To quote Alain Mérieux, “without diagnostics, medicine is blind.” The paradox is that only 2% of total healthcare costs go towards in vitro diagnostics but 60% of treatment decisions are made based on in vitro information. The dominant model of laboratory testing throughout the world remains the centralized laboratory in which most of the analytical processes are nowadays automated to enable the analysis of large numbers of samples at relatively low cost. This trend is well established in biochemistry and hematology and is now extending to other disciplines including microbiology and anatomical pathology. However, healthcare is changing, due to economic pressure and shortage of personnel, economic growth of developing countries, and a shift towards a more patient-centered approach. There is always the urge to provide even faster results allowing rapid decisions and need to facilitate testing of chronically ill patients or patients with limited access to medical care. All the above together with the recent advances in technology have contributed to the development of point of care testing (POCT). The term “point-of-care testing” (POCT) describes the clinical laboratory testing that is carried out at patient’s bedside or in the direct proximity of the patient. A generally accepted definition has still not been agreed.

To be continued on page 2
Other terms used are: "near-patient laboratory testing", "remote rapid testing", "bedside testing", "decentralized testing", "Patient self-management". The National Academy of Clinical Biochemistry (NACB) defines POCT as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients themselves (self-testing)". POCT refers to any testing performed outside of the traditional, core, or central laboratory. The typical characteristics of POCT are the following: the test is performed near the patient; no sample preparation is required; whole blood can be used; no pipetting steps; "Ready-to-use" reagents; single sample measurement; no medical technical expertise is required; the results are available in short time.

What are the criteria for the selection of a POCT system? The clinical and operational needs along with facility needs. The clinical needs include the evaluation of POCT results on patient management (i.e., improved TAT compared to laboratory testing) and the requirements for POCT implementation in clinical practice. The operational needs include staffing needs, storage, space, and temperature requirements, information technology requirements (i.e., patient and QC data, LIS, HIS), and cost (financial justification of POCT vs laboratory testing).

What characteristics of a POCT system should be evaluated? Test complexity, QC mode, type of device, operator management, type of connectivity, type of specimen, training, cost assessment, and users training. Sufficient concordance between POCT results and results obtained in the central laboratory must be assured within acceptable tolerance limits with accuracy relative to lab reference method, precision, and specificity.

The primary goal of POCT is "reducing turnaround time without compromising the quality of information on which clinical decisions are based" resulting in faster diagnostic and therapeutic processes, shorter length of stay (LOS), lower total medical cost, clinician and patient’s satisfaction. Additionally, epidemics, pandemics, disasters are confronted and health care in rural areas is supported.

Medical device legislation for POCT. All systems or devices used in the field of POCT are classified as IVDs (in vitro diagnostics). For this classification according to the IVD Directive, it is irrelevant whether the devices used for diagnosis are applied in medical laboratories by trained personnel (laboratory diagnostics), on the ward (POC diagnostic devices) or for self-testing (home diagnostic devices, "home-use"). Since May 2017, IVDs have become subject to a separate, directly applicable European regulation, Regulation (EU) 2017/745. There are perspectives for establishing a new product category named “devices for near-patient testing”, certainly to account for the increasing importance of POCT diagnostics. This category will contain devices which are not intended for self-testing, but for the application outside the (conventional) laboratory environment, generally near or at the patient. Product information (labeling, instructions for use, identification) will be provided in the language(s) of the Member State(s) in which the intended users will be supplied with the device. Moreover, devices for near-patient tests are additionally tested on their performance in different medical environments (e.g., patient’s home, emergency department, outpatient centers). All sites that perform POCT are required to have a Clinical Laboratory Improvement Amendments (CLIA) certificate. According to CLIA regulations in 1988, tests are divided as follows:

- Tests of low complexity that are "simple tests with an insignificant risk of an erroneous result", so-called "Waived tests". The CLIA Waived Testing Requirements include a Certificate of Waiver (CW), a fee certificate, and conformity to manufacturers’ instructions. Waived Tests evolved from a few to hundreds.
- Tests of medium and high complexity so-called "No waived tests". POCT does not specifically refer to CLIA-waived tests but also includes a wide variety of non-waived medium complexity tests.

POCT accreditation

"All laboratory tests regardless of their location require the same accreditation criteria". EN ISO 22870 was the first international standard on quality management for POCT, 2006 and modified at 2017. The requirements of the ISO 22870 included: Quality control, establishment of a committee, training programs management, and quality assessment. In the present, accredited POCTs exist in several European countries and in the USA.

Quality assurance

Instrument and method validation

a. Calibration studies: accuracy, linearity, repeatability • Record keeping (calibration, maintenance, washing, storage, troubleshooting)
b. Supplier selection • Maintenance and control of reagent supply / storage, expiration dates • Record keeping

POCT regulatory requirements focus on two areas: training and competency of the personnel doing the testing and verification of strict adherence to the manufacturer-specified procedure for each test.

Internal quality control twice daily (with exception of waived tests) and external quality assessment.

Quality management manual

a. Educational programs • Training and certification test • Continuing education and testing • Keeping user registers
b. Instructions for use next to the instrument • Procedures for recording the results • Procedures for infectious waste disposables • Recording of compliance with other security procedures

The ideal requirements for a POCT System are the following:

First results in a minute or less, portable instruments with consumable reagent cartridges, single-step operating protocol, capability of analysis on non-processed samples (whole blood, CSF, urine, and stool), simple operating procedures, flexible test menus, results comparable with those of the central laboratory, built-in/integrated calibration and quality control, ambient temperature storage for reagents, result storage and transmission, and low instrument cost.

Areas of application: The main areas of application of POCT are within the hospital (Emergency Department (ED), Intensive Care Unit (ICU), Operating Room/Reanimation, Delivery Room/Neonatal Ward, CT scanning/ Invasive Radiology, Diabetic Care Ward, Dialysis/ Reanimation unit) and outside the hospital (physician’s office, pharmacy, home care and nursing care, ambulances and emergency vehicles, health centers, patient’s home, disaster and pandemic locations).

The clinically analytes or parameters in use for POCT include blood gases, electrolytes, metabolites, coagulation factors, enzymes, hormones, drugs and narcotics, hematology factors, cardiac markers, viruses etc. POCT emergency parameters should be provided in all emergency departments and ICUs, to achieve fast answers. The most common parameters are blood glucose, electrolytes, blood gases, cardiac markers, coagulation parameters, β-HCG.
POC diagnostic market
POC systems make up an important segment of the in-vitro diagnostic (IVD) market, nearly the 30%. The global POC diagnostic market is anticipated to show rapid growth over the next years and is estimated to reach USD 50.6 billion by 2025 from USD 29.5 billion in 2020, at a CAGR of 11.4%. because it offers significant growth potential for product manufacturers. Additionally, technological evolution in POC devices, rising incidence of infectious diseases, and increased investments by key players are the main reasons for POC diagnostics growth. It is a multi-billion-industry with high competition and various sectors. By product, the glucose monitoring products will dominate, by platform, the lateral flow assay system will be the largest share, by end user the home care segment will be the fastest-growing end-user segment, by region North America will account for the largest share of the market, and by mode of purchase the over the counter (OTC) products segment will have the highest growth rate. The most important Key Market Players are the following: Abbott (US), Roche (Switzerland), Siemens (Germany), Danaher (US), Becton Dickinson and Company (US), Johnson & Johnson (US), Instrumentation Laboratory (US), PTS Diagnostics (US), Quidel (US), Chembio Diagnostic Systems (US), Sekisui Diagnostics (US), Nova (US), EKF Diagnostics (UK), AccuBioTech (China), Trinity Biotech (Ireland), etc.

Types of POC devices
POCT devices according to their size are classified into small handheld devices and large bench-top devices. POCT handheld devices first appeared in the form of paper strips many years ago for the testing of urine. Test strips as we know them today were introduced in the 1940s and 1950s through companies such as Ames and Roche, while the first disposible immunochemical test could be deemed to be the relatively rapid (2 hours) pregnancy test presented by Wampole in 1970. This type of devices ranges from the simplest form, the dipstick, to sophisticated, small cartridge devices. Unprocessed whole blood can be applied directly to the device without any prior preparation. Dipsticks are of a single use, give qualitative or semi-quantitative and can detect one or up to 10 analytes; each strip is composed of several layers each with designated functions such as separation of plasma from the red cells, spreading or support. Chemical or immune reactions take place. The measuring signal can either be read off directly or recorded on a simple read-out device. The sensors are incorporated into the test strip. The spectrum of available tests varies greatly and depends on the sensors employed. Dry chemical methods are implemented, e.g., glucose-converting enzymes that are immobilized on reagent strips. Any calibration in these devices is usually replaced by electronic or physical standards, more sophisticated handheld devices are the so-called integrated cartridges best exemplified by the i-STAT. After placement of a small sample of whole blood the cartridge is inserted into a reader for measurement. The cartridge utilizes thin-film sensors in combination with microfluidics, and cartridges are produced in various formats for different analytes. Their popularity is due to the extensive critical care testing menu that is available on a single device. The i-STAT represents an economical way to provide relatively low numbers of critical tests. The Epoc critical care testing system is also a handheld POC device but of a different construction being based on so-called Smart Card Technology. Here the biosensors and microfluidics are printed on a 35 mm format. Once again, different cartridges are available to provide a range of POC tests.

POCT Large Bench-Top Devices
This type of instruments presents more complex built-in fluidics and mimics miniaturized automated analyzers. They are multiple use instruments, for single-sample measurements. Reagents and solutions are contained in prefabricated disposable disks or cartridges with different combinations for multiple selections. 100 microliters are enough for 10 analyses. Self-calibrators and controls are integrated. After transferring the sample onto the uptake point, the disc is inserted into the analyzer drawer where the sample is moved by centrifugal and capillary force to the appropriate site inside the cuvette where the reaction occurs. In this way, diluents and reagents also flow to the “correct” reaction site. After a few minutes, the analysis is performed photometrically, self-calibration and continuous quality controls are integrated in the analyzer. Small desktop instruments are also available to measure a wider range of general chemistry analytes such as the Piccolo express which uses a small disposable rotor that contains all the required reagents and diluents to perform a particular group of tests. The major difference of the cartridge-based systems here compared to the hand-held devices is that the sensors are reusable. Constructed using thick-film technology, the sensors for each of the tests and all the required reagents for calibration and washing are packaged into a single cartridge pack which is inserted into the instrument. The lifespan of the cartridge when inserted into the machine is based on the number of samples analyzed and the life-duration of the cartridge.

Click here to read the rest of this interesting Hot Topic News

EFLM EXECUTIVE BOARD INFORMS

EFLM Action plan for 2021

Reported by Ana-Maria Šimundić, EFLM President

Dear Colleagues,
in January 2020, we have asked you to share with us your view of EFLM and help us improve EFLM. You were asked to fill out a form and return it back to EFLM office by not later than 31st January 2020. The form was sent to all Executive Board members (EB), Committee (C) and Working Group (WG) Chairs and all EFLM National societies (NS). The plan was to use your feedback to brainstorm, do a SWOT analysis and produce a 2-year action plan, during the first EB meeting which was supposed to take place in Vienna, but the COVID-19 pandemic has made us change our plans. Not only have we had to cancel all our face-to-face meetings for the rest of 2020, but our priorities suddenly shifted from whatever it was until then, to the global race aimed to control and fight back the deadly virus. This battle has consumed very much of our time and resources, leaving us very little for anything else. And 2020 is now almost gone by. Looking back, one must not think of it as of a lost year, because through this battle we have learned a lot and now we have to use this experience
to improve ourselves and our profession. I am sure that the future of our profession is bright. Due to the above-mentioned reasons, it is only now, that we give back to you the results and outcomes of the survey performed in January 2020. We have received feedback from 17 WG and C Chairs, 18 NS (Belgium, Bosnia and Herzegovina, Croatia, Czech Republic, Estonia, Finland, France, Greece, Italy, Lithuania, Macedonia, Romania, Slovakia, Slovenia, Spain, Switzerland and Turkey) and the entire EB.

You can find summary results by clicking here. Individual replies are available in the Appendix.

We have gathered the most valuable opinions and suggestions from you, which will help us shape the EFLM in the future to better fit your needs and expectations. Based on the outcomes of the survey, an action plan was designed with 30 specific actions points – each of them being a particular project/activity which addresses a particular issue/need identified in the survey (click here and go to page 6-7-8 for the action plan).

We hope that you will welcome our Action plan 2021 and we look forward to our future collaboration.

Thank you for your feedback and ongoing support of EFLM.

Kind regards,
Ana-Maria Simundic, EFLM President
(on behalf of EFLM Executive Board)

Free access to CLSI documents
Reported by Tara Rolić, EFLM Communication Committee

The EFLM President is delighted to inform on the successful negotiation with CLSI for the free access of CLSI documents for EFLM Academy Members enrolled collectively through their National Society! This greatly appreciated benefit of the EFLM Academy membership is available again starting with January 2021, exclusively for EFLM Academy Members enrolled through block enrolment by their National Member Society. EFLM Executive Board will do its best to continuously increase the number of benefits, by providing exciting opportunities for your professional and academic growth and by offering you a true value for your membership. EFLM Academy Members registered on individual basis can benefit of CLSI membership at a reduced rate: 25% of discount on CLSI individual membership fee.

COFFEE WITH THE EFLM PRESIDENT

Coffee with Pilar Fernández-Calle

When did you join EFLM? What is your current role in EFLM? What are the activities of the functional unit in which you work?

I joined the EFLM in 2013, when I first met the Working group of Biological Variation as a corresponding member. At that moment, the chair was Bill Bartlett and I’d like to think that since then, we have joined forces, the EFLM and the Spanish Society of Laboratory Medicine who had actively worked in Biological Variation for more than 20 years and who was initiated, published and continuously updated the BV database, having agreed with Prof. Westgard to show the BV estimates on the internet, in order to expand this knowledge worldwide. Dr. Bartlett leading the WG, gave a tremendous push to the project that was consolidated under the current chair of Dr. Aasne Aarsand. Additionally, apart from this exciting role, I have the chance of now being part of the Executive Board, as a member-at-large. I only started in 2020, with some difficult times but it is challenging to adapt to new ways of communicating and working, but quite exciting at the same time. Nothing from EFLM has stopped.

These short interviews are a wonderful opportunity to show who are the quiet, humble, modest people behind the scenes, who work for EFLM and make EFLM what it is today. I wish to thank my dear guests for giving us the opportunity to get to know them on professional and personal level. The recording of the interviews are available as Podcasts. I hope that you will enjoy these interviews as much as I did!

Ana-Maria Šimundić
EFLM President

Free access to CLSI documents
Reported by Tara Rolić, EFLM Communication Committee

The EFLM President is delighted to inform on the successful negotiation with CLSI for the free access of CLSI documents for EFLM Academy Members enrolled collectively through their National Society! This greatly appreciated benefit of the EFLM Academy membership is available again starting with January 2021, exclusively for EFLM Academy Members enrolled through block enrolment by their National Member Society. EFLM Executive Board will do its best to continuously increase the number of benefits, by providing exciting opportunities for your professional and academic growth and by offering you a true value for your membership. EFLM Academy Members registered on individual basis can benefit of CLSI membership at a reduced rate: 25% of discount on CLSI individual membership fee.
What do you like most about EFLM? The opportunity to meet extraordinary people, of course in the scientific, but also in the personal field. As Dr. Abdurrahman Coskun, one of the colleagues of the BV-WG says, in the EFLM there are WG (Working groups), TG (Task Groups) and FG (Family Groups). Well, I have the fortune to be part of some FG in the EFLM, as well as in the EB and all the people that work in the EFLM. To connect and exchange knowledge and experiences with them is absolutely enriching. The other aspect that I like the most is to have the opportunity to contribute to create a common framework of laboratory medicine specialty in Europe.

How do you see EFLM in 10 years from today? I think EFLM will become more and more representative of Laboratory Medicine practice, being at the cutting edge of multiple issues, creating tendencies, guidance, encouraging and representing a different style to understand and practice laboratory medicine. I mean, nearer to the patient, side by side with the clinician for the patients’ care.

What do you see about your current job? I am the Quality Director of the Department of Laboratory Medicine of the Hospital Universitario La Paz in Madrid, one of the biggest in our country. Our department covers all kind of areas and disciplines from basic biochemistry and hematology, gastroenterology, endocrinology, inborn errors of metabolism, dementia markers, tumor markers, reproductive medicine. In summary, more than 300 magnitudes that are the basis for the diagnosis of multiple and complex pathologies; we have accredited the 99.9% of our portfolio and to lead this procedure gives me a holistic vision of our specialty and allows me to be aware of most of the technical and clinical aspects and advances of our specialty.

Do you have a role model? If you do, what makes this person so special? I have had the chance to meet great people throughout my professional life, but I do realize that people who leave a mark on you are always those that are personally even greater than their professionalism. To highlight some of them could be unfair to others. All people that have worked close to me at the Hospital, the National Spanish Society, SEQCML, the CLSI and the EFLM, have had an impact on my way of understanding our profession and some of them has been and still are really inspirational minds for me in the personal and professional field.

What are the qualities you appreciate most about people? Honesty, loyalty and sense of humor, a good amount of humor.

Do you have some hobbies? What are the things outside of your work that you are passionate about? How do you like to spend your free time? I have a lot of things that passion me. To travel is one of them. To know other countries, other cultures, other people, is exciting! I also love everything related to nature, especially trekking. Apart from that, I love dancing (tango, waltz, ballroom dances, well, dancing in general) and I am also a good fan of cinema and reading.

What are your greatest challenges? Well! In some respects, to live is a challenge! To struggle with people concerns, family and so on is a constant test of resilience. Actually, science probably give us the most secure and peaceful moments!

Are you good in time management? No. I am not. Deadlines always approach to me dangerously!

What do you value most about your country and its culture? The feeling of enjoying life and to be kind and warm to others, making them feel at home.

Do you have a pet? Yes, we have a dog, a golden retriever female named Kenna.
When did you join EFLM? What is your current role in EFLM? What are the activities of the functional unit in which you work?

I joined the Russian Federation of Laboratory Medicine in 2017, participated with presentations at national congresses, and in 2019 won a grant to attend the 23rd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine in Barcelona, and this changed my whole world =) and filled me with new ideas about clinical chemistry and laboratory medicine. I learned more about the education of the specialists and their work in various countries, and also met young active members of the EFLM and the current president, Ana-Maria Simundic. So, 2019 is the official year I think when I joined EFLM.

In 2020, I found out about a vacancy in the Communication Committee, applied, had an interview and my application was approved, I became a Member Young Scientist of Working Group: Promotion & Publications. As part of our working group, we hold meetings once a month or even more often, developing a strategy for the development of EFLM’s presence in social media. We are responsible for EFLM Facebook, Twitter, LinkedIn and Instagram pages, for issuing a bimonthly EFLM Newsletter. We are also trying to create infographics of the most important articles of EFLM working groups that are published in the EFLM official journal – Clinical Chemistry and Laboratory Medicine (CCLM), and it seems to me that it is very important to inform the audience through non-core channels about the main achievements and developments. Within the framework of this group and our work, I learned a lot about social networks, effective interaction with the audience, about analytics to assess the effectiveness of our messages, we are constantly developing new ways, looking for new ideas how to disseminate information about the activities of our community and draw attention to its achievements.

What do you like most about EFLM?

Most of all, I like people in the community who are highly motivated, open to everything new, willing to cooperate and give advice in a difficult situation. I like the unique approach of the community, bringing together professionals from different fields of healthcare that are relevant to clinical chemistry. And I am grateful for the opportunity to do my part for the benefit of the EFLM.

How do you see EFLM in 10 years from today?

I would like to see EFLM in 10 years an active, dynamic, fast decision-making community and ready for change. I would like the EFLM weight in the professional world to be greater, our brand will be well-known and community members will be from more different backgrounds and diversity will be increased. Maybe in 10 years people can join the organization directly as individuals, including students and, for example, patient advocates. I would like to increase the impact factor of our official journal with even more high-quality articles and I will plan to see more various events and new formats. For example, the «Clubhouse» is gaining popularity now and if we think about being present in it now, in the future it can be useful.
Do you have a role model? If you do, what makes this person so special?
I do not have a role model, I just formulate for myself some goals and values that are important to me. And I see that success is not always determined by power or money, and some results are invisible to the general public, but still very significant.

What are the qualities you appreciate most about people?
Honesty and self-confidence are very important to me. I appreciate people who keep their word, do not forget about promises, and do not say what they cannot do. I trust people and I want them to trust me too. For me, a sense of humor is also very important, and the understanding that there is not only black and white, but there are shades of gray and we cannot know everything is essential for effective people.

Do you have some hobbies? What are the things outside of your work that you are passionate about? How do you like to spend you free time?
I practice classical vocal as a hobby for about 15 years, from the end of school to the beginning of quarantine, albeit with breaks, sometimes for a year, sometimes for several years. I really love to sing. I like the process itself, but opera is a harsh art with strict rules, I clearly understand that it is a hobby, it is difficult to reach great heights, but I am content with what I have. I love cuisine shows, I watch «MasterChef» show from different countries, Australian «My kitchen rules» and «Chef’s Table» on Netflix, sometimes I try to repeat something. Part of my time I take pleasure in volunteer work, in societies, mentor students, I think this can also be attributed to a hobby, but related to work.

What do you value most about your country and its culture?
I live in Russia, this is a huge country with a rich heritage, and I really like its diversity, way of life, art. I am attached to traditions, we have a lot of celebrations, I love national cuisine, we have a very good basic education. I really like nature in different regions, I recently discovered Siberia.

What do you like most about EFLM?
Its role as European forum of exchange of ideas and experience, and giving opportunities to so many national societies’ members and experts to work in EFLM functional units and contribute to shaping laboratory medicine in Europe. Personally, I like working in this inspiring international atmosphere and meeting colleagues from other countries – many of them became my friends.

How do you see EFLM in 10 years from today?
I see EFLM as the key organization with leadership position in laboratory medicine. It is the scientific and professional authority producing recommendations, endorsing guidelines, organizing education and training, promoting harmonization and standardization across European countries, and anchoring the role of laboratory medicine specialists in healthcare.

What do you like about your current job?
The unique mix of science and clinical work, made possible by the position of our job at the interface between laboratory and clinic. I have good co-workers and many possibilities to apply new diagnostic approaches and research – not easy in a non-university lab, but my predecessor paved the way for this.

Do you have a role model? If you do, what makes this person so special?
The late Vic Blaton, my predecessor in the Department of Clinical Chemistry, AZ St.-Jan Hospital, Bruges. He was founder and past-president of EFLM. Prof. Blaton inspired me with his great personality, passion for lipidology, and gentle approach of people to achieving the goals he aimed for.
What are the things outside of your work that you are passionate about? How do you like to spend you free time?

My wife and I like to go hiking or cycling in the weekends, to recharge the battery. The Alps are my favorite travel destination in holidays. On a lazy Sunday in winter, I enjoy watching a movie (James Bond is my favorite) or listening to music. I can dream away with unforgettable film scores and, more recently, my son’s music on lute or my daughter playing violin in concert. I love my family with three great kids, they are my source of happiness and energy.

How would your wife describe you?
She describes me as a dreamer, with a positive attitude to life and who believes in the good of every person (so sometimes a bit naive and then I get hurt). A traveler, interested in other cultures. Ambitious, aiming to have contributed to shaping the future of laboratory medicine. A patient man with a good heart. Based on the latter statement, I am reassured my coronary arteries are still free of atherosclerosis.

What are your greatest challenges?
To say NO to proposed tasks – I still haven’t learned to refuse even when it seems impossible to realise it. My biggest challenge, however, is trying not to forget the tasks – at home and at work. Fortunately, my wife and my coworkers are very tolerant with me.

Are you good in time management?
No, not at all. I am rather chaotic in my personal organization. But surprisingly I manage to meet the deadlines and realise the things I want to do – this is still a mystery to me.

What do you value most about your country and its culture?
Belgium is a small country with a complex and inadequate system of governance, maintained by need to represent two main linguistic groups. That makes following politics an exciting thriller in daily news on TV, it never becomes boring. Despite its political and linguistic divisions, Belgium is enjoyable for its great beers, good restaurants, beautiful arts, and fairy-tale cities like Bruges and Ghent. Our capital, Brussels, hosts official seats of the European Union institutions as well as the EFLM.

Do you have a pet?
Yes, we have a cat called Mila. She likes to join me in the seat watching daily news on TV, although I guess she doesn’t understand politics. (I share its photo with you)
When did you join EFLM? What is your current role in EFLM? What are the activities of the functional unit in which you work?

I took on the role of Chair of the Science Committee of the EFLM at the end of 2015. I help oversee the activities of the ten Working Groups and 4 Task/Task and Finish Groups within the Committee. These Groups cover a whole host of topics related to many aspects of the laboratory medicine including, for example, the pre- and post-analytical phases, biological variation, uroanalysis, cardiac markers and chronic kidney disease.

What do you like most about EFLM?

From a European perspective, I think it is important that the National Societies have a means of collaborating together and coordinating effort and the EFLM is able to facilitate this in so many different ways. My impression is of a group of like-minded individuals whose involvement is not for personal advancement or promotion, but rather simply to improve the ways in which our profession provides care for patients. I think the EFLM have also taken some wise decisions over the years to help ensure every country of the Federation can participate in its activities as well as encouraging our younger colleagues to take an active role. In relation to the Science Committee, this has translated into each Group having a Young Scientist member by right as well as each country having a limit of only one person as a Full or Corresponding Member.

How do you see EFLM in 10 years from today?

There is no doubt that the EFLM has developed a great deal over the last decade, whether looked at from its clinical activities and guideline output, its organizing of training, education and conferences, in influencing the regulation of the profession or solely in its profile on the world stage. In the next 10 years I can only see each of these activities expanding further in order to meet the changing demands of our discipline and informed by the needs of the national societies.

What do you like about your current job?

I was fortunate that when I graduated from medical school, I knew then I wanted a career in Clinical Biochemistry. I feel I am a General Practitioner for the hospital because I get to offer advice to every discipline within it as well as to my primary care colleagues. Compared to becoming, say, a cardiologist or respiratory physician - where I would likely just see patients with the same few types of problems - I get to influence the care of people with all manner of conditions and there is seldom a day goes by that I am not challenged with something new. I entered my training assuming that everything of importance about the speciality was already known. I soon realized that nothing could be further from the truth and so, over the years, I have thoroughly enjoyed trying to fill some of these gaps myself. For someone entering the profession now I can assure them that the number of these unanswered questions just keeps growing!

Do you have a role model? If you do, what makes this person so special?

Looking back at my younger self, there was a mathematics teacher at school called Mr Biggar who inspired many of us at the time to achieve far more than would normally be expected given our much-less-than-affluent backgrounds. He would encourage us to think beyond what was being taught and to question everything we did. During what should have been normal classes he even took us on field trips to explain the direct relationship between mathematics and the real world. He also felt there was no reason why any of us should not go on to fulfil our potential and guided us as to how to achieve it. I hope I am able to convey some of his values to the colleagues I work with.

How would your spouse (wife, husband) describe you?

Hah, I dare not ask!

What are your greatest challenges?

Most recently it was moving back to the UK in the middle of a pandemic after working in Qatar. This would have been challenging at the best of times but was especially so during this period. After (re)starting in Manchester it has also proved more difficult to get to know everyone I work with when much of the time conversations occur over videoconference.

In respect of the EFLM, it will be interesting to see how this and national professional organisations develop post-covid given, I feel, that there will be a continued uncertainty about travel and meeting with one another. As we have all found, meeting virtually is a good second best to meeting face to face, but it is still second best.

Are you good in time management?

I try to be, but am not sure how successful others would say I am. Also, no matter how efficient anyone is, there is never enough time to do everything you would wish. I was born as a parallel processor rather than a serial one and so while it is really interesting for me to be dealing with several tasks together, all these balls in the air at once does risk them ending up on the floor.

What do you value most about your country and its culture?

In respect of the UK, I can categorically say that I do not often value its weather! Actually, having worked in other countries, including outside of Europe, deep down I think people are much the same the world over: we have much more in common with one another than we have differences. Having said that, there are aspects to the UK which I would definitely not wish it to lose. Like other countries, I suspect, coronavirus has amply demonstrated that most people have a compassion to one another and a determination that everyone should come through this together. On a lighter note, the UK has an innate sense of humour and has the ability to laugh at itself and to gently tease one another without offence.
EFLM is pleased to announce the EFLM Awards 2021 to be presented at the 24th IFCC-EFLM EuroMedLab Congress in Munich (28 November - 2 December 2021):

- EFLM Award for Scientific Achievements in Laboratory Medicine - sponsored by Roche - [Info]
- EFLM Award for Achievements in Advancing Laboratory Medicine in Europe - sponsored by Roche - [Info]
- EFLM Award for Excellence in Outcomes Research in Laboratory Medicine - sponsored by Abbott Diagnostics - [Info]
- EFLM Award for Excellence in Performance Specifications Research - sponsored by Abbott Diagnostics - [Info]
- EFLM Cardiac Marker Award - sponsored by HyTest - [Info]

The deadline to submit application is: 31 May 2021.

EFLM awards are made possible thanks to kind and unconditional support of:

Although the key standards for the preanalytical phase are determined by The International Organization for Standardization (ISO) 15189:2012, there are significant differences in the interpretation of these requirements. To overcome these challenges, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Pre-analytical Phase (WG-PRE) have published consensus to review ISO requirements and to guide laboratories on how to meet these requirements. Authors hope that laboratory professionals will improve the preanalytical phase quality in their laboratory by applying the minimal recommendations or best-in-class solutions based on ISO1592:2012 requirements described in this consensus. Each ISO requirement described in ISO15189:2012 including pre-analytical quality indicators and sample collection, transport, reception, and acceptance have been reviewed and agreed on the recommendations. The authors are aware that the laboratories will have difficulties with the implementation of the best-in-class solutions based on the state-of-the-art, but they believe that professionals will improve their procedures with this extended guide and approach the best-in-class solutions by putting them above the minimal requirements.

Executive Board is calling National Representative to nominate candidates in the election of the new Executive Board (EB) for the two-year period: 1 January 2022 – 31 December 2023. The deadline to send nominations is 31 May 2021. Each EFLM National Society can submit one nomination only to be chosen among one of the available positions:
- President-Elect (to serve for 2024-2025)
- Secretary
- Treasurer
- Two Members-at-Large

Procedure for applications: each EFLM National Society Member in good standing with the membership fee can submit one nomination using the form circulated to the National Society’s representatives to be sent back to silvia.cattaneo@eflm.eu. A letter from the candidate explaining why she or he want to take the position. Together with the application, a short CV should also be submitted underlining the qualifications and prior experience and publications. Candidates must be officially recommended by their National Society through a formal letter of support.
UPCOMING EFLM EVENTS

The EFLM Postgraduate Courses, organized by EFLM Working Group on Congresses and Postgraduate Education (WG-CPE), aim to focus on attractive topics for young trainees, and specialists. These educational courses are generally organized on 1 or 2 days and the theme, programme and speakers are proposed by the WG-CPE. Due to current pandemic, EFLM is offering these courses on-line on these following two topics: Leadership Skills and Biostatistics.

Haemostatic disorders in COVID-19 patients

EFLM Academy webinar

On April 20th, 2021, at 18:00 CET Dr. Tatiana Vavilova (RU) will present interesting topic about hemostatic disorders in COVID-19 patients. Moderator of the webinar is Dr. Ksenia Zagorodnikova (RU). Do not miss the opportunity to learn more about the pathogenesis of COVID-19-related haemostatic disorders, the development of hypercoagulability with clinical manifestation and how it differs from DIC or sepsis. The mechanisms of haemostatic disorders in COVID-19, laboratory diagnostic methods, principles of anticoagulation and its monitoring, as well as international recommendations for the diagnosis will be included in this presentation. The webinar is accessible for the EFLM Academy members only.

Register for this webinar at the EFLM e-learning platform.
Reference intervals verification by indirect methods

EFLM Academy webinar

On March 2nd, 2021, at 18:00 CET Dr. Matteo Vidali (IT) held a webinar on the reference intervals verification by indirect methods. In this presentation, advantages, limitations, and the main statistical algorithms of the indirect approach were addressed. The focus of the webinar was advantages over traditional direct approach: reduced costs, better matching between preanalytical and analytical conditions with routine conditions, narrower confidence limits, usefulness in specific age groups or with uncommon sample types, possibility to derive continuous reference limits. These approaches were conveniently explained by the examples. The webinar has attracted high interest of professionals in laboratory medicine and had notable number of registered participants.

More information can be found in EFLM eLearning platform (accessible for EFLM Academy members only).

1st EFLM-AFCB Conference “Laboratory Medicine for Mobile Societies”

On February 18 - 20 2021 Arab Federation of Clinical Biology (AFCB) in the frame of the activities of the Joint EFLM-AFCB Task Force “Laboratory Medicine for Mobile Societies” and in collaboration with the Tunisian Society for Clinical Biology organized virtual congress. During this congress, 3 plenary conferences, more than 30 conferences, 30 speakers from 20 countries, 450 posters and several workshops were organized. Interesting scientific themes in laboratory diagnosis of COVID-19 including IFCC TFYS confronting pandemic and physiopathological mechanisms of thrombotic events linked to COVID-19, as well as relationship between migration and genetics, drug addiction and emerging infectious diseases were presented. Moreover, laboratory medicine in the era of digitalization and interventions in epidemiology and in common health care, followed by topic in diagnostic test associated with target therapy, updates in diagnosis of acute coronary syndrome and delayed hemolytic transfusion reaction in sickle cell disease were presented. Pre-Congress workshops in molecular biology were organized. The conference was visited by notable number of registered participants and has attracted high interest of laboratory medicine professionals.

The monograph Scientific Foundation “Professor Ivan Berkeš” published by the Society of Medical Biochemists of Serbia

In 2020, the year of the global pandemic the activities of the Society of Medical Biochemists of Serbia (SMBS) were suspended. Planned activities, like the national congress and the Belgrade Symposium for Balkan region were postponed, and the annual scientific conference “Professor Ivan Berkeš” did not take place. However, the year 2020 was also the year of the 110th anniversary of the birth of Professor Ivan Berkeš. On this occasion, SMBS published a monograph dedicated to professor Berkeš’s life and work, to the review of the previous scientific conferences organized to honour his legacy, also to the Foundation “Professor Ivan Berkeš”, and to the laureates of its annual award. The authors of the monograph are Professor Nada Majkić-Singh, the founder of the Foundation and its spiritus movens, and Snežana Jovičić, who, as the IFCC eNewsletter liaison member, was writing a series of articles covering the conference over the past years.

Photo 1 – Book cover of the monograph Scientific Foundation “Professor Ivan Berkeš”
Professor Ivan Berkeš established medical biochemistry as a modern scientific and diagnostic discipline of medicine and pharmacy in Yugoslavia and Serbia. Under his guidance generations of medical biochemists were educated at the Faculty of Pharmacy of the University of Belgrade. But not only. As a versatile individual (he was passionate in music, art, history, and philosophy, and spoke five languages) he inspired his students with his charismatic personality. Professor Berkeš graduated and completed his Ph.D. thesis in Zagreb, Croatia. He worked at several universities in former Yugoslavia – at the Faculty of Medicine in Zagreb, Faculty of Medicine in Skopje (North Macedonia), and Faculty of Pharmacy in Belgrade (Serbia), where he was elected Senior Professor in medical biochemistry and was a long-term director of the Institute of Biochemistry until his retirement. For nearly 20 years professor Ivan Berkeš invested all his efforts into the methodological research in clinical biochemistry, general and clinical enzymology. This work resulted in numerous specialists, master, and doctoral theses. During his working years, professor Berkeš published several books and over 200 scientific papers in renowned journals in Yugoslavia and worldwide. He was actively engaged in the Federal Committee for Medical Biochemistry and the Section of Medical Biochemistry of the Pharmaceutical Society of Serbia.

appreciating the work of their teacher and a renowned expert, professor Ivan Berkeš, upon the proposal of Professor Nada Majkić-Singh, in 1997 the Society of Medical Biochemists of Yugoslavia at the time, now the Society of Medical Biochemists of Serbia, and the Faculty of Pharmacy, University of Belgrade, established the Scientific Foundation and the Annual Scientific Conference „Professor Ivan Berkeš”. Beginning in 1998, Scientific Conferences have been presenting masters and doctoral theses in medical biochemistry and related disciplines defended during the previous academic year. Also, the best graduate students in pharmacy and medical biochemistry of the Faculty of Pharmacy in the previous year have been awarded the monetary awards of the Scientific Foundation. The monograph reviews all the twenty-one scientific conferences that took place so far, concluded with the last one, held in December 2019. Also, presents the biographies of all the forty-eight laureates of the Scientific Foundation, informing us briefly about their careers in pharmacy and medical biochemistry, in Serbia and worldwide. The 2020 Scientific Conference could not take place because of the restrictions imposed by the global pandemic that prevented us from gathering. However, the Foundation did not miss to hand the well-deserved awards to the best students of the Faculty of Pharmacy in 2020, Milena Simić (Master of Pharmacy-medical biochemist) and Milan Beljkaš (Master of Pharmacy). SMBS congratulate them on their first success, wishing them fruitful careers in pharmacy and medical biochemistry, like the ones their predecessors have. We hope that the 2020 would be the only year in which the Scientific Conference did not take place, and that the memory of Professor Ivan Berkeš will be alive for many years to come through the activities of Scientific Foundation, annual Scientific Conference, and many young laureates of the Foundation award.

The Scientific Committee of the Spanish Society of Laboratory Medicine (SEQC\textsuperscript{ML})

Reported by Merce Ibarz, Spanish Society of Laboratory Medicine (SEQC\textsuperscript{ML}), Executive Board member

As this expert notes, “the format of the courses and the combination of the topics covered in each lead to them being very well received, among both experienced professionals and residents, allowing them to update their scientific knowledge of the topics covered”. These courses – adds Dr. Guillén – combine new topics or those of greater current interest with more academic topics, condensing the most important aspects related to the topic at hand. “The distribution and duration of the talks allows the speakers to adequately transmit the content, leaving a space for the attendees’ participation, which is always very attractive and interesting”, she points out.

Reliability and confidence of laboratory results

The ISO 15189 standard assesses technical competence and is the most effective tool to ensure the quality and competence of laboratory results.

“Accreditation facilitates the work of the clinical professional by giving them added confidence in the reliability of the result they receive and provides greater trust to the patient when it comes to viewing their reports and analytical results.

XVIII Conference of the Scientific Committee of the Spanish Society of Laboratory Medicine (SEQC\textsuperscript{ML})

The XVIII Conference of the Scientific Committee of the Spanish Society of Laboratory Medicine (SEQC\textsuperscript{ML}), as it does every year, held its traditional meeting, the XVIII Conference of the Scientific Committee, which addressed and updated various important aspects in the clinical laboratory field. This year’s meeting took place in virtual format.

Accreditation of clinical laboratories is key to guaranteeing the reliability of results, making clinical decisions, and responding to the desire to optimize the care of clinical laboratory clients (requesting physicians / clinicians), while always focusing on the main beneficiary: the patient. To analyze the current situation and advance in this field, the Spanish Society of Laboratory Medicine (SEQC\textsuperscript{ML}) has organized the course “Accreditation in Genetic Diagnosis Laboratories: Key Aspects”, within the framework of its Scientific Committee Conference, which was held for the first time in virtual format from March 1 to 5.

“The Scientific Committee Conferences are one of the most important activities in which the Society’s commissions participate and are one of its main objectives”, says Dr. Eva Guillén Campuzano, president of the Scientific Committee of the SEQC\textsuperscript{ML}.

The EFLM Newsletter n. 2/2021
It is estimated that there are more than 85 accredited clinical laboratories in the various areas and around 23 have an accredited scope that falls within molecular genetics and/or molecular biology.

In recent years, there has been a slight increase in requests for accreditation in the molecular area, especially in techniques increasingly implemented in genetic diagnostic laboratories such as massive sequencing (NGS, Next Generation Sequencing), by means of panels highly aimed at diseases related to neurological and cardiological areas, intellectual disability, oncology, digestive issues, predisposition to hereditary cancer, etc. Many of these opt for a more flexible scope (so as to be able to expand the number of genes involved in these syndromes/diseases).

In this line, Dr. Izquierdo asserts that for the genetic diagnostic laboratory that has decided to enter the accreditation process, it may be more complicated to know how to meet the requirements of the standard, especially the technical requirements, given the distinctive features of the tests in this laboratory area, both with respect to the methodological complexity of the techniques and the variety of types of results/reports that are produced, among other aspects. Hence the interest in and importance of this course for laboratories.

To date, accreditation is not mandatory in Spain, while it is in other European countries such as Belgium (for all genetics laboratories), or France and Romania (for all clinical laboratories including molecular genetics/molecular biology).

Currently, the Ministry of Health, Consumption, and Social Welfare has established the accreditation requirement for Neonatal Screening laboratories that want to be designated as Reference Centers (CSUR) and “it can be foreseen that the requirement will expand to other laboratory disciplines such as molecular genetics, at least those that are a reference center; hence the need to gradually implement ISO 15189 in these areas”, explains Dr. Izquierdo.

In conclusion, Dr. Izquierdo details other genetic diagnostic techniques, in addition to NGS panels, accredited by clinical laboratories:

-- The TP-PCR (Triplet Primed Repeat-PCR) for the analysis of expansion of diseases such as Friedreich’s ataxia, fragile X syndrome, Steinert’s disease, spinocerebellar ataxias, C9orf72 gene expansion (ALS, amyotrophic lateral sclerosis / FTD, frontotemporal dementia).
-- RT-PCR (Real Time-PCR) to detect mutations and/or polymorphisms in studies of thrombophilia, hereditary hemochromatosis type 1 (HFE).
-- Allele-specific PCR (ARMS), for the study of cystic fibrosis mutations, for example, or QF-PCR.
-- There is also a range of techniques such as aCGH (60K, 180K), MLPA, Sanger sequencing for more frequent point mutations in certain syndromes/diseases, and other variants of PCR (Huntington’s disease).

Advances in the accreditation of genetic diagnostic tests

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IFCC President’s Message

My sincere greetings to you all in the IFCC family. I hope everyone is coping well with the ongoing pandemic although there is now clearly a light at the end of the tunnel and hope for a semi-normal life later this summer or fall. The strong evidence coming out of vaccination studies are showing that once vaccinated the risk of serious illness or death from COVID-19 is extremely low even in seniors.
Thus, I am hopeful that we will soon begin our normal IFCC business and in person conferences and events.
I am pleased to inform you that we had a very successful virtual conference on COVID-19 last week. This was the first virtual conference held by IFCC and it turned out to be very popular. We had nearly 2900 registered participants from 118 countries around the world including a large number of Young Scientists. There were three plenary sessions, 10 scientific symposia, 16 industry workshops and a total of 116 speakers and chairs from 34 countries. Importantly, there was strong support from corporate members with 18 corporate sponsors and a special industry panel to highlight the industry voice including four excellent presentations from different industry scientists in the field of clinical laboratory medicine. In addition, a special Young Scientists Forum was held with 6 young speakers from around the world followed with a very vibrant panel discussion. I want to take this opportunity to express my sincere thanks to all participants, speakers, chairs, and corporate sponsors. Special thanks also go to MZ Congressi who did a fabulous job of organizing the virtual presentations with no major technical issues. Over 100 presentations throughout the three days of the conference were delivered smoothly and with very few minor issues. This is a major achievement considering that the presentations were being given by speakers from every corner of the world. My congratulations to you all.

Click here to read the full message.

The IFCC is happy to present two of its news Functional Units:
- IFCC Task Force on Global Newborn Screening (TF-NBS), chaired by dr Dr Van LEUNG-PINEDA (US) and Prof James BONHAM, (UK).
  Click here to know better the new TF-NBS.
- IFCC Working Group on Artificial Intelligence and Genomic Diagnostics (WG-AIGD), chaired by Prof. Larry Kricka.
  Click here to know better the new WG-AIGD.

Save the date for the IFCC Live Webinar 6th April: Application of laboratory techniques in the diagnosis of Infectious Diseases
- 实验室技术在感染性疾病诊断中的应用 (Simultaneous translation in Chinese)
Mark it on your agenda next IFCC webinar! Registration link soon available on the IFCC website

Infectious Disease is a Prominent Focus Among Top Performing Teams Recognized with UNIVANTS of Healthcare Excellence Awards
Infectious diseases represent over 1/3 of all recognized best practices in 2020 through UNIVANTS. Unsurprisingly, many are related to the COVID-19 pandemic. However, there has been a multi-year trend of best practices on hepatitis identification and elimination. This suggests that while the pandemic has necessitated new innovation and processes, elimination of hepatitis remains a key priority across the globe. Learn more: https://www.univantshce.com

Calendar of EFLM events and events under EFLM auspices

Do not miss the opportunity to have your event listed here.
Apply for EFLM auspices! For more information visit here or email eflm@eflm.eu
Due to COVID-19 alert throughout the world, some upcoming events could have been cancelled or postponed, please direct check with the organizers if the date is confirmed.

20 April 2021
Haemostatic disorders in COVID-19 patients
EFLM webinar, online
Click here for information

29 May - 4 June 2021
XIII Jornada Ibérica Virtual AEFA-OF on-line
Click here for information

Accessible till 12 May 2021
2020 Annual Meeting of the Royal Belgian Society of Laboratory Medicine (RSBLM) on-line
Click here for information

10-11 June 2021
8th International Symposium on Critical Care Testing and Blood Gases Biarritz (FR)
Click here for information

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1 September - 3 November 2021
1st EFLM online Postgraduate course: Biostatistics in Laboratory Medicine
EFLM Course, on-line
Click here for information

8-11 September 2021
XXVIII Balkan Clinical Laboratory Federation Meeting and XIII National Conference of Clinical Laboratory
Sofia (BU)
Click here for information

13-23 September
2nd EFLM online Postgraduate course: Leadership skills in Laboratory Medicinealliance”
EFLM Course, on-line
Click here for information

DATE TO BE ANNOUNCED
XXII Serbian Congress of Medical Biochemistry and Laboratory Medicine and 16th Belgrade Symposium for Balkan Region
Belgrade (SRB)
Click here for information

5-10 October 2021
FEBS Advanced Course: 360-degree Lysosome; from structure to genomics, from function to disease-update
Izmir (TR)
Click here for information

7-10 October 2021
46th ISOBM Congress
Bled (SL)
Click here for information

10-12 October 2021
XIV Congress of Slovak Society of Clinical Biochemistry
High Tatras (SK)
Click here for information

10-11 February 2022
International Congress on Quality in Laboratory Medicine 2021
Helsinki (F)
Click here for information

23-26 May 2022
The 10th Santorini Conference “Systems medicine and personalised health & therapy” - The odyssey from hope to practice: Patient first - Keeps Ithaca always in your mind
Santorini (GR)
Click here for information

Boost your brand and increase your company’s visibility through the EFLM Newsletter!

EuroLabNews is the digital bi-monthly newsletter of EFLM targeting more than 7,500 laboratory medicine professionals and is also published on the EFLM website. The Newsletter features information on EFLM initiatives and activities of its functional units, news from EFLM National Society members and includes a calendar of the major events in the Clinical Chemistry and Laboratory Medicine field.

The EFLM IVD partners are offered the possibility to advertise on EuroLabNews as follows:

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