Where is the Reform of French Medical Labs Going?

by Dr. Bernard Gouget

SFBC-EFLM Representative; IFCC Treasure; Secretary General, International Francophone Federation of Clinical Biology and Laboratory Medicine (FIFBCML)

Ordinance No. 2010-49 of January 13, 2010, relating to laboratory medicine, which completely changes this field, aroused reactions among specialists in laboratory medicine. This bill has since been the subject of a real legislative imbroglio between the Senate and the National Assembly, the two assemblies that constitute the French Parliament. After final passage through the Senate in January, the proposed law will be discussed at the end of March in the National Assembly. We can finally hope that the law ratifying the ordinance will be adopted in spring 2013 in order to allow the providers concerned to practice in a peaceful and legally secure manner.

Medical biologists play a leading role in dialog with other healthcare providers and in direct contact with the population, for proper management thereof. Medical laboratories are an important link in the chain of care services of the French healthcare system both in private and hospital practice. An increasing share of medical decisions is made from biological data. These decisions require this data to be infallible and quickly accessible. Quality local laboratory medicine is a necessity that providers in the field wish to preserve and of which users overwhelmingly approve.

Professional practice has been considerably modernized under the combined effect of technical progress, the growing demand for quality and traceability of results, and the European Regulation of July 9, 2008 that requires an accreditation body in every country of the European Union. The improvement in the initial and continuing education of providers, respect for good practice nationally, and implementation of quality control for procedures demonstrate efforts to maintain excellence in laboratory medicine in France. Via the new law, these efforts must be continued and supported by the entire profession and government authorities, in order to guarantee the best patient care.

Indeed, laboratory medicine must respond to major economic changes. Although the majority of French medical laboratories are currently small local structures, there is a movement for concentrating laboratories, increasingly pursued by investment funds. This intrusion of the finance industry challenges the practice of medical biologists and may have risks in terms of public health and access to care. While the density of medical biologists in France is 16 per 100,000 residents (versus 5.8 for the rest of the EU), this average conceals disparities according to region. At a time when the healthcare needs of the population are increasing and the fight against medical deserts is a priority, it is essential to preserve the regional network of laboratories. Four major objectives are pursued by this bill:

- to ratify the 2010 ordinance regarding laboratory medicine,
- to enhance the medicalization of the profession. The medicalization of this profession has been enhanced; in order to be recognized as a medical biologist, it is necessary to hold a pharmacist or medical degree and a degree in specialized studies in laboratory medicine. The conduct of the preanalytical phase of a laboratory medicine test is secured by guidance from the practice of providers authorized to participate in it. Adjustments have also been made at various points, especially regarding the question of the practice of healthcare providers coming from the European Union and not holding a medical biology degree, or management of transitional provisions relating to laboratory technicians. Consistent with the fact that laboratory medicine is a medical discipline rather than a technical one, the practice is ended of exceptions to the pricing rules by common law acts, called "rebates (discounts)", excluding cooperation between institutions.
- to ensure the quality of biomedical testing. One article sets a double objective regarding laboratory accreditation. It ensures that medical biologists have an optimal organization in place and are proven to be competent to conduct testing: as of November 1, 2016, medical laboratories will not be able to operate without an accreditation covering 50% of medical biology tests. As of November 1, 2018, medical laboratories will not be able to operate without an accreditation covering 70% of medical biology tests. As of November 1, 2020, medical laboratories will not be able to operate without an accreditation covering 100% of medical biology tests. The accreditations in principle cover all families of tests.
- to define the organization of laboratory medicine and slow the Intrusive process of the finance industry. One article seeks to slow the Intrusion of the finance industry by restoring the principle of majority ownership of company capital by medical biologists practicing within companies. Regional health agencies are responsible for regulating the provision of public and private laboratory medicine in the regions where they operate, in order to guarantee that local laboratory medicine is sustained.

There have been many hearings between members of parliament and representatives of professional organizations. We hope to have been heard; the challenge is to guarantee locally based quality laboratory medicine, a requirement that providers in this sector wish to preserve and of which users overwhelmingly approve.

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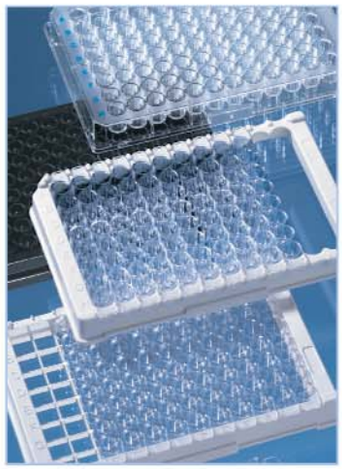

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Tailored Tools for Diagnosing Heart Failure

by Dr. Damien Gruson, Chair, Task Force for Young Scientists

As the 2013 World Salt Awareness Week calls for "Less Salt, Please," it may be time for Europeans to seriously consider the implications of their seasoning habits on their health, notably their heart health.

Heart failure (HF) is characterized by the inability of the heart to respond to the blood flow demands of the body, a condition that is becoming increasingly common, with more than 20 million directly affected worldwide. The overall prevalence of HF is increasing because of an aging population, prolonged survival in patients suffering from coronary events, and effective prevention in those at high risk or those who have already survived a first event. In addition to a high prevalence, HF is also a deadly and costly disorder, carrying an overall prognosis that is worse than with cancer. The signs and symptoms of HF include fluid overload, tachycardia, shortness of breath, and chest pain. The symptoms are not specific for HF and diagnosis in an emergency can be difficult. Electrocardiography (ECG), chest X-ray, echocardiography, and use of biological markers (or biomarkers) are thus recommended as the most practicable ways of assessing cardiac function.

The use of "markers" in the blood for diagnosis of patients admitted to the emergency room with suspected HF is constantly increasing and is now part of routine practice in industrialized countries. Most of the biomarkers used for diagnosis and prognosis derive from the neurohormonal response to the failing myocardium, which in the case of HF are specifically focused on assessing the presence of natriuretic peptides - in vitro diagnostic (IVD) blockbusters used in routine clinical and laboratory practice.

Emerging biomarkers represent potential new tools with added value for monitoring of HF patients and identification of patients at increased risk. Expectations are also being placed on their ability to support guided treatment, to allow more tailored therapies and monitor the safety and efficiency of medical devices. The pressure for biomarkers is on.

As the sector continues to develop, the quality of life for patients with chronic cardiovascular conditions may improve, and for those who are identified at risk for HF, diminishing the impact of risk factors, such as high blood pressure, is a primary step. A diet rich in sodium, responsible for high blood pressure and increased risk for stroke, HF and other cardiovascular problems, is perhaps the easiest point of attack. By cutting down on the amount of sodium consumed, blood pressure medication may improve in effectiveness and patients who have already suffered from a heart condition can limit their chances of a reoccurrence.

Emerging biomarkers for heart failure identification are stimulating the medical community and enhancing the management of HF patients. Laboratory technicians, IVD manufacturers, and physicians will have to make joint efforts to provide broad-spectrum validation and confirm the potential added value of innovative biomarkers in heart failure. Patients, on the other hand, will have to take it upon themselves to also consider their diet and its relationship to cardiovascular health problems.

News from the Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM)

by Dr. Jasenka Wagner, chair of the CSMBLM Committee for information and public relations

Starting from this calendar year, CSMBLM Committee for continuous professional development has developed a new form of continuous education: WEBINARS. During the year 2013, four e-seminars will be organized: two in February and two in September. Topics covered by the webinars will be various CLSI guidelines. In this trial year, e-seminars are mainly addressed to CSMBLM members so they will be conducted in Croatian language only. In addition, participation in the webinars is recognized and certificated by the Croatian Chamber of Medical Biochemists. Depending on their success and gained interest, more webinars will be organized in the year 2014. All details can be found on CSMBLM official web page www.hdmblm.hr/hr/kalendar/skupovi-hdmblm/e-seminari

Publishing activities of CSMB are related to CSMB's scientific journal Biochemia Medica (www.biochemia-medica.com). With its international Editorial and Advisory Board, it continues to publish articles by Croatian and international authors dedicated to professionals from laboratory medicine and various fields of biomedicine that share the same interests. BM is indexed in Medline, SCIE, JCR, Thomson Reuters, EMBASE/Excerpta Medica, Scopus, CAS, EBSCO/Academic Search Complete, and DOAJ. The journal's impact factor for 2011 was 1.343. Editorial board of Biochemia Medica strongly promotes research integrity and aims to prevent any type of scientific misconduct, such as fabrication, falsification, plagiarism, redundant publication, and authorship problems. Starting from the first issue in 2013, all submitted manuscripts are revised by Research Integrity Editor and checked using CrossCheck screening system for potential plagiarism (more information available at: www.crossref.org/crosscheck.html). In resolving any potential scientific misconduct, Biochemia Medica follows flowcharts provided by the Committee on Publication Ethics (COPE) and additionally consults COPE for any unclear cases. (Available at: http://publicationethics.org/resources/flowcharts). Also, starting from the issue 23(1), all published articles will be given unique DOI number, making them more visible to the world scientific community.

News from the Spanish Society of Clinical Biochemistry and Molecular Pathology (SEQC)

by Josefina Mora,
Liaison to the IFCC eNewsletter

The SEQC recently inaugurated a new lecture hall, the Aula Enric Concustell, to hold scientific symposia and conferences. The room is fully equipped with state-of-the-art audio-visual equipment, built-in LCD projection screens, and Wi-Fi.

To celebrate the inauguration of this Centre, a series of humanistic lectures have been organized for 2013:

– The opening lecture, Brain and Power was given by Adolf Tobeña, professor of Psychiatry at the Autonomous University of Barcelona, on February 14. Dr. Tobeña analyzed the common traits of people who occupy positions of power, showing that individuals who are astute, dominant, persuasive, false, manipulative, and audacious are optimal candidates to seek such roles.

– On March 14, Maria Barbal will present a lecture entitled The Building of a Novel. Her book Stone in a Landslide (Pedra de Tartera) has over fifty editions and has been translated into thirteen languages.

– The next lecture will take place on June 13. It is entitled Communication and Happiness, and the speaker will be Sebastià Serrano, professor of Linguistics and Communication Theory at the University of Barcelona and author of several books.

– On October 17, Fernando Bandrés, professor of Toxicology and Legal Medicine at the Complutense University of Madrid, will present his lecture entitled Medicine, Ethics, Values, and Law.

– The closing lecture in this cycle, 200 Years of Giuseppe Verdi, will be delivered by Marcel Gorgori, a radio and television journalist whose specialty is opera.

Revolution in Laboratory Medicine, Paris 2015!

Dear Colleagues, dear Friends,

On behalf of the French Society of Clinical Biology (SFBC) and of the Congress Organizing Committee, it is a great pleasure to invite both academics and specialists in laboratory medicine and partners to attend the 21st IFCC - EFLM European Congress of Clinical Chemistry and Laboratory Medicine (EuroMedLab Paris 2015).

This unique event, including the Journées Internationales de Biologie (JIB) 2015, will be held in Paris, France, on June 21-25, 2015, in the Palais des Congrès de Paris, one of the capital's legendary venues.

EuroMedlab Paris 2015 will be an innovative and invigorating EU and International congress reflecting the direction of Laboratory Medicine in the 21st century with an intellectually stimulating combination of presentations, symposia, discussions, sessions and exhibitions. Well-known European and International speakers and colleagues will address their vision and current challenges in the field of Laboratory medicine in the context of a changing health environment taking account medical and scientific innovations. We are confident that they will spark the minds of both young and established Laboratory Medicine professionals, scientists, researchers, clinicians, as well as all relevant stakeholders in the health care and Laboratory Medicine sectors.

Paris is a major international center for research in life sciences and a creative cultural destination in perpetual renewal being one of the highest-ranking cities in terms of tourism attraction. We are sure that both the scientific and social programs will provide opportunities to help foster exchanges between EFLM/IFCC members, to forge new collaborations and to connect with the leaders of the diagnostic industry at the largest IVD product show in Europe linked to the three-day conference/ workshop program.

EuroMedlab 2015 will provide ideal surroundings for participants to leverage knowledge, promote education, and build awareness about the future of Laboratory Medicine placing the patient at the heart of all our efforts and discussions.

EuroMedlab Paris 2015 is everything you have never wanted in a Laboratory Medicine congress. We look forward to your participation in the fascinating scientific networking event and welcoming you all for a memorable and enjoyable experience!

The Congress Presidents, Philippe GILLERY, Joelle GOUDABLE, Bernard GOUGET

IFCC-EFLM EuroMedLab Congress in 2017

As you know, the venue for the IFCC-EFLM EuroMedLab Congress in 2017 will be chosen by ballot at the EFLM General Assembly in Milan to be held on Sunday May 19, 2013, from 9:00 to 13:00 in Room Amber 5-6 at the Mi.Co. Congress Center. Three National Societies have submitted their applications to host the EuroMedLab 2017:

GREECE - Athens,
CZECH REUBLIC. - Prague
SPAIN - Barcelona

The IFCC Congresses and Conferences Committee (C-CC) and the EFLM Education and Training Committee (C-ET) have evaluated the submitted applications according to the EuroMedLab Guidelines (www.ifcc.org/ifcc-congresses-and-conferences).

We confirm that the members of both evaluation committees, who scored the bids, have no "conflict of interest" with any of the bidding societies. Results of this evaluation yielded the following rankings which we present to your Society as a guide only:

Rank	Venue	IFCC/EFLM Scores
1	Barcelona	62.9
2	Prague	62
3	Athens	56.6

We would be most grateful if your Society could give careful consideration to the bid documents and select the city you feel is best suited to host the EuroMedLab Congress in 2017. The criteria in the Appendix of the Euromedlab guidelines might help your Society in the evaluation of bids objectively. The documentation supplied by each bidder is available on the EFLM website (link from the homepage) as well as on the IFCC website (congresses&conferences, congress calendar, EuroMedLab Congresses). To open the PDF files please use the password bid-eml-2017.

All EFLM member societies, who paid the 2012 annual membership fee before the date of the General Assembly, will have one vote to be cast by the EFLM National Representative of the Society or an accredited representative notified to the EFLM office before the meeting. Details of the election procedure and a request for the name of your Society's representative will be circulated with the agenda of the General Assembly.

To complete the information, we have listed for you the previous locations of the EuroMedLab Congresses starting from 1974:

Munich DE (1974); Prague CZ (1976); Brighton UK (1979); Vienna AT (1981); Budapest HU (1983); Jerusalem IL (1985); The Hague NL (1987); Milan IT (1989); Krakow PL (1991); Nice FR (1993); Tampere FI (1995); Basel CH (1997); Florence IT (1999); Prague CZ (2001); Barcelona ES (2003); Glasgow UK (2005); Amsterdam NL (2007); Innsbruck AT (2009); Berlin DE (2011); Milan IT (2013); Paris FR (2015).

We are looking forward to meeting you at the EFLM General Assembly in Milan. With best wishes,

Graham Beastall, President, IFCC; Ian Watson, President, EFLM; Tomris Ozben, Chair, IFCC Congresses and Conferences Committee; Elizabeta Topic, Chair, EFLM Education and Training Committee

News from EFLM Working Groups

New EFLM Working Group on "Patient Focused Laboratory Medicine"

Accession to Laboratory Medicine data with support to aid comprehension is limited and difficult for many patients. In chronic disease management, where laboratory medicine values are key indicators, there is an opportunity to engage patients with their disease management by enabling access to results and support to understand them the better to enable their disease management.

A new EFLM Working Group on "Patient Focused Laboratory Medicine" has been created under the EFLM Science Committee with the aim to improve patient ownership of their disease and provide a service that better reflects patients' expectations.

For further information, please visit the EFLM Science Committee section at http://efcclm.eu

Report of the 5th Meeting of the EFLM Working Group on Test Evaluation Oct 15-16, 2012, Dubrovnik

In this time of austerity, justification of costs associated with the introduction of new laboratory tests should ideally be based on demonstration of proportional benefits to patients. However, new laboratory tests are often released to market with limited supporting evidence regarding their value or impact in clinical practice. Test evaluation should be performed with informed and carefully devised study design, yet evidence-based methodology to this regard is often lacking in the scientific literature, and when available is often poorly understood. As a consequence, inadequately designed biomarker evaluation studies may lead to early market release and consequently erroneous clinical utilization and decision making that threatens patient safety. The root of the problem is that evaluation of medical tests is much more difficult and differs in many ways from the evaluation of therapeutics. The most important differences are that: medical testing rarely improves health outcomes directly; biomarkers used for several different purposes (diagnosis, monitoring, prognosis, etc.) are often part of a more complex intervention; and most clinical outcomes follow from subsequent clinical management decisions guided by the test results. Therefore, the Science Committee of the EFLM has established the Test Evaluation Working group (WG-TE) with the aim of developing guidance for the appropriate evaluation of new laboratory tests.

The Test Evaluation Working Group is a joint collaboration between the EFLM and AACB (Australasian Association of Clinical Biochemistry). Membership of this WG represents collaboration between experts in evidence-based laboratory medicine, evidence-based diagnosis, and epidemiology, and of IVD industrial partners. The WG is chaired by Rita Horvath (AU) and members are Patrick Bossuyt (NL), Christa Cobbaert (NL), Sally Lord (AU), Phillip Monaghan as a young scientist (UK), Sverre Sandberg (NO), Andrew St John (AU), Wilma Verhagen-Kamerbeek and Christoph Ebert from Roche Diagnostics, Lieselotte Lennartz from Abbott and Alexey Bugrov as corresponding member (RU). EFLM receives an educational grant from Roche Diagnostics to support the work of this WG.

The aims and objectives of this working group are:

- To develop a framework and guidance for the appropriate evaluation of the clinical effectiveness and impact of new laboratory tests.
- To develop practical toolboxes which support the design and conduct of clinical research studies for the above purposes.
- Education and training of laboratory scientists and researchers via pilot biomarker studies on how to design test evaluation studies.
- Collaboration with epidemiologists, industry, and regulatory authorities in setting standards for clinical evaluation of new biomarkers.

contributed by Dr. Phillip Monaghan Member Young Scientist, Working group on Test Evaluation (WG-TE) Senior Clinical Scientist, The Christie Hospital, Manchester, UK.

Meeting of the EFLM Working Group on Test Evaluation

The 5th meeting of the EFLM WG-TE in Dubrovnik was a two-day event, Day 1 being devoted to discussing the key principles and components of the test evaluation process, whilst Day 2 comprised of brainstorming sessions on the development of new guidance for critical elements of the devised test evaluation framework.

Day 1: The WG launched into the finalization of the WG-TE scoping paper which aims to set out how exactly test evaluation should be done when a new biomarker is discovered. This is taking the form of a test evaluation framework to provide an evidence-based approach to study design, thus setting standards for test evaluation in the research and clinical setting, forming guidance for researchers, clinicians and laboratory professionals. The WG came to consensus on a number of key definitions and illustrative examples for the key components of the test evaluation framework. These include analytical performance, clinical performance, clinical effectiveness, cost-effectiveness, and impact of testing. We have defined and tightly integrated these components into a unifying evidence-based framework. This dynamic framework clarifies the link and sequence between the various stages of test evaluation and describes the journey of a new biomarker in becoming a medically useful test in the research translation continuum. Our WG takes the view that no new test should be subjected to tedious trials and released to the market if it is unlikely that the test will result in improved clinical actions and measurable outcomes. Therefore, in our framework the clinical purpose and role of testing and the intended application of the biomarker in a well-defined clinical pathway drive all stages of the test evaluation cycle and define the most appropriate study designs that have the potential to provide the highest level of evidence as proofs. We concluded the meeting on Day 1 by agreeing on a set of example laboratory tests with different purposes (e.g., screening, diagnosis, and monitoring) for which we could generate and apply key questions and criteria for identifying unmet clinical needs in current clinical pathways, which are the very first key steps in the test evaluation cycle.

Day 2: The meeting commenced with a brainstorming session on the theme of developing and testing questions and criteria for identifying unmet clinical needs and addressing ways of analyzing how a new test would fit into an existing clinical pathway. By defining the source(s) of limitations in current practice, we were able to establish opportunities for process improvement. This strategy was applicable to tests with different purposes and the group concluded that this principal phase of test evaluation was to be an immediate focus of attention for the WG-TE in elaborating the proposed test evaluation framework. The topic for the afternoon session was of establishing clinical performance criteria for medical tests, an aspect of test evaluation for which there is a paucity of methodological criteria in the literature. The group discussed novel ideas on grading clinical performance, including how to express clinical performance criteria through a hierarchical approach with proxy outcome levels. With clinical performance in mind, we looked at the aim of various test roles (e.g., triage, add-on tests) and addressed the clinical performance criteria in each particular scenario while contemplating the various modifiers that may impact overall clinical performance and what study design application is best to evaluate a particular testing scenario. We concluded the meeting by approaching the difficult question of setting predefined values for quantifying clinical performance standards for new medical tests analogous to criteria available for analytical specifications. This final session generated some interesting novel ideas, which the WG-TE will now develop and refine as part of the test evaluation framework.

The WG will present its work in a number of publications and will deliver a symposium on May 21, 2013, at the Euromedlab congress in Milan (www.milan2013.org). So watch this space!

For more information on the EFLM's WG-TE please visit: http://efcclm.eu/science/wg-test-evaluation