for the first time. We could therefore not expect that they would all pass with flying colours the first time around. And, in actual fact, their performances were not the greatest when compared to the global evaluation of their institutions except for a few noteworthy exceptions. It has to be realized that presently we are still in the process of learning, of sensitizing everyone to the importance of total quality assurance programmes, of their development and application. With some

rare exceptions, laboratories have to first of all concentrate on putting in place the framework for accreditation: basic SOPs, required documentation, plans for continuing education for personnel, etc. They had neither the time nor the resources to prepare SOPs describing higher levels of laboratory functionality: indices of quality assurance, programmes for quality assurance improvement, a programme for evaluation of personnel competency, logging of nonconformity incidents and the measure taken to rectify them, etc. Generally speaking, documents dealing with purely analytical aspects of the laboratory were well organized (SOPs were pretty complete, like those for quality control, etc.) Where there were deficiencies was with SOPs on the quality of service to laboratory users. The aspect that has to be addressed is user satisfaction in terms of turn-around-time, accessibility of services, reliability of analytical reports, etc. I also found that in some sectors even the notion of quality control (internal and external) leaves to be desired. The most notable exception is biochemistry where quality control has been standard practice since many years.

However, the most disturbing observation made by us, as Accreditation-Canada visitors, were the numerous deficiencies in workplace safety and health. The security of everyone entering a hospital be it patients, visitors or personnel is of the utmost importance for Accreditation-Canada and so it is essential that this oversight be rectified. Here are some examples: secure and restricted laboratory access, the establishment of a workplace health and safety programme including education of personnel, verification of protective equipment, the naming of a safety officer other that the chief technologist where the size of the laboratory permits and the implantation of a WHIMS programme. Several laboratories have insufficient space putting the safety of personnel in jeopardy.

Transfusional services' quality assurance programme was already fairly well established even before the initiation of Accreditation-Canada's programme. The tainted blood scandal and the intense reaction ($$) of the authorities resulted in a "clean-up" of this sector. Procedures are standardized, documents are complete and incident reporting is exhaustive. What has been done for blood banking could set the example for the other laboratories for years to come. This clearly demonstrates that when there is a will and the appropriate resources, anything is possible. It is therefore not surprising that we found little nonconformity in tranfusional services.

One of the invaluable benefits of these site visits that should not be underestimated is the opportunity that it gave to many hospital administrators: hospital CEOs, DPSs, DHSs and directors of nursing, who make up the teams of visitors, to appreciate the laboratories and their staff. They now all have a better understanding of what we do in our "mysterious" laboratories and are able to appreciate the complexity and difficulty of our operation. As well, these visits gave an opportunity to laboratory professionals to interact with their co-workers from other sectors of the hospital and to better appreciate their role. Too often we are hunkered down in our labs and forget the "big picture". We tend to underestimate to difficulties of Administration to meet their many objectives while at the same time obliged to live up to the rigid standards fixed by the many agencies responsible for overseeing the maintenance of quality (like Accreditation-Canada!).

I also had the opportunity to carry out an accreditation visit in a private hospital in Saudi Arabia. To say that this institution was not lacking for money would be a gross understatement. Before the visit we asked ourselves the following question: given that their resources are essentially unlimited, what quality assurance system would they have in place? What priority would they have given to it? In Canada when we read an SOP on quality assurance from one of the laboratories that we visit, we inevitably find a sentence like"…we are committed to give the best service possible with the resources available to us….". It must be realized that the key word here is not *quality* but *resources.* It therefore comes as no surprise that we found there an exceptional quality assurance programme, much superior to what we have found here. Considering the enormous resources dedicated by this hospital to the acquisition of the most advanced diagnostic equipment (PET scan etc.), we expected to find the laboratory equipped with the latest in robotics and instruments. However, this is not what we observed: of course the instruments were adequate, but nothing to write home about. What was particularly impressive was the number of personnel: many professionals, many technologists and the innumerable hours and effort that were dedicated to implanting a quality assurance programme that was practically faultless. The implication of the professionals, particularly the pathologists, in the support and development of the quality assurance programme was remarkable. The priority given to quality was genuine and not just lip service. This is a radical departure from the attitude of our Canadian clinical laboratories, where too often the priority is given to technology, performance, administrative efficiency and where the quality assurance programme, at best plays a modulating

role by fixing the limit at which overproduction could reduce the quality of the work performed. This is a complete reversal of priorities.

What direction should the Accreditation-Canada survey programme now take and what will be the impact on the organization of diagnostic services? There are several options. Could it be a gradual transition to a true laboratory accreditation programme either independent or ISO 15189? Could it be a programme with teeth that would penalize laboratories with serious non-conformity issues that could jeopardize the well being of the population served? Could it be the granting of a permit of operation dependent on a satisfactory level of performance? Would there be a system of oversight and coaching of sub par laboratories by other organizations? Would these laboratories close with the centralization and regionalization of services in order to maintain a better control? Would the accreditation programme be expanded to include other diagnostic services and in the process diminish the importance of the evaluation of laboratory services in relation to other sectors? This remains to be seen. One this is certain, the time has come to reevaluate the programme, its content, its methodology and its objectives.

News from the Royal Belgian Society of Clinical Chemistry

Contributed by Professor Jean-Pierre Chapelle, IFCC representative for the RBSCC

In 2008, the Royal Belgian Society of Clinical Chemistry (RBSCC) organized its National Symposium on the following theme : Guidelines for cost effective use of Clinical Chemistry. This meeting was held in Grimbergen (Brussels) on April 25th, 2009. A joint meeting of the RBSCC and the Belgian Society of Clinical Biology (BSCB) took place in Mont Godinne Hospital (Namur, Belgium) on October 17th, 2009. The main topic of this meeting was Laboratory investigation of renal diseases.

On March 27th, 2009, the Euregio Conference of Clinical Chemistry and Laboratory Medicine, a joint organization of the Universities of Liège (Belgium), Maastricht (The Netherlands) and Aachen (Germany) was held in Liège under the auspices of the RBSCC.

The next national meeting of the RBSCC will be held in Grimbergen (Brussels) on April 22nd 2010 with, as main topics, developments in allergy and mass spectrometry applications in Clinical chemistry.

CLSI Promotes Global Harmonization of Clinical Laboratory Practices

The Clinical and Laboratory Standards Institute (CLSI) is a proven leader in the field of laboratory standards and guidelines-dedicated to developing best practices in clinical and laboratory testing and promoting their use throughout the world. CLSI is a volunteer-driven, membership-supported, nonprofit organization that promotes the development and use of voluntary standards and guidelines through a unique consensus process that involves stakeholders from health care professions, government, education, and industry. CLSI links professionals from around the world with a common purpose and mission.

Ferruccio Ceriotti, MD, of Diagnostica E Ricerca San Raffaele in Milan, Italy, an International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) member and CLSI volunteer, agrees that the CLSI consensus process is valuable. He says, "I think the international participation on CLSI committees is important because it ensures that perspectives that may be different from those of the United States are represented. CLSI manages the process of collaboration and consensus quite well, which is reflected in the excellence of the results."

CLSI documents serve the medical laboratory community in several ways. The guidelines outline a pathway to standardization of laboratory practices that serves to improve quality, safety, and consistency, and at the same time, contains costs. Quality patient care begins with an accurate lab test, and CLSI documents lay the foundation for meeting that objective. Laboratory professionals use CLSI guidelines to meet requirements for regulatory compliance and accreditation. This is possible because regulatory agencies and accrediting bodies recognize the value of implementing CLSI standards and guidelines in establishing best practices that meet regulatory requirements. In addition, CLSI volunteers participate in Global Health Partnerships with the goal of improving health care around the world-specifically in resource-constrained countries that are bearing a heavy burden of disease.

CLSI documents do more than just serve as instruction manuals for laboratories; they also provide scientific explanations for procedures, and connect theory to practice for professionals. They also help professionals keep current with new technologies in areas such as molecular methods and point-of-care testing. Graham White, Associate Professor, SA Pathology, Flinders Medical Centre, Australia, and a CLSI volunteer, explains, "The regular appearance of new topics and updated editions of published documents in the CLSI library highlights the rapid pace of expansion and change taking place in laboratory medicine. CLSI documents provide theory and evidence that underpin the practical guidance. In this way, CLSI documents are not just recipe manuals for the bench, but they also educate laboratorians with a scientific understanding of the 'why' as well as the 'how.'"

International Focus and Shared Goals

IFCC and CLSI are proud of their nearly decade-long partnership aimed at promoting global harmonization of clinical laboratory practices. The partnership has lead to the development of several consensus standards and guidelines that meet the goals of all CLSI documents to reflect a global perspective, help to improve the quality of laboratory results, and ultimately improve patient care. The partnership of IFCC and CLSI grew out of the recognition of shared goals and a mutual focus of interest. IFCC's involvement in CLSI's projects is one of the many important relationships with organizations and societies in the health care field that CLSI supports to ensure that a broad international perspective is maintained in its products and services. In addition, both organizations are dedicated to assisting developing countries in improving analytical results and helping those nations learn about better and more efficient approaches to clinical chemistry and laboratory practice.

Graham White notes the growing importance of consistency in clinical laboratories worldwide, saying, "Increasing mobility of patients and doctors within and between health care systems, and expanding use of international clinical guidelines for diagnosing and managing disease, are increasing the need for clinical laboratories to provide, for any given test, high quality results that are comparable over time, regardless of the method and laboratory used. The collaborations between CLSI and IFCC bring together the broadest available expertise to generate unified best practice evidence-based guidelines, procedures, and documents that, when widely implemented, provide the practical framework for achieving high quality consistency across routine clinical laboratories, wherever they are located."

IFCC and CLSI have also partnered with the National Institute of Standards and Technology (NIST) to sponsor the *IFCC/NIST/CLSI Robert Schaffer Award for Outstanding Achievements in the Development of Standards for Use in Laboratory Medicine*. Professor Lothar Siekmann, PhD, was selected to receive the first award, which honors an individual who has made unique contributions to the advancement of reference methods and/or reference materials for laboratory medicine. Dr. Siekmann is Professor of Clinical Chemistry of the Medical Faculty of the University of Bonn, Germany, and Director of the Reference Laboratory I of the German Society of Clinical Chemistry (DGKL).

IFCC/CLSI Documents

There are several joint IFCC/CLSI documents in the CLSI library that demonstrate the benefits of an international approach to clinical chemistry. Examples include the following:

- C28-A3 - *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline-Third Edition* contains guidelines for determining reference values and reference intervals for quantitative clinical laboratory tests.
- C49-A - *Analysis of Body Fluids in Clinical Chemistry; Approved Guideline* provides guidance for the application of widely available measurement procedures for testing body fluids and for reporting and interpreting those results.
- X05-R - *Metrological Traceability and Its Implementation; A Report* provides guidance to manufacturers for establishing and reporting metrological traceability.
- EP17-A - *Protocols for Determination of Limits of Detection and Limits of Quantitation*; *Approved Guideline*provides guidance for determining the lower limit of detection of clinical laboratory methods, for verifying claimed limits, and for the proper use and interpretation of the limits.

This is just a partial list of the types of useful projects that IFCC and CLSI have produced.

Become a Member of CLSI

There are many ways to become a part of the CLSI membership community. CLSI has several membership options to meet the needs of organizations, professional

societies, and associations. CLSI members consist of organizations rather than individual members. Membership in CLSI ensures that members' needs are addressed in the standards and guidelines they use daily. Additionally, membership provides the opportunity to network with representatives from government, industry, and the health care professions, as well as colleagues in related disciplines while working collaboratively to develop solutions to relevant issues. Membership dues help support standards and guidelines that directly impact the delivery of quality patient care. All members receive a savings of up to 50% on standards and guidelines.

Volunteering with CLSI is a way to join the more than 2, 000 experts from around the world involved in the development of documents using the consensus process. Graham White believes his time as a CLSI volunteer has been rewarding, adding, "The value of an individual's expertise can remain local unless harnessed and made available to the global clinical laboratory community, and major enablers of this are professional societies such as CLSI and IFCC. By offering volunteers many opportunities to contribute their expertise in participating in the development and/or revision of consensus standards and guidelines, commenting on draft documents, participating in presentations on implementation of best laboratory practices, and in many other ways, laboratorians can significantly contribute to the advancement of their professional discipline and the improvement of global health." Visit www.clsi.org for more information about membership and to learn more about the more than 200 products offered by CLSI.

Welcoming new corporate members

I have the pleasure to announce that the following have joined the ranks of IFCC as Corporate Members:

Sentinel CH. Spa

Sichuan Maker Biotechnology Co., Ltd Professor Zhenhua Yang, Contact person

Agappe Diagnostics Ltd Professor Jon Thomas, Contact person

Edgard Delvin PhD, FCACB, FACBEditor