EDITORIAL: LABORATORY MEDICINE – A CHALLENGE FOR THE FEDERATION

During the last decades advances in biomedical science and communication technology have created new expectations in healthcare, in service and among healthcare professionals. By providing accurate information about their health status, patients become empowered customers. This development enables the individual to become more informed about his current status, and consequently increases the individual's responsibility to manage his own health. Having access to more information, patient demands might increase or at least diversify. In response to this development, we should not lose sight of essential humane values, considering that all citizens do not have the same access to basic health care information and services - and even if they would, one has to understand that not all individuals have the same problem solving capability. In this changing environment, the traditional concept of Clinical Chemistry and Laboratory Medicine moves toward patient care and health management. Laboratory professionals increasingly deal with prevention, detection and monitoring of diseases and treatments. The ever-growing number of clinical tests and the complexity of data from investigating normal and abnormal gene forms and their expressions will force us to manage and interpret these observations through bio-informatics tools and to share this knowledge with clinicians. Accepting this challenge, laboratory professionals will gain new competency and responsibility, becoming progressively valuable partners to both patients and clinicians.

The human genome project is completed; yet there are many questions related to cellular regulation and function that still remain unsolved. Diagnosis of diseases might evolve from investigating body fluids to the examination of cells. Cell functions triggered and regulated by numerous proteins and mediators, influenced by biochemical and physical stimuli will become key elements for diagnosing diseases. Determination of molecular fingerprints will allow risk assessment for a disease on individual basis. Pharmacogenetic profiling will lead to custom-tailored drug regimes that reduce toxic side effects and ultimately enhance clinical and cost benefit. New technologies like mass spectrometry, flow cytometry and PCR will support this development. Chip-information on cellular functions will be directly communicated to the Clinical Chemist who will integrate these results into the overall report. With these future aspects in mind the professional skills of laboratory staff will be challenged towards cellular, genome, proteome and metabolic based laboratory medicine.

Modern computer systems and multi-functionality of new analysers will provide opportunities for improving laboratory organisation, efficiency and communication. By shifting the routine mass analyses to fewer workstations using on-line communication
with the laboratory information system, the workflow will be organized more efficiently. Reducing the number of internal processes, the workload for the laboratory workers, the turnaround time and costs for mass analyses become key aspects of this reorganization process. As a result the available capacity and resources can be used for implementing technological innovations, expending the diagnostic profile and competence of a clinical laboratory. By introducing new technologies, modern concepts for request and the usage of laboratory tests will be developed in order to compensate for higher laboratory expenses. The laboratory report (numbers, figures) will contain a written interpretation that either supports or refutes the clinical diagnosis. Integrated computer systems will assist laboratory professionals in the interpretation of increasingly complex test results.

The inter-disciplinary clinical consulting process will expand laboratory obligations by individualizing your services. Integration of point of care devices and the exchange of data with diagnostic-medical centres through telecommunication will allow the monitoring of home care patients. By providing patient care diagnostic expertise, the diagnostic laboratory specialists will be qualified partners in the health care system of the future. There will be a fostering of active interaction in a patient oriented environment, which demands interdisciplinary knowledge as well as willingness to accept responsibilities. The diagnostic laboratory will prosper by showing flexibility. To reach this goal one has to appreciate the need for continuous training and education within our discipline.

These expectations also stress the IFCC to change towards a more multidisciplinary federation building on its historic strength. Like in the past IFCC has to be considered as the international forum of diagnostic laboratory professionals. The federation and its membership are facing new challenges and will be forced to expand their expertise in order to retain their supremacy in scientific projects and programmes for continuous education and training. In order to implement some of the new areas mentioned above integration of experts “fresh blood” beyond the traditional concepts of Clinical Chemistry on a national and an international basis is needed. This IFCC evolutionary process was successful so far by collaborating with other international organisations. However in the future we should put some thoughts in broadening the horizon of the IFCC national societies and their federation.

Virtually yours.

**Mathias M. Müller**

IFCC President
Institute of Laboratory Diagnostics, Kaiser Franz Joseph Hospital, Vienna, Austria
More than 260 clinical laboratory professionals from 10 countries attended the 5th National Congress of Clinical Pathology CONAPAC’2004, which took place at Hotel Nacional, in Havana City, CUBA, from September 29th to October 1st, 2004.

During the Congress 56 presentations were given as lectures, round tables and symposia, as well as 291 posters. Simultaneously, the EXPOLAB’2004 showed the most recent products and laboratory technology from 4 national and 6 foreign In Vitro Diagnostic companies.

Among Congress activities was the 2nd International Symposium on “Selected Topics in Laboratory Medicine”, dedicated to the Canadian Society of Clinical Chemists (CSCC) and with the participation of four of its members. In this Symposium the SCPC honoured its association with CSCC by presenting a plaque. This acknowledged the continuous support of the CSCC to the development of Clinical Laboratory Speciality in Cuba through the 10-year-old twinning agreement between both national societies. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) promoted this relationship.

Dr. Daniel Mazziotta, member of the Executive Board, represented IFCC while the Latin American Confederation of Clinical Biochemistry (COLABIOCLI) took part through its current President, Dr. Norberto Cabutti. Both personalities were appointed Honor Members of the SCPC. Prof. Guillermo Ruiz Reyes, de México, was appointed Correspondent Member of the Cuban Academy of Sciences.

The SCPC EB also had official meetings with CSCC, IFCC and COLABIOCLI representatives from which important agreements were achieved.

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**IUPAC PRIZE FOR YOUNG CHEMISTS**

**IUPAC Prize for Young Chemists**

*Supporting the future of chemistry*

The encouragement of young research scientists is critical to the future of chemistry. With a prize of USD 1000 and paid travel to the next IUPAC Congress, the IUPAC Prize for Young Chemists encourages young chemical scientists at the beginning of their careers. The prize is based on graduate work and is given for the most outstanding Ph.D. thesis in the general area of the chemical sciences, as described in a 1000-word essay.

**Call for Nominations:** Deadline is 1 February 2005.

For more information, visit [www.IUPAC.org/news/prize.html](http://www.IUPAC.org/news/prize.html) or contact the Secretariat by e-mail at secretariat@iupac.org or by fax at +1 919 485 8706.
Following a funding competition in the summer of 2004, the Canadian Genetic Diseases Network is pleased to announce the awarding of $1.47 million to research projects headed by two senior CGDN scientists.

It is well recognized that many health problems, including cardiovascular disease, cancer, diabetes, obesity and osteoporosis, that contribute to the economic and social impacts of disease have significant genetic components. CGDN investigator, Dr. Francois Rousseau of the Centre hospitalier universitaire de Québec and Université Laval, is leading a team that will address the “translation gap”, or how despite the fact that in the past decade, Canada has invested approximately $600 million in human genetic research in the past decade, the use of those discoveries in clinical practice is still relatively low. Little research has been undertaken to determine how these discoveries can be translated into practice and therefore improve health.

The team will identify and validate new genetic tests and genetic laboratory approaches, study their cost effectiveness and develop tools to increase the efficiency of their evaluation and implementation into Canadian health care. CGDN has committed $512,000 to this project.

"This commitment from CGDN, which is allowing us to create a unique pan-Canadian consortium on translational research in genetic laboratory services, will place Canada at the forefront of this field worldwide by allowing us to tackle it with a systematic approach and a broad range of expertise,” said Dr. Rousseau. “This should definitely impact Canadians and the Canadian health care system as it will help us to harvest the benefits from the Human Genome Project in a cost-effective manner.”

Dr. Rousseau’s team is made up of 17 principal investigators, 21 collaborators and 5 national and international partner organizations with expertise in fields including laboratory medicine, clinical research, epidemiology, health economics, public health, decision making, primary care and knowledge transfer.

In addition, CGDN awarded $960,000 to a team of scientists led by Dr. Philippe Gros, a CGDN investigator at the McGill Centre for the Study of Host Resistance. The team will study tuberculosis, diarrheal diseases, coronavirus and malaria, four major threats to global health that have made dramatic comebacks due to antibiotic resistance and the lack of efficacious vaccines.

According to World Health Organization statistics, over 3 million people died from malaria and tuberculosis combined in 2002. Malaria is Africa’s leading cause of death in children under five years of age and kills one African child every 30 seconds.

The scientists will implement a strategy of identify genes and proteins associated with resistance and susceptibility to infection in humans and animal models and pathogen-associated virulence determinants that together determine disease on-set, progression
and outcome of infection. It is hoped that this study will identify new avenues for vaccine development.

The research team is made up of world leader in the field of genetic susceptibility to infection in humans including Drs. Erwin Schurr, Marcel Behr, Ken Morgan, Danielle Malo, Samantha Gruenheid, Silvia Vidal and Mary Stevenson of McGill University and Dr. Kevin Kain from the University of Toronto.

THE CHRONICLES OF A BELGIAN CLINICAL CHEMIST

Contributed by Dr Damien Gruson, IFCC News WG

One month ago I was taking my train in Bruxelles-midi station to go to Paris for the International days of clinical biology (J.I.B), the place to be for a French speaking biologist. After 2 or 3 transitional years, the J.I.B congress grows again more and more popular, become the biggest laboratory medicine event in France and try to compete with MEDICA in Düsseldorf (end of November). Ten days before this congress in CNIT la Défense, there was another French speaking congress, named CORATA, focused on immunoassay, proteomics and laboratory consolidation. CORATA took place in the congress centre of the science city of La Villette, also in Paris. In spite of a good scientific program (French tendency in proteomic technologies, new BNP assays, new trends for BNP testing – additional prognostic value in coronary syndrome, state of BNP in renal failure -, laboratory immunoassay consolidation) only few sessions were successful. May be these two important French laboratory medicine congresses are too close in the same time period. So, Paris is, and will stay forever, a very special city for me, because I had the chance to study a part of my biochemistry in the department of Pr. A. Legrand, to meet a wonderful laboratory team in le Kremlin Bicêtre, to do my first laboratory assays (BNP for example) and to learn more about paediatric biochemistry and mucoviscidosis.

After my short train travel (only one hour between Bruxelles and Paris), I arrived in the CNIT la Défense for the congress, did my registration and after few steps I realized that I was a lucky man. Why was I so lucky? Because I met one more time my old friend, BNP. Once again, like a movie star, my old friend was everywhere and everybody listen to him for this congress time.

Of course BNP is not the shortening for Banque Nationale de Paris or for Bicêtre National Peptide. It is so well known that BNP is used to abbreviate the Brain Natriuretic Peptide or B-Type Natriuretic Peptide. BNP had a little brother Nt-proBNP (N-terminal fragment of the pro-hormone BNP, the bio-inactive part), also becoming a star for cardiac diseases diagnosis. After Roche Diagnosis, DPC and Dade Behring try now the Nt-proBNP experiment and bough the patent.

BNP/Nt-proBNP was one of the most popular subjects during the national day of the Belgian Clinical Chemistry Society in October, during the French immunoassay congress CORATA and during the JIB in Paris. What could we hold about this popular diagnostic test? Actually, we could recognize the diagnostic, prognostic values of BNP in heart failure management and its capacity to monitor effectiveness of the treatment in this cardiac pathology. So, BNP clinical value is well established, as same as troponins in acute coronary syndromes. One other important point about BNP and Nt-proBNP is
the very important economical issue for hospitals, laboratory, BNP/Nt-proBNP manufacturers and for the patient. A rational good use of BNP will reduce the patient hospital stay and the cost of diagnosis and treatment. But BNP testing remains expensive. For example, In Belgium, there is no reimbursement for BNP testing and patient has to pay 35 euros for a single BNP test. Actual laboratory literature is full of articles about economical issues of BNP testing and a research on the web will give you all financial consequences of BNP for healthcare systems.

Another important point, underline in the September Clinical Chemistry’s edito by Allan S. Jaffe (*why we don’t know the answer may be more important than the specific question*), is that BNP analytical issues are not really known. Only few papers exist about stability, CVs, RCV and other matrix than EDTA possible use for BNP testing. Effectively, BNP often need for testing an EDTA tube, additional to the common tube used for cardiac markers testing (lithium heparinate or serum), and this EDTA tube is a “heavy” pre-analytical condition for patient, laboratory and emergency unit. In the other hand, used of Nt-proBNP is more easy because its needs a serum tube and could be associated with other biochemistry tests done on same serum tube, like us-CRP, troponine T….

In spite of a well recognize clinical value, there is an effort to do in standardization for BNP/Nt-proBNP testing and in the development of more accurate analytical evaluations for a better understanding of BNP/Nt-proBNP assays.

Standardization is THE actual word for the immunoassays world and a session in CORATA about consolidation in laboratory insists on this current laboratory problem. Immunoassay consolidation is a key issue in laboratory productivity enhancement and an actual conclusion is that is difficult or impossible to consolidate immunoassays in only one platform. May be it could be a good idea to organize in Europe a congress or symposium on standardization and consolidation solutions for laboratory immunoassays as same as the automation session which took place this year in Amsterdam and created by AACC.

Lack of standardization in BNP/Nt-proBNP testing is an example of the work pending for laboratory immunoassays and consolidation solutions in this field.

Remembering my travel between Paris and Bruxelles in November, I could say that high speed train north Europe line (a union between TGV, Thalys and Eurostar) is a good example of standardization and harmonization and a good way to see my clinical chemist’s friends in Paris.

To conclude this few words and my IFCC year, I would like to thanks Ellis Jacobs for his wonderful job as editor of the news and Andrew Wooton for the CPD coordination. I had note that CPD division hold the conclusions of the IFCC general conference in Sousse and will try to follow and cover as best as possible all IFCC activities in 2005, another important year in IFCC history with the European congress in Glasgow, the join venture with AACC in Orlando and the board elections. Finally, I would like to thanks all the Belgrade clinical chemistry team (especially Sandra and Nada Sing), my “second mum”, Rosa Sierra Amor and Dr Bernard Gouget for their every moment support and their prettiness with a Belgian man.
On 1 January 2005, NCCLS will officially change its name, becoming Clinical and Laboratory Standards Institute (CLSI). Glen Fine, MT(ASCP), MS, MBA, the organization’s newly appointed Executive Vice President, explains, “The name change is not a shift of our core organizational mission to develop and distribute standardized best practices for the healthcare and medical testing community. Instead, it is a better reflection of our organization’s expanded standards-development activities and global membership base.”

CLSI is a nonprofit organization that relies on its members and volunteers for the development of voluntary consensus standards and guidelines. For more than 35 years, the organization has become the global healthcare community’s leading resource for standardized best practices. Mr. Fine says, “CLSI’s gold standards are invaluable tools that allow our distinct constituencies to meet their responsibilities with efficiency, effectiveness, and global acceptance.” He adds, “Our organizational values will remain the same—only our name is changing.”

The organizational name change decision came after an extensive brand identity study was conducted in 2003. Based on the results of this extensive market research, the organization found that a name change was imperative and that the name should more accurately represent the organization today and in the future. The organization’s Board of Directors asked for feedback on potential new names from the membership base, volunteers, and key stakeholders. From the results of this feedback, the Board presented Clinical and Laboratory Standards Institute as the organization’s new name. The membership delegate vote to implement the organizational name change, by amending the Articles of Incorporation and Bylaws, ended with approval on 19 July 2004.

The announcement of delegate approval of the new name was a pivotal moment in the evolution and recognition of Clinical and Laboratory Standards Institute. It was decided that the well-recognized logo would be retained. In addition, the transitional statement, providing NCCLS standards and guidelines, ISO/TC 212 standards, and ISO/TC 76 standards, will be used in communications and documents for an extended period of time in order to associate the new name with the established name recognition of NCCLS.

Partnering for the Development of Global, Harmonized Consensus Standards

NCCLS/CLSI and IFCC have a long-standing partnership agreement with the mutual goal of providing worldwide consensus standards. Promoting harmonization and a sense of global cohesiveness in standards-development is a key strategic priority for both organizations. In September 2001, NCCLS and IFCC signed a Memorandum of Understanding (MOU), with the intent to improve the global applicability of reference materials and voluntary consensus standards; to improve, implement, and encourage their use among clinical chemistry and medical laboratory communities worldwide; and to collaborate and develop joint projects. In March 2004, an agreement, which strengthened the partnership, was expanded to include: implementing electronic
communication to minimize travel for standards-development participants; and coordinating standards activities between the organizations.

Currently, NCCLS/CLSI and IFCC collaborate on the development of 12 joint projects. IFCC nominates and supports the participation of its representatives on the subcommittees of NCCLS/CLSI-IFCC cooperative projects. There are approximately 15 IFCC-supported volunteers working on the projects. Collaboratively, NCCLS/CLSI representatives participate on two IFCC projects.

Joint projects include the following:

**Measurement of Free Thyroid Hormones** (C45) addresses analytical and clinical validation of free (nonprotein-bound) thyroid hormone (FTH) measurement procedures.

**Application of Biochemical Markers of Bone Turnover in the Assessment and Monitoring of Bone Diseases** (C48) provides information on how bone markers can be applied to facilitate and harmonize data interpretation and help to answer clinical questions in the area of bone diseases.

**Analysis of Body Fluids in Clinical Chemistry** (C49) is a project in development for the application of widely available analytical methods for testing body fluids and for reporting and interpreting those results.

**Mass Spectrometry in the Clinical Laboratory** (C50) is a project in development that provides a series of guideposts, references, standards, and quality assurance markers to ensure ease of implementation and correct operation of an NMS system for the many applications in the clinical laboratory.

**Protocols for Determination of Limits of Detection and Limits of Quantitation** (EP17) 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.

**Body Fluid Analysis for Cellular Composition** (H56) is a project in development that provides recommendations for the collection and transport of body fluids, numeration and identification of cellular components, and guidelines for qualitative and quantitative assessment of body fluids.

**Performance of Single Cell Immune Response Assays** (I/LA26) contains methods of intracellular cytokine evaluation, major histocompatibility complex (MHC) tetramer quantitation, and enzyme-linked immunospot (ELISPOT) technology. This document provides basic aspects of specimen collection, transport, and preparation, in addition to quality assurance and test validation approaches.

**Diagnostic Nucleic Acid Microarrays** (MM12) is a project in development that provides recommendations for many aspects of the array process including: a method overview; nucleic acid extraction; the preparation, handling, and assessment of genetic material; quality control; analytic validation; and interpretation and reporting of results.
Collection and Handling of Specimens for Molecular Methods (MM13) is a project in development that provides guidance related to proper and safe biological sample collection and nucleic acid isolation and purification. These topics include methods of collection, recommended storage and transport conditions and available nucleic acid purification technologies for each specimen/nucleic acid type.

Proficiency Testing for Molecular Methods (MM14) provides guidelines for a quality proficiency testing program, including reliable databases; design control in the choice material of analytes; good manufacturing processes; documentation procedures; complaint handling; corrective and preventative action plans; and responsive timing of reports.

Determining the Clinical Utility of Genetic Tests (MM15) is a project in development that provides guidance on methods by which to assess the analytical and clinical validity, and clinical utility, of molecular genetic tests. Consideration is given to a variety of contexts, including diagnostic testing, newborn screening, prenatal testing, presymptomatic and predispositional testing, carrier testing, and pharmacogenetic testing.

Point-of-Care Connectivity (POCT1) provides the framework for engineers to design devices, workstations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data concentrators, and laboratory information systems from a variety of vendors.

Total Plasma Homocysteine
The aim of this project is to produce a homocysteine calibrator that will be internationally accepted for all tHcy assays. Methods available for tHcy analysis are either commercial kits or in-house laboratory methods. Commercial kits include enzyme immunoassay [EIA] and fluorescence polarization immunoassay [FPIA], both using an aqueous solution of $S$-adenosyl-homocysteine as calibrator. Aqueous-based, in-house standards are widely used for HPLC and GC-MS methods.

Immunosuppressive Drug Monitoring
The goal of this project is to review current consensus documents on monitoring cyclosporin, tacrolimus, sirolimus, and mycophenolic acid, and to identify areas which require updating or rewriting. Prepare review style articles which can be used by medical laboratory workers, pharmacists or clinicians as reference documents on best practice for monitoring these drugs, and as guides to the interpretation of the results.

A joint report in development, Metrological Traceability and Its Implementation (X5-R), will provide guidance to manufacturers of IVD devices and associated materials (e.g., calibrators) for compliance with ISO 17511 and ISO 18153. It will explain traceability and its place in the clinical enterprise, and will include information regarding validation of comparisons, commutability, and uncertainty.

The strong communication between NCCLS/CLSI and IFCC has been very beneficial in identifying partnership benefits and goals. Mathias M. Müller, M.D, IFCC President says, "We are excited about NCCLS'S name change to Clinical and Laboratory Standards Institute. The new name expresses the global reach and focus of the organization. CLSI and IFCC have an outstanding partnership with effective
communication which will continue in the future.” Mr. Fine adds, “With the continued collaboration of IFCC and CLSI, our organizations will be able to promote joint development of global, harmonized consensus documents that meet the needs of the healthcare community worldwide.”

For more information about Clinical and Laboratory Standards Institute references and best practices, visit www.clsi.org.

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**IFCC DOCUMENTS PUBLISHED IN 2004**

The following documents have been published by IFCC Units in 2004:

**Special IFCC publication**


**C 8.2.13 Plasma Proteins**


**C 8.2.19 Standardisation of Markers of Cardiac Damage**


**WG 8.3.16: Standardization of Lp(a).**


**WG 8.3.19: Standardization of HbA1c.**


**LIGHT-HEARTED CLINICAL CHEMISTRY**

Expected mail messages.
In the early 1950s the popularity of Fred Mitchell's laboratory in the Jessop Hospital for Women in Sheffield took a long time to recover from the following episode. They still remember it in Sheffield. Hormones couldn't be measured in blood in the 1950s as they can now – the amounts present were too small. So all measurements had to be on 24-hour specimens of urine. These came in by post in glass Winchester bottles in special boxes. There were no plastic bottles then. One particular specimen had been travelling for a few days in the heat of the summer when of course the bottle broke in the middle of the hospital mailbag. The volume of a 24-hour specimen can be quite large, the summer quite hot and it can be imagined how the patients and the hospital office enjoyed opening their saturated mail. That wasn't so hilarious.

Recollected by Fred Mitchell, United Kingdom

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**UPCOMING IFCC RELATED MEETINGS IN 2005/2006**

37th Annual Oak Ridge Conference -Pushing the Technology Envelope II: An Exploration of the Future of Clinical Laboratory Testing, Baltimore, Maryland, USA, 14-16 April, 2005, [www.aacc.org/meetings/oakridge/2005](http://www.aacc.org/meetings/oakridge/2005)

9th International Congress of Therapeutic Drug Monitoring and Clinical Toxicology, Louisville, Kentucky, USA, 23-28 April, 2005, [www.iatdmct.org/congress](http://www.iatdmct.org/congress)

IFCC/Beckman Coulter Conference Series: Protein Conference and Award, Glasgow, United Kingdom. 6-7 May, 2005, [www.beckmancoulter.com](http://www.beckmancoulter.com)


Laboratory Automation Conference, Orchard Hotel, Singapore, 12-13 May, 2005, [www.aacc.org/meetings/singapore_labauto/](http://www.aacc.org/meetings/singapore_labauto/)


X International Congress of Pediatric Laboratory Medicine (ICPLM) East Meets West: Meeting the Challenges in Pediatric Diagnosis and Management, Raffles City Convention Center, Singapore, 3-6 Sep, 2005, [www.sacb.org.sg](http://www.sacb.org.sg)