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International Federation of Clinical Chemistry and Laboratory Medicine



2017



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A new approach at IFCC Worldlab 2017 – making posters available on an app



Poster presentations are an integral part of many conferences. In the case of the IFCC conferences they are the mainstay of delegate presentations and are accompanied by scheduled poster presentation sessions where the author may be required to be present at the poster and be available to answer questions.



There are many challenges with this approach. Depending on the number of posters, the posters may only appear for a day. Often the author may be available or present at the poster.

Another major constraint is time. If posters are being judged for the award of a prize, the judges often have to go around and view the posters.

by Tahir Pillay IFCC eNews Editor Congress Co-president, WorldLab 2017

In the countless times, by now, that I have either taken part as a poster presenter or been a judge of posters, it has proven difficult because of time constraints to either view the posters or be present at the posters at the scheduled time.

There is almost always insufficient time to view all the posters and poster presenters are disadvantaged by this, especially if they have spent time and effort in producing, firstly, the data for the poster, and then assembling and printing the physical poster.

For the first time in the history of IFCC conferences, presenters will be asked to make their posters available as PDFs a week prior to the IFCC Worldlab 2017 Conference. The PDFs will be available via the conference application/"app". This will be in addition to the conventional poster presentation schedule.



This means that delegates and judges will be able to view the posters at their leisure and will be able to read the posters on their devices or computers. They can also pose questions to the presenters via the "app".

Presenters who submit their posters for the "app" will be eligible for the prize draw. *Prizes will be awarded to the three best posters as determined by the judges.*

Dr. Rolf Hinzmann elected 2018-2020 IFCC Corporate Members representative

The IFCC Nominations Committee is happy to announce that the Corporate Representative in the Executive Board for the period 2018-2020 is Dr. Rolf Hinzmann. The term of his position will commence on January 1st, 2018 and last until December 31th, 2020. Thank you to all the candidates who actively took part in the IFCC electoral process and best compliments to Dr. Hinzmann for his reconfirmed position within the IFCC Executive Board. We wish him a fruitful term in the promotion of clinical chemistry and laboratory medicine worldwide.

The elections have been conducted via an electronic system in order to ensure wider participation in this important moment in the IFCC life.



Dr. Rolf Hinzmann

As the re-elected Corporate Representative on the IFCC Executive Board I would like to give you some information about who I am, and how I see my current role.

WHO I AM

After having studied biochemistry and having completed my PhD in endocrinology I studied medicine and then specialized in what we call "laboratory medicine" in Germany which is something between clinical chemistry and clinical pathology, comprising microbiology as well.

After a period of time at the university lab I moved to the in vitro diagnostic industry in 1996 and worked as a Scientific Marketing Manager for Beckman Coulter. Later, I was appointed Medical Director of Sysmex Europe; and, more than six years ago, I moved to Roche Diabetes Care, where I am now the Head of Global Medical & Scientific Affairs for Self-Monitoring of Blood Glucose and for Continuous Glucose Monitoring.

I have been with the IFCC for sixteen years now, first serving as Corporate Representative in the Executive Committees of the Scientific Division and the Education & Management Division, later as a member of the Task Force on Point of Care Testing. For already more than 2 1/2 years I have been representing the Corporate Members on IFCC's Executive Board.

I have always had a strong interest in standardization, immunodiagnostics, metabolic diseases, evidencebased medicine, philosophy of science, and didactics of medicine.

HOW I SEE MY ROLE AS CORPORATE REPRESENTATIVE IN THE IFCC EXECUTIVE BOARD

A couple of factors have dramatically changed the diagnostic landscape, e.g.:

○ A shortage of money in public health systems and price pressure make it more challenging to find ways that the medical value provided by diagnostic lab tests is adequately reimbursed. • At the same time hurdles for registration of new tests and devices are increasing and the procedures differ from country to country.

With the often very beneficial spread of testing from the central lab to the point of care quality assurance and training become more and more important.

In many countries the recognition of the importance of clinical chemists / clinical pathologists being in charge of lab testing, quality assurance and result interpretation is declining.

Data analytics will provide new opportunities for generation of medical value in laboratory diagnostics and might dramatically change the way we will conduct medicine in the future.

There are various ways how IFCC can support its Corporate Members to address these topics.

At IFCC's General Conference in Madrid, in April 2016, we had for the first time a session fully organized by the IVD industry. During this session I invited all delegates to submit proposals how IFCC could become more attractive for corporate members. We received around a hundred proposals which were later classified, consolidated, discussed by the IFCC Executive Board, and incorporated into IFCC's Strategic Action Plan.

The following list contains examples that are considered high priority from the Corporate Members' point of view:

IFCC needs to better serve the needs of its
 Corporate Members, instead of regarding Corporate Members mainly as a source of income.

IFCC must make it easier for employees of Corporate Members to actively participate in IFCC working groups and committees (and not only as corresponding members).

IFCC needs to more strongly collaborate with clinical societies to harmonize guidelines and support medical claims leading to reimbursement for lab tests.

IFCC needs to align stronger with others (CLSI, FDA, clinical societies, etc.) to avoid inconsistency and duplication of regulatory guidelines and recommendations. IFCC needs to embrace emerging technologies and data analytics.

➡ IFCC needs to continue providing opportunities for exhibitions, industry symposia and networking with lab professionals during high-level academic conferences, thereby following the rules defined by the IVD industry in the MedTech Europe Code of Ethical Business Practice and other applicable codes to avoid that Corporate Members face challenges when sponsoring and exhibiting at congresses.

In all these areas IFCC and diagnostic manufacturers can achieve more if they collaborate strongly. Both lab professionals and Corporate Members share the final goal to improve the lives of patients worldwide.

In the past 2 1/2 years we have already achieved a lot together. On the IFCC Executive Board I will continue being an active, impartial representative, facilitating the collaboration between laboratory professionals and the IFCC's Corporate Members.

Mannheim, July 2017

With kind regards,

Rolf Hinzmann, MD, PhD

Clinical Pathologist & Biochemist Head of Global Medical & Scientific Affairs Glucose Monitoring and Science

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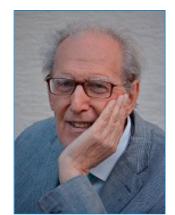
IFCC Medals for Outstanding Service

The IFCC is happy and proud to announce that IFCC Medals for Outstanding Service have been awarded to:

- Prof. Paivi H. LAITINEN (FI)
- Prof. Paolo MOCARELLI (IT)
- Dr. Cas WEYKAMP (NL)
- in memory of Prof. Daniel MAZZIOTTA (AR)



Prof. Paivi H. Laitinen Finland



Prof. Paolo Mocarelli Italy

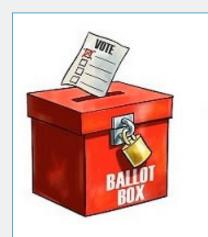


Dr. Cas Weykamp The Netherlands



Dr. Daniel Mazziotta Argentina - *In Memoriam*

The IFCC Executive Board has introduced the *"IFCC Medal for Outstanding Service"* to be awarded to an individual in recognition of sustained service to IFCC at the highest level in promoting the international practice of Clinical Chemistry and Laboratory Medicine worldwide. The recipients were selected among highly regarded nominations.



News from the IFCC Website

IFCC Regional Representatives 2018-2020 Candidates

The IFCC Nominations Committee has completed its assessment of nominations for the election of the IFCC Regional Representatives. The term of these positions will commence on January 1st, 2018 and end on December 31th, 2020. All applications were declared valid. Each Regional Federation's Full member Societies will vote for their Regional Representative. Elections will take place electronically between September 1st – 30th, 2017. Results will be announced in October 2017.

Read more

IFCC-CPD: 2017 annual survey results



Prof. Edgard Delvin

The Communications and Publications Division (CPD) of the IFCC and the Committee on Public Relations (C-PR) initiated an annual survey last year to receive feedback from IFCC national representatives, IFCC divisions/committees/taskforces/working groups, as well as individual laboratory scientists around the world. The most recent survey, issued in March 2017, aimed at probing the laboratory scientists worldwide on their awareness, usage and perception of the IFCC Website and IFCC media including eNewsletter, eNewsflash, Electronic Journal of IFCC (eJIFCC), the eLearning program eAcademy, and the newly developed IFCC App. The present report highlights the 2017 survey findings and summarizes the key observations.

by Edgard Delvin Chair, Committee on Public Relations (C-PR)

The survey was sent to all National Representatives as well as to National Society administrators, asking them to distribute the survey to their respective membership. A total of 831 responses were received from 63 countries, representing approximately 68% of IFCC member societies but only about 2% of the total number of society member scientists worldwide. Two out of three responders reported accessing the website with a minority (19%) accessing it through social media, with Facebook being the most frequently used and Twitter the least. It was reassuring that the responders unanimously found the website easy to navigate and useful.

The responses related to the eNewsletter, eNewsFlash and eJIFCC suggest significant interest in these publication and excellent readability. Interestingly, 40-50% of responders report receiving them, of which 75% were informed of these publications through their National Representatives. Here again, almost all responders reading them highly valued their content and format. With respect to the eJIFCC, it is interesting to note that 40% of the responders already knew it was recently indexed in PubMed.

The eAcademy webpage content, although visited to a lesser extent, is mostly perceived as very good to excellent. The majority of those who visit the webpage commented that they would be interested in obtaining Continuing Education Credits (CEC) through the eAcademy program. Fortunately, these new features are already planned in phase 2 and phase 3 of the eAcademy program development and will be available later this year.

Finally, although the IFCC App has been released and promoted in the eNewsLetter only recently, a fair number of responders claim they have downloaded and accessed it. In summary this survey shows that the IFCC tools are well appreciated by individual members. However, further efforts will have to be made to increase rate of survey responses to ensure that the results are more representative of the IFCC community.



IFCC welcomes a new member: Belarus!

Belarus Society of Clinical Laboratory Diagnosticians (BSCLD)

by Svetlana Bespalova National Representative Belarus Society of Clinical Laboratory Diagnosticians (BSCLD)

National Non-Governmental Organization "Society of Clinical Laboratory Diagnosticians" is the national professional organization in the sphere of laboratory medicine of the Republic of Belarus and existed from 8 November 2016. Its main objectives and goals are as follows:

Development and improvement of the laboratory service in the Republic of Belarus by uniting the clinical laboratory diagnosticians to provide for coordinated solution of scientific, practical and organizational tasks;

Ensuring legal and social protection for the specialists, working in the field of clinical laboratory diagnostics;

- Improving professional knowledge:
 - In the professional sphere by additional education and using remote training technologies;
 - In state and international legal fields on the matters of labour law, legal aspects of public procurement, issues of reclamation activities;

Organization of expert activities under professional responsibilities

with participation in public expertise of sectoral, national and international projects, related to the development and performance of the laboratory service of the Republic of Belarus;

Integration of the lab service into the world community of specialists of laboratory medicine, in order to expand international scientific and practical communication, and also to promote a positive image of the Republic of Belarus.



Doctor Snezhana Yurkevich



Doctor Svetlana Bespalova



Doctor Irina Demyantseva

EuroMedLab Athens 2017

EML 2017 – An overview

by Katherina Psarra, Aggeliki Grigoratou and Alexander Haliassos on behalf of the Editorial Committee of EuroMedLab Daily News

The 22nd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine, "EuroMedLab Athens 2017", took place in Athens, the cradle of western civilization, the birth place of Philosophy, under the shadow of the Acropolis. Held every two years, the congress was organized by the Greek Society of Clinical Chemistry - Clinical Biochemistry (GSCC-CB), the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). This year's conference was co-organized together with the 25th Balkan Clinical Laboratory Federation (BCLF) meeting, and the 15th National Congress of GSCC-CB.

This was the accomplished achievement of enthusiastic people and devoted committees working together for a long time. "EuroMedLab Athens 2017" contributed to the promotion and recognition of the academic and clinical work in the field of diagnostics", as was pointed out by the president of the congress, Dr. Alexander Haliassos. Through creative dialogues it aimed to broaden the cognitive field and deepen the knowledge of cutting-edge matters, promoting reflection and exchanges on the latest developments and innovations in Laboratory Medicine.

The scientific program included, inter alia, lectures whose speakers are visionaries of the future in healthcare and laboratory medicine, in particular – "New vaccines and immunotherapies for AIDS and cancer", "Human gene editing: The dawn, the zenith and the dusk", "The influence of stress in human disease risk", "Whole genome sequencing in health and disease" and 33 symposia with aggregate participation, especially from young colleagues. For the first time in EuroMedLab congresses and in cooperation with the "Young Scientists" Task Force of the IFCC, we introduced the "Meet the expert" sessions, referred to in general interest subjects. All six of these sessions "Accreditation and laboratory management: why and how to do it", "Success in research - academic career: Lessons and opportunities a workshop on how to draw up a scientific paper", "How to succeed in science and laboratory medicine as a woman", "Assessing vitamin D status in the clinical laboratory: Assays and interpretation are the key issues", "Established and emerging biomarkers in heart failure diagnosis and management", "Existing and emerging technologies in PoCT: The laboratory tests from the central laboratory to clinic to family practitioner to patient"- gave the opportunity for interactive discussion among the audience and expert scientists.

Another highlight of the congress program included the public debates. The choice of debates aimed to make scientific achievements more understandable to the general public as well as to specialized journalists of the healthcare sector. They offered them the opportunity to estimate the difficulties, with emphasis on those subjects which raise moral dilemmas. The debates covered capturing and interesting topics such as : "Lessons from 30 years of cancer screening", "The ethics of gene editing", "Direct to consumer testing (DCT). Ethical issues and confidentiality, "Antidoping testing".

The programme also included scientific workshops delivered by in-vitro diagnostic companies, which presented the Europe's largest and most interesting commercial exhibition of related products (instruments and reagents). Delegates welcomed the opportunity to get in direct contact with them.

EuroMedLab Athens 2017 was full of world-renowned professors, researchers and accomplished professionals that made it the exciting and unforgettable event that it was. More than 5778 scientists from Europe and elsewhere, altogether 117 countries all over the world registered and actively participated in the EuroMedLab Athens 2017. We would like you to remember Greece with its glorious tradition and ever-active myth, the Aegean waves and the hospitality of the people. We hope we will meet you again in IFCC-EFLM EuroMedLab Barcelona, in May 2019.

Meanwhile, as the poet says, "to protect you I placed three guards: the sun on the mountain, the eagle on the plain, and the fresh north wind on the ships." *Until we meet again! Kali adamosi.

*George Seferis, Greek poet (Nobel Prize in Literature, 1963)

EuroMedLab Athens 2017: The view of a Latin American congress participant

EuroMedLab is the largest scientific gathering of professionals dedicated to the Clinical Laboratory, in Europe, which because of the importance of this scientific forum has managed to capture the attention of other professionals from different continents, including from Asia, Africa, America, and particularly Latin America, who all participated in EuroMedLab Athens 2017.

The possibility that we can access this type of event is hampered by the high costs of air tickets, the cost of lodging, food and the high cost of registration fees, which are often unattainable for the countries of Latin America to participate and to this must be added many times the language difficulty.

For me, participating in the EuroMedLab Athens 2017 was an extraordinary experience from a scientific and technological point of view. I must, thus, consider the collaboration of the organizing committee, which, through its chairman, Dr. Alexander Haliassos, and the invaluable Dr. Rosa Sierra-Amor, member of the IFCC Executive Committee, allowed several Latin American professionals to participate as co-chairs in symposia and conferences during the event. **by Álvaro Justiniano Grosz** President Bolivian Society of Clinical Biochemistry 1st Vocal COLABIOCLI National Representative to IFCC



EuroMedLab Athens 2017 was organized jointly by the Greek Society of Clinical Chemistry-Clinical Biochemistry

COLABIOCLI participants under the IFCC EuroMedLab banner

(GSCC-CB), the European Federation of Laboratory Medicine (EFML) and the International Federation of Clinical Chemistry (IFCC).

Approximately 5570 registrants were received from 117 countries, including biochemists, laboratory physicians, biologists, biochemists and pharmacists, scientific chemists from clinical diagnostic centers, university



COLABLIOCLI participants Left: at the congress; Right: during the closed meetings



Dr. Justiniano Grosz, author of this article; Dr Sierra Amor, IFCC EB member; Prof Ferrari, IFCC President

COLABIOCLI delegates at the IFCC booth

teachers and research centres. The scientific program included, among others, 33 symposia, 6 expert meetings, 35 corporate-sponsored educational workshops and four satellite meetings, with the aim of expanding the field of knowledge and deepening current issues, through a reflexive dialogue and scientific exchange on the latest advances and innovations in laboratory medicine.

An important technological exhibition of equipment and clinical laboratory supplies was added, with the participation of more than 70 companies that exposed the continuous technical development and the sophisticated perfection of the diagnostic systems in the laboratories.

Latin American participation was formed by approximately 21 laboratory professionals from various countries, from central and South America, such as: Argentina, Bolivia, Brazil, Chile, Ecuador, Guatemala, Mexico, Paraguay

and Uruguay. The meeting of the Latin American Working Group (WG-IANT) was also held, and the participation of colleagues as Co-Chairs in specific conferences, symposia, meetings in other IFCC working groups and a number of administrative and scientific activities also occurred. When there is participation and integration of Latin American professionals in this type of international events, there is a need to renew and make feasible the participation of the Young scientists, the professionals of the future, a theme to strengthen in our countries since in this event their participation was evidenced through IFCC Task Force of Young Scientists, a pending structure yet to materialize in our countries.

Just imagine if the majesty of the Parthenon and the Herodion Theater had allowed a magnificent opening ceremony! Unfortunately, due to the inclement weather, this was not possible. However a sober ceremony at the Megaron Convention Center gave rise to appreciating both Greek culture and through the Olympic spirit of its cultural manifestations and a warm welcome to foreign visitors and to the Greek professionals themselves.

There is no doubt that we should further strengthen the bonds of brotherhood of laboratory professionals, a fact that will allow continuous improvement in the least developed countries through the transfer of knowledge and technology and also the achievement of a harmonious and more efficient development in all the countries, which would translate into better benefits for the health of our patients, and in particular the improvement of our communities in general.

We bid farewell to Athens 2017 and hope to meet again in Barcelona in 2019.

Congreso Europeo de Laboratorio Clinico, Atenas 2017: Desdela mirada de un congresista Latinoamericano

El EuroMedLab es el mayor evento científico de los profesionales dedicados al Laboratorio Clínico en Europa, que por la trascendencia de este foro científico ha logrado acaparar la atención de otros profesionales de diferentes continentes, como el asiático, africano, americano, y particularmente latinoamericano que participaron hoy el EURO-MEDLAB ATHENAS 2017.

La posibilidad de que podamos acceder a este tipo de eventos se ve dificultada por los altos costos de los billetes aéreos, los gastos de hospedaje, alimentación y el precio elevado del costo de registro al congreso, lo que hacen muchas veces inalcanzable para los países de Latinoamérica el participar, a esto se suma muchas veces las dificultades del Idioma.

Participar en el EUROMEDLAB ATHENAS 2017, significo personalmente, una experiencia extraordinaria, desde el punto de vista científico y tecnológico, por ello, debo ponderar la colaboración del comité por Álvaro Justiniano Grosz Presidente Sociedad Boliviana de Bioquímica Clínica 1º Vocal COLABIOCLI Representante Nacional ante IFCC

organizador que a través de su presidente, el Dr. Alexander Haliassos y las invalorables gestiones de la Dra. Rosa Sierra-Amor miembro del Comité Ejecutivo de la IFCC, permitieron que varios profesionales Latinoamericanos participasen como Co-Chairs de simposios y conferencias del evento.

El EUROMEDLAB ATHENAS 2017 estuvo organizado por la Sociedad Griega de Química Clínica-Bioquímica Clínica (GSCC-CB por sus siglas en ingles), la Federación Europea de Medicina de Laboratorio (EFML) y la Federación Internacional de Química Clínica (IFCC).

En el cual se recibieron aproximadamente 5.570 registros de participantes de 117 países, entre ellos bioquímicos, médicos de laboratorio, biólogos, bioquímicos y farmacéuticos, químicos científicos de centros de diagnóstico clínico, docentes de universidades y centros de Investigación. El programa científico incluyo, entre otros, 33 simposios,

Article continued on next page

6 sesiones de encuentro con expertos, 35 talleres educativos patrocinados por empresas y cuatro reuniones satélites. Con el objetivo de ampliar el campo del conocimiento y profundizar en temas de actualidad, a través de un diálogo reflexivo y de intercambio científico sobre los últimos avances e innovaciones en medicina de laboratorio. A ello se sumó una importante exhibición tecnológica de equipos e insumos de laboratorio clínico, con la participación de más de 70 empresas que expusieron el continuo desarrollo técnico y el sofisticado perfeccionamiento de los sistemas de diagnóstico en los laboratorios.

La participación latinoamericana estuvo formada por aproximadamente 21 profesionales de laboratorio de diversos países, de centro y sud américa; tales como Argentina, Bolivia, Brasil, Chile, Ecuador, Guatemala México, Paraguay y Uruguay.

También tuvo lugar la reunión del Grupo de Trabajo Latinoamericano (WG IANT), y en programa académico la participación de los colegas como Co Chairs en conferencias específicas, simposios, reuniones en otros grupos de trabajo de la IFCC y múltiples actividades administrativas y científicas que naturalmente se dan cuando existe la participación e integración de los profesionales Latinoamericanos en este tipo de eventos internacionales. Hay necesidad de renovar y viabilizar la participación de los Jóvenes científicos, los profesionales del futuro, un tema fortalecer en nuestros países ya que en este evento se evidencio su participación a través de IFCC Task Force of Young Scientists, una tarea pendiente de materializarse en nuestros países.

Imaginemos que la majestuosidad del Parthenon y el teatro de Herodion hubiesen permitido una magnifica ceremonia de inauguración, lamentablemente por las inclemencias del clima esto no fue posible, sin embargo una sobria ceremonia en el Centro de Convenciones Megarón dio lugar a apreciar tanto la cultura griega a través del espíritu olímpico de sus manifestaciones culturales y una gentil bienvenida a los visitantes extranjeros y a los propios profesionales griegos.

No cabe duda que debemos fortalecer aún más los lazos de hermandad de los profesionales de laboratorio, hecho que permitirá el mejoramiento continuo en los países menos avanzados por medio de la transferencia de conocimientos y tecnología y también el lograr un desarrollo armónico y más eficiente en todos los países, lo que se traduciría en mejores beneficios para la salud de nuestros pacientes, y en particular a la mejora de nuestras comunidades en general.

Nos despedimos de Atenas 2017 y esperamos reencontrarnos en Barcelona 2019.

EuroMedLab Athens 2017: The Young Scientists (YS) Volunteers thank you!

I am thankful for having been selected for the Volunteer Programme at EuroMedLab 2017. This was a unique experience – we had an opportunity to hear and see the scientific and technological novelties in laboratory medicine, but we also had a chance to meet other young scientist and professionals from all around the world. We enjoyed sharing our experiences, knowledge, and ideas, and hopefully, this

by Marina Pijanović Society of Medical Biochemists of Serbia

will help our global community of medical laboratory scientists grow and thrive, and keep us enthusiastic even when we are not in the "young" group anymore. It is a great privilege and responsibility to participate in the organization of an event this big and important, and this will surely help us in future. Therefore I hope this program will be continued and I encourage my colleagues to apply.

by Anna Velts Estonian Society for Lab Medicine

When I first heard of the volunteer programme at EuroMedLab in Athens I knew it was an opportunity not to be missed. I had some previous experience with organizing Baltic Congress of Laboratory Medicine in Tartu, Estonia in 2016, so I was aware that one must go behind the scenes to really see how much effort and dedication it takes to put together one of the biggest events in laboratory medicine that is Euromed-lab. Behind the scenes is also where you find the people with highest motivation and a true passion for the profession. I was determined to meet those people so I applied for the volunteering programme.

I greatly appreciated understanding of the organizers who didn't overwhelm volunteers with tasks, but rather created an opportunity and left enough time and freedom to explore the wonderful scientific programme of the conference. Daily schedule was arranged in a way that focused on the interests of young people and personal preferences. I am very grateful to our host Evgenia Konsta who was always available and helpful throughout the congress.

With a conference of that scale, it is sometimes difficult to have personal contact and meaningful communication while trying to navigate scientific sessions and social events. Volunteering gave me a chance to connect with both speakers and delegates, and I definitely accomplished my goal of meeting many amazing people who love what they're doing. It was a pleasure to share ideas with bright young people who are the future of our profession. Not only useful contacts, but also true friendships were made. I left Athens feeling extremely inspired and motivated and I am confident that laboratory medicine is in good hands for the years to come.



IFCC Young Scientists Volunteers group with EuroMedLab President, Dr. Alexander Haliassos

by María Belén Martí Sociedad Argentina de Investigacion Clinica

In the context of EuroMedLab 2017, in Athens, I would like to share my fabulous experience of attending as a volunteer, under the Volunteer Program for Young Scientists of IFCC. Personally it was wonderful to be able to contact, meet and share this international scientific event with colleagues from different parts of the world. I met with very intelligent and kind people, with whom I was able to share and learn from about my profession. In addition, we become friends and now we maintain the contact to be able to meet each other in future events of this nature.

At the professional level, I was able to update myself in Clinical Biochemistry and learn about new

laboratory technologies in the world. Also, let me say that there are many very interesting International Committees and I think it would be very interesting to be able to participate. All this new knowledge and life experiences I will share with my colleagues in Argentina and I want to spread it so that more Argentinian biochemists can participate and take advantage of this very important opportunity.

I would like to thank the IFCC for giving me this comfortable opportunity and The Greek Society of Clinical Chemistry - Clinical Biochemistry (GSCC-CB) for the kind treatment we received from all the volunteers.

Meet the IFCC-Roche Travel Scholarship recipients who attended EML 2017



L-R: Benjamin Chijioke Esogwah, University College Hospital, Ibadan, Nigeria; Santosh Pradhan, Samyak Diagnostics, Kathmandu, Nepal; Prof. Vanessa Steenkamp, IFCC EB Liaison for Young Scientists; Padmavathi Parthasarathy, ACS Medical College & Hospital, Chennai, India; Aaron Tembo Konzani, Samfya District Hospital, Samfya, Lusaka, Zambia IFCC and Roche are happy to present the recipients of the IFCC-Roche Travel Scholarships. They were selected to attend the EuroMedLab IFCC Congress, held in Athens. Congratulations to the following recipients:

Padmavathi Parthasarathy (Chennai, India); Benjamin Chijioke Esogwah (Ibadan, Nigeria); Aaron Tembo Konzani (Lusaka, Zambia); Santosh Pradhan (Kathmandu, Nepal); Trilis Yulianti (Jakarta, Indonesia).

The IFCC-Roche Travel Scholarship programme enables Young Scien-

tists from emerging countries to attend the major conferences of clinical chemistry and laboratory medicine. Watch the video to see the awardees express their views on the scholarship programme and share their experiences during EuroMedLab 2017 Athens, and interviews with Prof Ferrari, IFCC President, and Dr Beastall, IFCC Past President.

EFLM symposia at EuroMedLab Athens 2017

The three symposia organized by EFLM during the 2017 EuroMedLab covered topics of pivotal importance in laboratory medicine.



The first one, held on 12 June 2017, was related to Harmonisation. Harmonisation is a fundamental aspect of quality in Laboratory Medicine; its aim is to provide a better outcome for the patients producing comparable laboratory information irrespective of where and how the laboratory data have been produced. Harmonisation involves all the steps of the total testing process (pre-analytical, analytical, post analytical) but includes any aspect of our profession and ranges from laboratory accreditation to professional development to uniform recognition of the profession in Europe. The symposium was specifically dedicated to these aspects. The speakers were all chairs of EFLM functional units devoted to work in these specific areas.

The first topic concerns the pre-analytical phase; we had the pleasure to listen to Ana-Maria Simundic, chair of the EFLM WG, on preanalytical phase. The important and long-lasting experience of the EFLM WG on preanalytical phase specifically on the harmonisation of the venous blood sampling in Europe was presented in detail and focused, in particular, on the description of the recommendations issued by the WG in these years. The issuing of recommendations will be of great help in harmonizing the pre-analytical phase activities across Europe.

and **Juan Robles Bauzai** on behalf of the EFLM Communication Committee and the Promotion & Publications WG

by Maria Stella Graziani

The second presentation was about harmonisation of medical laboratory accreditation, by Wim Huisman, chair of the EFLM Committee Quality & Regulation. The speaker explained that the harmonization of a quality management system for medical laboratories starts by using the same standard. In Europe only one institute in each country is allowed to perform accreditation.

These National Accreditation Bodies cooperate in EA (European cooperation on Accreditation) and they have a mutual recognition for most of the standards we use. EFLM has been working in this field for almost 20 years, in the firm belief that harmonization helps medical laboratories to attain the quality of information the patients deserve.

Gilbert Wieringa, chair of the EFLM Profession Committee, presented the EFLM efforts to press the EU Commission for acceptance of a Common Training Framework that recognises the role of the 'Specialist in Laboratory Medicine'. The importance of a Common Training Framework is that it acts as a passport to allow free professional migration across EU borders at 'specialist' level under EU Commission Directive 2013/55/EU. The recent (end of 2016) integration of the European Register (EC4) into the EFLM infrastructure will facilitate the management of applications to hold the title European Specialist in Laboratory Medicine (EUSpLM).

The forth presentation was by Elizabeta Topic, chair of the EFLM TFG on Continuous Professional Development (CPD) crediting system. We heard about the need to ensure harmonisation of life-long education in Laboratory Medicine. The CPD programs introduced in the majority of EFLM countries vary in contents, accessibility, and impact on relicensing. The recently created TFG is aimed at solving this problem, standardizing, harmonizing and implementing common rules for the CPD crediting system. Harmonized CPD crediting systems in EFLM national societies will lead to the same high quality of Laboratory Medicine in all EFLM member countries, in the face of free movement of laboratory specialists and patients throughout Europe.

The audience (more than 200 attendees) was very attentive and the number of questions from the participants to the speakers testified to the interest in the topics.

The other two EFLM symposia at the EuroMedLab 2017 were about *Performance Specifications in Laboratory Medicine* and took place on Wednesday, 14 June 2017 - one in the morning and the other one in the afternoon.

There were 3 conferences in the morning session, the first was given by M. Panteghini from the Research Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan (Italy) and entitled 'Defining performance specification in laboratory testing'. Prof Panteghini illustrated the importance of measurements in clinical laboratories that produce results needed in the diagnosis and/ or monitoring of patients. All laboratory results are characterized by some uncertainty. What degree of quality is needed and what measurement errors can be tolerated without jeopardizing patient safety should therefore be precisely defined and specified for each analyte having clinical use.

The next presentation, 'The new EFLM biological variation database based on a critical appraisal check*list'* was given by S. Sandberg, from the Norwegian Quality Improvement of Laboratory Examinations (NOKLUS), in Bergen (Norway), on behalf of the EFLM Task and Finish Group Biological Variation Database. Prof Sandberg explained that data regarding biological variation are used for many different purposes; the two most common are to set laboratory performance specifications and to generate reference intervals as well as reference change values for the improvement of verification and validation tasks. Therefore, it is crucial to generate a comprehensive database on the EFLM website with essential information about the biological variation and derived performance specifications for different measurands, along with the underlying evidence.

The last morning lecture, by F. Ceriotti, from the Central Laboratory, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milano (Italy), was about the 'Criteria for allocation of laboratory tests to the three Milan models for performance specifications'. The three different models from the EFLM Strategic Conference in Milan 2014 were presented. Model 1 was based on the effect of analytical performance on clinical outcome; Model 2 was based on components of biological variation of the measurand and Model 3 was based on the state-of-the-art of the measurement.

In the afternoon, this interesting symposium continued on the same topic with three more conferences. The first of them was given by W.P. Oosterhuis, from the Zuyderland Medical Centre (the Netherlands) and was entitled 'Are total error and uncertainty of measurement two sides of the same coin?'. Different aspects of the uncertainty and error quantification methods were presented, together with their advantages and disadvantages.

The second presentation was about the Performance Specifications in EQAS, by G. Jones, SydPath, St Vincent's Hospital, Sydney (Australia). He emphasized that the satisfactory participation of laboratories in external quality assurance schemes (EQAS) is both a regulatory requirement and a vital tool to ensure analytical quality in medical laboratories.

Finally, the last presentation of the day was about the 'Specifications in extra-analytical phases', given by M. Plebani, from the Department of Laboratory Medicine, University-Hospital, Padova (Italy). In this conference, Prof. Plebani highlighted that the main priority in the current healthcare scenario should be to address errors in laboratory testing, that account for a significant proportion of diagnostic errors. Valuable quality indicators and extra-analytical performance specifications are currently required for guidance in improving all total testing process steps.

This symposium on performance specifications was a complete and indubitable success, testified by the large number of attendees (more than 200 participants in each session) and the questions afterwards, which led to a very enriching and informative debate.

Healthcare systems worldwide are facing increased challenges

by Bernard Gouget

Councillor for Public Health FHF, Chair-Human Health Care Committee-COFRAC Chair IFCC-Nominations Committee, General Secretary-International Francophone Federation of Clinical Biology and Laboratory Medicine (FIFBCML)



We are facing a rapidly changing society affected by underlying trends such as globalization, spread of newly-emerging and rapidly changing infectious diseases, bioterrorism and changes in disease patterns, all around the world. Significant climate change patterns anticipated in the decades ahead can be expected to modify disease patterns, while fear of the future in a post-modern world could lead to new mental health challenges. Furthermore, a changed demography skewed toward an aging population would result in an increased demand for healthcare.

An aging population is not just a concern for high-income countries. The majority of older people already live in low-and middle-income countries, and this is where some of the fastest rates of population aging are occurring. This demographic transition in the elderly population constitutes a significant challenge for health authorities worldwide, including a rise in the occurrence of multiple chronic diseases associated with emerging highcost treatments.

Bernard Gouget

In order to cope with such challenges, every country needs robust and affordable healthcare systems for the well-being of its population. This means that every patient needs to have easy access to a wide network of hospitals, medical doctors, care facilities and services, including medical laboratories.

A good healthcare system should also ensure that every patient could afford efficient common treatments and medications. Simultaneously, new technological advances, whether in the volume of health data generated, or in our ability to process and analyse the same data, are increasingly impacted by advances in robotics or a meteoric rise in mobile and wearable technologies and remote monitoring systems. Such advances are breaking down the information walls of the hospitals and doctors' clinics, thereby empowering people to better assess and monitor their own health in real time.

It has become something of a cliché that organizations need to change like never before. We can project that

advances in healthcare are de-facto driven by original, innovative, high-quality biomedical research and its rapid applications in diagnostics, therapy, healthcare, and public health. However, a first ever-global study, organized by the Institute for Health Metrics and Evaluation, finds massive inequity of access to and quality of healthcare among, indicating that an extensive number of people are dying from problems whose treatments already exist.

The study, published recently in The Lancet, set out to assess the availability and quality of healthcare services worldwide from 1990 to 2015 in 195 countries. Researchers created a Healthcare Access and Quality (HAQ) index based on numbers of deaths from 32 causes, including tuberculosis, breast and other cancers, leukaemia, cardiovascular and respiratory diseases, haemopathies, diarrhoea-related diseases, diabetes, kidney and maternal- neonatal disorders, adverse effect of medical treatment, etc., that could be avoided by timely and effective medical care.

The study aimed to use these results to understand gaps and opportunities better to improve healthcare access throughout the world. The paper does offer some favourable signs of improvement in healthcare access and quality.

Since 1990, several countries have achieved progress that met or surpassed levels reached by other nations with similar levels of development. These countries included Turkey, Peru, South Korea, the Maldives, Niger, Jordan, and several Western European nations such as Iceland (2nd), Switzerland (3th), Norway (5th), Spain (8th), Netherlands (9th) and France (15th). 13 of the top 15 countries are from Europe, the two others are Australia (6th) and Japan (11th). The UK's health performance (30th) is better than the US ranked in 35th place, but has a low score in cancer care and lags behind many of its European neighbours, including Finland (7th), Sweden (4th), and Italy (12th), which have similar health systems. The top-ranking country is the tiny principality of Andorra.

Nonetheless, nations in much of sub-Saharan Africa, as well as in South Asia and several countries in Latin America and the Caribbean experienced the lowest rankings. India has to improve its targets in neonatal disorders, maternal health, and tuberculosis. At the bottom of the table are Somalia, Afghanistan, and Central African Republic. China and Ethiopia have seen sizeable gains since 1990.

The results revealed about healthcare access and quality are somewhat disturbing. Virtually all countries improved over 25 years but many especially in Africa and Pacific regions fell behind the others in providing basic care for their citizens as well as in equality between the best and worst performing countries has grown. The warning sign is that having a strong economy does not guarantee good healthcare and having great medical technology does not either! The interesting outcome of these data is to provide a necessary baseline for the governments to move ahead and track progress.

In this context and through its regions, the IFCC has a key role to play in promoting an integrative approach based on multidisciplinary expertise to advance healthcare-related research and management, as well as in implementing Predictive, Preventive and Personalized Medicine.

We need to be most effective in delivering not only high-quality results, but also to be more involved in applying early detection efforts, such as screening at-risk populations, as well as strategies for appropriate management of existing diseases and related complications. The objective of Lab Medicine is to identify knowledge gaps, to advance research with innovative biomarkers, and ultimately to promote best practices and solutions for achieving more inclusive and sustainable services toward delivering relevant and optimal patient-centred health systems accessible by each citizen.

eJIFCC calls for Case Reports

The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine

The eJIFCC calls for case reports that illustrate new approaches to established clinical – diagnostic problems or describing a new clinically associated diagnostic problem.

For more information, see the section on instructions for authors, available at: http://www.ifcc.org/ifcc-communications-publications-division-(cpd)/ifcc-publications/ejifcc-(journal)/#inf.

NEWS FROM REGIONAL FEDERATIONS AND MEMBER SOCIETIES



News from Jordan's MTLS

MTLS membership in the High Health Council of Jordan



Based on the decision of the Senate and Parliament, the law of the High Health Council (HHC) was amended to include the incorporation of Medical Technology and Laboratory Society (MTLS) within the Council member-

ship. The decision was officially issued in the Official Gazette on 16/5/2017.

This is the first time, in more than 50 years since HHC's establishment in Jordan, that the Medical Laboratory

by Lina M. Assaf Medical Laboratory Professional Chief Editor of 'Lab pulse' magazine

profession is identified as part of the health professions composing the HHC membership.

The objective of the Council is to formulate the general policy of the health sector and to put forward the strategy to achieve it in order to organize and develop the health workforce as a whole, so as to extend health services to all citizens according to the most advanced methods and scientific technology.

The presence of a representative of MTLS in this Council helps pave the road towards the real representation and recognition of the profession of Medical Laboratory Technology as one of the genuine health professions in Jordan. It also means that MTLS will have a role in health strategy decision-making at the national level.



News from the Japan Society of Clinical Chemistry (JSCC)

2016 JSCC Technology Award

by Hideo Sakamoto and *Shu-Ping Hui* International Exchange Committee Japan Society of Clinical Chemistry

The Japan Society of Clinical Chemistry (JSCC) has been the leading society in the field of Clinical Chemistry in Japan for more than fifty years. The JSCC Technology Award is given annually to companies who have made progress in clinical chemistry. In 2016, two winners received the JSCC Technology Award. The award presentation was held at the 56th Annual Meeting of JSCC in Kumamoto, Japan from 2-4 December 2016. At the presentation, the award recipient was congratulated by Dr. Masato Maekawa, president of JSCC for the contribution to the advancement in clinical chemistry.

Article continued on next page

In this issue, we would like to introduce two winners, to celebrate their outstanding technology.

Daisuke MANITA, MS (Research and Development Department, Bioscience Division, Tosoh Corporation) is the winner of the 2016 JSCC Technology Award, entitled with *"Development of new lipoprotein analyzer, HLC-729LP2"*.

Dyslipidaemia is a risk factor for atherosclerosis, and is classified as either familial or acquired disorder of lipoprotein metabolism. World Health Organization (WHO) classification of hyperlipidaemia is a biochemical categorization based on raised lipoprotein patterns. Hence, analyzing lipoproteins in detail provides important clinical information for the prevention of atherosclerosis and the therapy of dyslipidaemia.

Major classes of lipoproteins can be isolated from serum with ultracentrifugation, but it is time-consuming and need large volume of serum. They have developed, for the measurement of cholesterol in the five major lipoprotein fractions [high density lipoprotein (HDL), low density lipoprotein (LDL), intermediate density lipoprotein (IDL), very low density lipoprotein (VLDL), and other fraction which include chylomicron and lipoprotein(a)].

This new method can measure cholesterol concentrations of the five lipoprotein fractions within 5.2 minutes per test with an amount of serum as little as 0.2



Award ceremony scene at the 56th Annual Meeting of JSCC L-R: JSCC President, Dr. Masato Maekawa and JSCC Technology Award winner, Mr. Daisuke Manita

mL. The cholesterol concentrations of serum lipoproteins (HDL, LDL, IDL, and VLDL + chylomicron) measured with LP2 had good correlation with those by ultracentrifugation method. HDL-C and LDL-C including IDL-C concentrations measured using LP2 agreed well with the concentrations using homogeneous assays or the Friedewald equation.

Kazuma HANAI, PhD (Diagnostics Research Laboratories, Wako Pure Chemical Industries, Ltd.) is the winner of the 2016 JSCC Technology Award, entitled with "Development of a new creatine kinase MB mass determination assay using a latex agglutination turbidimetric immunoassay".



Dr. Kazuma Hanai, JSCC Technology Award winner, presented a lecture about the work that received the award

For diagnosis of myocardial infarction (MI), it is important to investigate changes in electrocardiograms and increases in blood cardiac biomarker levels. CK-MB is a suitable clinical biomarker of myocardial damage such as MI.

They developed a reagent for CK-MB mass measurement, *"L-type Wako CK-MB mass"* (L-CK-MB mass), that can be used to perform latex agglutination turbidimetric immunoassay (LTIA) with an automated biochemistry analyzer. During the development of L-CK-MB mass reagent, they made the following two improvements to CK-MB mass measurement.

The first improvement is the high sensitivity of the latex aggregation reaction. Although polyethylene glycol 6000 (PEG 6000) was used for conventional reagents

Article continued on next page

for LTIA, this conventional reagent was not sensitive enough to measure low concentrations of CK-MB mass. However, the aggregation enhancer they developed can make reagents for LTIA more sensitive. The second improvement is the high specificity of their reagent for CK-MB. Serum samples containing CK-BB and macro CK type 1 (mainly IgG-bound CK-BB) caused a false positive result for CK-MB by LTIA, but not with electrochemiluminescence immunoassay (ECLIA). To resolve this cross reaction, they used anti-CK-B antibodies to inhibit cross reactions of anti-CK-MB antibodies with CK-BB and macro CK type 1.

In conclusion, L-CK-MB mass reagent was developed for the latex agglutination turbidimetric immunoassay method. This reagent is used with an automated biochemistry analyzer, and the CK-MB mass value determined using L-CK-MB mass assay was almost the same as that measured using ECLIA. These results suggest that L-CK-MB mass reagent is suitable for clinical routine measurement of CK-MB mass.



News from COLABIOCLI's headquarters in Uruguay

"Neonatal Research: What a drop of blood can prevent"

It is well known that Uruguay is the headquarters of COLABIOCLI. We want to share the impact achieved with the following on-line course:

"Neonatal Research: What can prevent a drop of blood"

This course was given within the framework of one



of the main projects of the confederation, coordinated by the President of COLABIOCLI, Prof. Graciela Queiruga, beginning on March 6, and concluding in June. It countained 11 modules

and was allocated six hours per week.

The design of the course was very complete, covering different aspects in the following modules:

- 1. Neonatal Research Programs
- 2. Congenital Hypothyroidism
- 3. Congenital Adrenal Hyperplasia
- 4. Biotinidase Deficiency
- 5. Phenylketonuria
- 6. Galactosaemia
- 7. Cystic Fibrosis
- 8. Haemoglobinopathies
- 9. Extended Search

by Stella Raymondo National Representative, Uruguay

- 10. Quality Control
- 11. New Technologies

There was a partial globalizing instance implemented from multiple choice questions at the end of each module and/or final if necessary. Another feature of the course was the implementation of a forum, attended by the course's teacher, which made it possible to clarify the participants> doubts and strengthen their knowledge.

This event was offered free to partners of the national societies belonging to COLABIOCLI.

It had a great impact amongst the members and with an initial enrollment of 696 people, 245 people passed the course. This has allowed COLABIOCLI to spread the knowledge of the subject in a highly satisfactory way.

This degree of satisfaction and appreciation was manifested by innumerable letters sent by National Societies.

COLABIOCLI is planning more courses in this modality. For more details, visit our website: http://colabiocli. com/; as well as our next XXIII Latin-American Congress COLABIOCLI 2017 and the XI Uruguayan Congress of Clinical Biochemistry: http://colabiocli2017uy.com/.



News from Romania

2nd Conference of the Romanian Association of Laboratory Medicine (RALM)

> by Ioana Brudașcă RALM President



The Second Romanian Association of Laboratory Medicine (RALM) Conference was held between 10-13 May 2017, in Timișoara. The congress was organized under the auspices of IFCC and EFLM and in collaboration with the Romanian Society of Microbiology, the Romanian Society of Haematology, and the Universities of Medicine and Pharmacy of Timișoara, Târgu Mureș, Cluj-Napoca, Iași, and București.

The congress was attended by over 550 participants (i.e. medical doctors, scientists and lab technicians working in medical laboratories). Four speakers from



Speakers at 2nd RALM Conference

abroad were invited to the conference: Prof. Sedef Yenice (Turkey), Prof. Elizabeta Topic (Croatia), Prof. Gabor Kovacs (Hungary) and Prof. William Au (China). The participation of Prof. Sedef Yenice and Prof. Elizabeta Topic was supported by the Visiting Lecturers Program of IFCC. Many of the Romanian speakers were teachers at the medical faculties of Bucharest, Cluj-Napoca, Târgu Mureş, Timişoara, Iaşi. As our association is very interested in motivating young laboratory professionals, many communications were presented by young colleagues, most of them PhD fellows. Two awards were granted, one for the best poster, and one for professional activity.

The scientific programme covered a large area of themes in laboratory medicine (clinical chemistry, microbiology, hematology, genetics, molecular biology) presented in 58 posters, 21 oral communications and 21 plenary re-

> ports. 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.

> Congress abstracts were published in a supplement of the Romanian Journal of Laboratory Medicine (RRML).

As our profession is in a permanent partnership with the clinical diagnostic industry, during the congress, an exhibition of reagents, equipment, supplies, software was organized by 19 companies. There were also nine 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, the appealing social programme, as well as the unique charm of the city of Timișoara, with its historical monuments, beautiful architecture, multicultural heritage and friendly life style fully contributed to the success of this scientific and professional event.

Assoc. Prof. Dr. Ioana Brudașcă RALM President



News from Pakistan

Pakistan Society of Chemical Pathologists (PSCP) organizes the 8th Annual PSCP Course

Pakistan Society of Chemical Pathologists (PSCP) organized the 8th annual course in Chemical Pathology at CMH Lahore Medical College on 28-29 April 2017.

The president and a dedicated team of chemical pathologists made a very successful endeavour of a very scientific and educational programme in these sessions. The inaugural session had a state of the art session on novel Cardiac Markers by Maj. General Ahmed Khan HI (R), Patron PSCP.



Organizing Committee of the PSCP Course

by Nusrat Alavi Shalamar Medical and Dental College Secretary Treasurer of PSCP

After that very informative and innovative talks were delivered by our senior chemical pathologists in very well attended sessions covering following topics:

- Precocious Puberty
- Short stature and chemical analysis
- Laboratory safety
- Acid base balance and albuminuria update
- ADA recommendations of standard of medical care in diabetes
- Unveiling the secrets of cushingoid features in infants

There were total of three sessions on the first day followed by mock objective structured practical examination (OSPE) exam for trainees. The second day had two sessions including a meet the expert session. The activity targeted the clinicians, pediatricians and post-graduate trainees of Chemical Pathology.

PSCP always keeps the tradition of promoting academic and research culture in the country and keeps updating the guidelines according to international standards.

Article continued on next page



PSCP Executive Council Members



Maj. Gen (Rtd) Farooq A. Khan



PSCP Course participants



Interactive session



Academic session

Article continued on next page



Participants at the 8th Annual PSCP Course



Updates on EFLM publications

Biological Variation Estimates Obtained from 91 Healthy Study Participants for 9 Enzymes in Serum *Carobene A, Røraas T, Sølvik UØ, Sylte MS, Sandberg*

S, Guerra E et al. Clin Chem 2017;63:114150.

This is an important study by the EFLM WG on Biological Variation (BV), reporting on withinsubject and betweensubject BV for 9 commonly measured serum enzymes.

The enrolled subjects came from a number of European Countries and the samples were collected in a biobank created by the EuBIVAS (European Biological Variation Study). The enzymes were measured by contemporary methods following a protocol designed to minimize analytical imprecision and enable traceability using frozen sera with target values assigned by reference methods. All within-subject and some *by Maria Stella Graziani Chair, EFLM Communications Committee*

between-subject BV estimates were lower than those reported in the online BV available database. The enzymes studied in the paper demonstrated a rather stable activity in healthy individuals for at least 10 weeks, and no clear differences were observed in enzyme activity between groups from Turkey, Norway, The Netherlands, Spain, and Italy.

These observations confirm that the obtained data are widely applicable across healthcare systems and that they can be used to deliver analytical performance specifications to be used internationally, in accordance to model 2 (BV based) proposed by the 1st EFLM Strategic Conference held in Milano (Italy) in 2014.

The full list of the EFLM publications is available on www.eflm.eu, under EFLM Publications, where you can download the full papers.



EFLM interviews: Wim Huisman about IVD Regulation 2017/746

by Ana-Maria Simundic EFLM Executive Board Secretary

Ana-Maria Simundic (AMS), EFLM Executive Board Secretary, interviews Wim Huisman (WH), Chair of the EFLM Quality and Regulations Committee.



For admission to the European Market IVD's (In Vitro Diagnostic materials and equipment) have to adhere to specific demands as formulated in the IVD Directive98/79/ EC. This is made visible by a CE symbol. Many have been convinced for a long time that this directive has to

Wim Huisman

be updated. About 10 years ago, stakeholders were asked for their opinion continuing discussion led to a new regulation acceptable to the European Commission, the respective countries and the European Parliament. In the official paper of the EC of 5 May, the new IVD Regulation was published, valid from May 26, 2017. A link to this publication has been placed on our *EFLM website*.

AMS: What are the main differences between the old directive and the new regulation?

WH: First a formality, but with consequences. As the name indicates, this is a Regulation and not a Directive. A Regulation leaves much less possibilities for countries to deviate. It has a stronger legal position than a Directive.

However, major differences exist between the old text and the new text as well.

There is more attention to risk in relation to patient safety in the classifications (A-D) of the IVDs;

Clinical Effectiveness and requires clinical studies to demonstrate this. Hence there are specific demands

in relation to the quality system of the manufacturers, especially in relation to Risk Management.

The majority of the IVDs will be placed in class B. The documentation concerning these IVDs and the quality management system of the manufacturer has to be approved by a Notified Body (NoBo). This is a certifying body, which has to fulfill demands comparable to becoming accredited, but nominated as such by an European country for this specific task: judging the claims for a specific type of IVD for conformity assessment. For class C and D stricter demands in relation to the role of the NoBo are formulated.

The demands for being accepted as a NoBo are much stricter than it used to be. Knowledge about the specific product has to be present; the list of accepted NoBo's will be published.

In house produced tests are only allowed if no CEmarked IVD with justifiable needed requirements is on the market. The laboratory which develops such a test must have a quality management system and validate the test. ISO15189 is specifically mentioned, but other systems approved in a country suffice.

Specific attention for IVDs for self-testing and Near Patient Testing. Self-testing is placed in category 3 For Near Patient Testing specific requirements are formulated.

Involvement of reference laboratories is demanded in specific settings.

An extensive Post-Market Surveillance system is required. This makes problems transparent for the user, because information becomes available in a specific database (Eucomed, European database for medical devices.).

All IVDs must have a specific unique number (UDI, Unique Device Identifier).

There is an explicit requirement for clinical evidence, to be collected and analyzed throughout the life cycle.

Article continued on next page

AMS: Will the new Regulation affect the quality of the products the laboratory will use?

WH: Many of the requirements for the products were already formulated in the present Directive. Some aspects are more strictly formulated like traceability and clinical effectiveness. For us it is very important that the manufacturer has to make the information about the validation and acceptable batch to batch differences available for the laboratories which use these products. Besides they have to show continuous improvement and updated information for the products once they are on the market, the post market surveillance system will facilitate this. The stringent demands in relation to the NoBo's, which is quite justified, and the fact that the majority of the IVDs (more than 80% instead of the present 20%) have to be assessed, will have a positive influence.

AMS: Do we expect improvements in the quality of our services as a consequence of the regulation?

WH: I expect it will facilitate and improve the work we do. For risk management we have to do this in our laboratories to comply with ISO15189, the manufacturers have to supply us with information about the residual risks left when the product is placed on the market. The information about validation and traceability will make it easier to perform verification in the laboratory. Unfortunately, the term Measurement Uncertainty is not mentioned in the regulation, but because the provided information, including the allowed batch to batch differences, it will be easier for the laboratory to decide if a specific test fulfills the requirement needed for the patient in that situation. For developing an in house method specific requirements concerning its quality have been formulated.

AMS: Do you think our profession had a role in the development of the regulation?

WH: We have reacted to the questionnaire about areas for improvement of the Directive98. We focused on traceability, availability of information, changing the classification system, in a way it was more focused on patient safety and in house testing. We sent around papers to the societies to approach the persons in their countries who were involved in

writing this regulation. In some countries extensive contacts were accomplished. Quite a lot of our wishes are fulfilled, but not only because our efforts. A specific point concerning information about the allowed lot to lot differences can be considered as our exclusive lobbying result. Concerning the in house tests we are glad with the possibility offered in relation to the classes (also C and D), and the demand for their validation with specific mentioning of the ISO15189, but not with the restriction to "if not available as an IVD".

AMS: What are the classifications used for the IVDs?

WH: Class D: transmutable agents in blood, high risk transmutable agents, specific blood groups.

Class C: rest of the blood groups, infectious agents, tests for sexual transmittable diseases, tests for pre and post-natal screening, genetic related tests, drugs, screening in life-threatening situations, and self-testing (except pregnancy tests, urine tests, fertility tests and cholesterol).

Class A: specimen receptacles, reagents for buffers, mediaforbacterialcultivation, instrumentation assuch. Class B: all others.

AMS: When will the Regulation become effective?

WH: For becoming effective the industry has five years. The period they have to adopt the demands formulated in this IVD Regulation ends 26 May 2022. The products produced under the IVD Directive98 will be no longer be available after 26 May 2024. This seems a very long time, but quite a lot of actions have to be taken. The NoBos have to be nominated and published, they have to change their quality system and include sufficient competence, they have to assess many more IVDs than before. The industry will have to adjust their quality management system, they have to put much more effort in the risk management, they must set up clinical studies for many IVDs, but above all they have to set up the Unique Device Identification system for all IVDs they produce. They have to set up the post-market-surveillance system. They must make sure they can provide all needed information for each specific IVD. The EC has to set up the database system of Eucomed and have made it publically available.

AMS: Do you want to add some remarks?

WH: Although the Regulation is an extensive document it is worthwhile to read at least specific parts. It concerns the preambles (for instance 29 about in house tests, 38 about UDI, and 41 about Eucomed) to have an idea about what is intended.

Chapter I gives scope and definition (it indicates the Regulation is not for External Quality material or research products).

Chapter III is about identification and traceability. Chapter VI is about clinical evidence and performance evaluation.

Chapter VI is about Post Market Surveillance.

Especially informative is Annex I, under 9, about the performance requirements, traceability; and, under 20, requirements regarding information supplied. Here one finds under 20 4.1 u-w the batch to batch variation.

IFCC PROFESSIONAL SCIENTIFIC EXCHANGE PROGRAMME (PSEP)



My experience in Lausanne, Switzerland

by Marie Lenski Department of Toxicology, University Hospital Center of Lille, France



Marie Lenski, resident in Laboratory Medicine

This research project was initiated at the Centre for Psychiatric Neuroscience of Lausanne, which missions are to teach and develop research in order to improve medical care in psychiatry. An important work is done on side effects of psychotropic drugs treatments like weight gain and metabolic complications. These health problems may ultimately lead to the development of cardiovascular diseases, reducing patients' quality of life and increasing their mortality. A clinical study in pharmacogenetics is already lead in Lausanne. I was asked to work on a new approach by using metabolomics tools in order to search metabolomics biomarkers to predict the occurrence of metabolic complications in patients treated with psychotropic drugs.

Metabolomics is one of the relative newcomers of the omics sciences and it represents an important asset for research and practical application in healthcare, as underscore by the theme of the next IFCC World-Lab Congress in Durban «Multi-omics, laboratory medicine & personalized medicine». This research project was therefore of high clinical relevance and could lead to improve patient-centered care. This approach consist in the study of the metabolome, final level of cellular regulatory processes constituted of molecules of small molecular weight, that is the ultimate response of biological systems to genetic or environmental changes. Metabolomics is an evolving discipline that relies more and more on the most upto-date scientific techniques in the fields of molecular biology and analytical chemistry.

> Read more on the IFCC website

IFCC's Calendar of Congresses, Conferences & Events

Calendar of IFCC Congresses/Conferences and Regional Federations' Congresses				
Sep 17 - 20, 2017	XXIII Congreso Latinoamericano de Bioquímica Clínica XI Congreso Uruguayo de Bioquímica Clínica	XXIII COLABLIOCLI Congress 2017 and XI Uruguayan Congress of Clinical Biochemistry	Punta del Este, UY	
Sep 18 - 22, 2017	International Federation of Clinical Chemistry and Laboratory Medicine	Flow Cytometry Course: Cell Processing and Purification	Munich, DE	
Oct 20 - 22, 2017	TO OCIOBER 2018	XIV International Congress of Pediatric Laboratory Medicine WorldLab Durban 2017	Durban, ZA	
Oct 21, 2017	International Federation of Clinical Chemistry and Laboratory Medicine	IFCC-POCT Satellite Meeting WorldLab Durban 2017	Durban, ZA	
Oct 22 - 25, 2017	IFCC WorldLab	XXIII IFCC WORLDLAB - DURBAN 2017	Durban, ZA	
Oct 22, 2017	International Federation of Clinical Chemistry and Laboratory Medicine	IFCC Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement	Durban, ZA	
Oct 26 - 27, 2017	International Federation of Clinical Chemistry and Laboratory Medicine	IFCC Satellite Meeting "Biomarkers for Diabetes" - WorldLab Durban 2017	Cape Town, ZA	

May 19 - 23, 2019	BARCELONA EUROMEDLAB 2019	IFCC - EFLM EUROMEDLAB 2019	Barcelona, ES	
May 24 - 28, 2020	FEE WorldLab SEOUL 2020 After Security Indices	XXIV IFCC WorldLab - Seoul 2020	Seoul, KR	
May 16 - 20, 2021		XXIV IFCC - EFLM EUROMEDLAB - MUNICH 2021	Munich, DE	
May 21 - 25, 2023		XXV IFCC - EFLM WORLDLAB - EUROMEDLAB - ROME 2023	Rome, IT	
Calendar of events with IFCC auspices				
Aug 11 - 12, 2017	High Quality Specialty Training Courses in Quality Control for Laboratory Sciences - MODULE II STATISTICAL TOOLS		Mexico City, MX	
Aug 22 - 25, 2017	72°Congreso de Bioquimica 2017		Buenos Aires, AR	
Aug 24 - 26, 2017	Updating in document managerisk management of the labor Preanalytic, analytical and po	Machala, EC		
	High Quality Specialty Trainin	na Courses in Quality Control		

Aug 22 - 25, 2017	72°Congreso de Bioquimica 2017	Buenos Aires, AR
Aug 24 - 26, 2017	Updating in document management and generation of AMEF for risk management of the laboratory process in all three phases. Preanalytic, analytical and post analytical	Machala, EC
Sep 8 - 9, 2017	High Quality Specialty Training Courses in Quality Control for Laboratory Sciences - MODULE III: "Technical Competence Indicators"	Mexico City, MX
Sep 11 - 16, 2017	XLI Congreso Nacional de Quimicos Clinicos y Expoquim	Merida, MX
Sep 19 - 21, 2017	18th International Metrologie Congress	Paris, FR
Sep 19 - 23, 2017	28th National/International Biochemistry Congress	Erzurum, TR
Sep 21 - 22, 2017	13th EFLM Symposium for Balkan Region	Belgrade, SRB
Sep 26 - 29, 2017	51st Brazilian Congress of Clinical Pathology/Laboratory Medicine	Sao Paulo, BR

Calendar continued on next page

Sep 27 - 29, 2017	1ères Journées Francophones de Biologie Médicale	Bordeaux, FR
Oct 1 - 31, 2017	Workshop and Course in clinical microbiology update, 2017	Quito, EC
Oct 3 - 4, 2017	High Quality Specialty Training Courses in Quality Control for Laboratory Sciences - MODULE IV: "Breaking rules"	Mexico City, MX
Oct 4 - 7, 2017	European Society for Pharmacogenomics and Personalized Therapy (ESPT) Annual Meeting	Catania, IT
Oct 4 - 7, 2017	3rd International Symposium on Advances in Circulating Tumor Cells (ACTC)	Rhodes, GR
Oct 5 - 6, 2017	CELME 2017	Prague, CZ
Oct 11 - 14, 2017	14th Annual Congress of the German Society of Clinical Chemistry and Laboratory Medicine (DGKL)	Oldenburg, DE
Oct 11 - 13, 2017	III Russian Congress of Laboratory Medicine	Moscow, RU
Oct 13 - 16, 2017	17°Congreso Internacional del Colegio Nacional de Bacteriologia	Cali, CO
Oct 16 - 18, 2017	49th National Congress of S.I.Bio.CLaboratory Medicine	Firenze, IT
Oct 16 - 17, 2017	Journées Nationales 2017 de la Société Française de Biologie Clinique	Paris, FR
Oct 18 - 20, 2017	LMCE 2017 & KSLM 58th Annual Meeting	Seoul, KR
Oct 26 - 28, 2017	Biochemistry Clinic and hematology workshop	Machala, EC
Oct 26, 2017	International Conference on Laboratory Medicine "Uncertainty, quality, safety and accreditation in Laboratory Medicine"	Padova, IT
Nov 1 - 4, 2017	Congreso Nacional Bioquimico Cubra XIV	Rio Negro, AR
Nov 8 - 11, 2017	2nd International Conference on Natural Products for Cancer Prevention and Therapy	Kayseri, TR
Nov 30, 2017	11th International Scientific Meeting of the Centree of Metrological Traceability in Laboratory Medicine (CIRME) "Measurement Uncertainty in Medical Laboratories: Friend or Foe?"	Milan, IT
Dec 1, 2017	51e Journée de Biologie Praticienne (JBP 2017)	Paris, FR
Dec 4 - 5, 2017	JCTLM Members & Stakeholders Meeting 2017	Paris, FR
Feb 8 - 9, 2018	International Congress on Quality in Laboratory Medicine	Helsinki, Fl
Jun 12 - 15, 2018	XXXVI Nordic Congress of Clinical Chemistry	Helsinki, Fl
Sep 30 - Oct 3, 2018	Santorini Conference "Systems medicine and personalised health & therapy" - "The odyssey from hope to practice".	Thira Santorini, GR

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