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International Federation of Clinical Chemistry and Laboratory Medicine



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EDITORIAL

Message from the eNews Editor

by Katherina Psarra
eNews Editor

Dear colleagues,

The summer is almost here. Outdoor activities are definitely safer and offer the opportunity for more normal life, for more joy but travel restrictions are still there and social life is definitely different. There are lots of questions about the future of conferences, seminars and meetings. Most of them, like the IFCC EB, divisions and working groups meetings are taking place at e-distance, a completely different experience from the face to face meetings, but still work is being done. Don't forget that a new deadline has been announced for the Seoul 2021 WordLab abstracts, where we all hope to be together once more!

Laboratorians of course keep working in the labs in research centers or in hospitals and try to understand better this new disease. It is IFCC's ambition to keep members fully educated and informed. The special IFCC Information Guide on COVID-19 on the first page of IFCC website is continuously renewed by the new IFCC Task Force on COVID-19, presented in this issue by Prof. Giuseppe Lippi, Chair of the task force.

In this issue of eNews you will find an important editorial in Clin Chem Lab Med by the new IFCC President, Prof. Khosrow Adeli, on the "Critical role of laboratory medicine in the global response to the COVID-19 pandemic". A more "philosophical" and social look on the consequences of the epidemic are presented by Dr. Gouget.

News from the societies, especially new members, are really interesting. The relationship between mentor and mentee may prompt young colleagues to explore and benefit from such opportunities.

Try to find joy and happiness in everyday moments, dear colleagues. Pay attention to the small successes in your professional and personal life. Look forward to our next face to face meeting!

Katherina Psarra



The IFCC is pleased to announce its new President: prof. Khosrow Adeli

Professor Adeli commenced his term in office on May 15th, 2020, to run until December 31st, 2023.

The results of the ballot for the ratification of the Executive Board recommendation for Prof. Khosrow Adeli, as President-elect, to assume the role of IFCC President effective May 15th, 2020, until the end of December 2023, was concluded on May 10th and the voting unanimously confirmed the Executive Board recommendation.

IFCC congratulates the new President and wishes him a fruitful and successful term of work for the promotion of Clinical Chemistry and Laboratory Medicine worldwide.

[Click here to read a short profile of Prof. Khosrow Adeli.](#)

THE VOICE OF IFCC

Message from the IFCC President

by Khosrow Adeli
IFCC President (2020-2023)



Prof. Khosrow Adeli
PhD, FCACB, DABCC, FAACC

My cordial greetings and compliments of the spring season to you all in the IFCC family. It is indeed an honour and privilege to become the President of IFCC at this challenging time. Thanks to the great leadership provided by Professor Ferrari, Professor Morris, and other former past presidents as well as members of the IFCC executive board, I have become responsible for a healthy, strong and financially secure organization that has enormous promise to contribute to advancing laboratory medicine around the world. Also, many thanks to IFCC member countries for their

support of my nomination and election. I have been amazed at the outpouring of support from many of you in regions around the world and your encouragement to take on this important responsibility. I very much look forward to working with all of you over the next few years to continue the IFCC's mission of "Advancing excellence in laboratory medicine for better healthcare worldwide".

Recent months have been tough for all of us around the world as we face and fight this unprecedented coronavirus pandemic. But while this crisis has caused many professional and personal challenges (medical emergencies, social isolation, economic recession, and many others), I want to assure you that the field of laboratory medicine will come out of this health emergency even stronger and much more visible in the eye of the healthcare system, governments, as well as the general public. The pandemic has clearly highlighted the critical role of laboratory medicine in the fight against this health crisis. It is unimaginable to face such a health emergency without appropriate laboratory testing and population screening using molecular and serological assays. During this crisis, the IFCC has been at the forefront of documenting and evaluating the emerging evidence for appropriate diagnostic and serological testing as well as biosafety guidelines for clinical laboratories. Please see my editorial below for more details on the IFCC Information Guide on COVID-19 as well as the IFCC taskforce and its recent publications.

I am passionate about laboratory medicine and at the opportunity over the next few years to contribute to a more impactful and activist role for IFCC in the global communities to inspire and drive value to the profession and across healthcare. The future holds considerable promise for the IFCC organization

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and its family of national societies and corporate members. I look forward to working with all of you in the IFCC's continued journey towards global leadership in laboratory medicine.

In partnership with all IFCC divisions and functional units, we will strive to enhance IFCC's leadership position in the field of laboratory medicine by:

- **Directly impacting healthcare and patient outcomes** by working with developing countries around the work to develop programs such as newborn screening programs in collaboration with WHO, Gates Foundation, industry, others
- **Developing an international IFCC external quality assurance program and innovative quality improvement strategies** and disseminate the concept of total quality management and quality systems approach to clinical laboratories and national societies, particularly in developing countries.
- **Becoming the largest provider of free Distance Learning/eLearning in the field of laboratory medicine worldwide.** Through the new eAcademy platform and its vast network of experts, IFCC can develop the most comprehensive database of eLearning programs to support education by its member societies particularly in *developing countries*.
- **Continuing to promote the value of laboratory medicine** by gathering the evidence to demonstrate the value of lab medicine in clinical decision making and healthcare delivery, communicating this to the public and all stakeholders.
- **Encouraging and supporting a culture of innovation** in the IFCC community and communicate technological and process innovations to laboratory scientists and physicians globally. In association with regional federations, member societies, young scientists and corporate members, ensure that IFCC is a driver of technological innovations such as artificial intelligence and machine learning, and their application in laboratory medicine.



This is a glimpse of our new strategic plan that I have been working on with support of the IFCC Executive Board over the past few months. In the next few issues of the newsletter, I will explain in more detail each of the key strategic plans and would like to seek feedback from all IFCC officers, IFCC member countries as well as our corporate members before finalizing and initiating implementation of these plans into practice with your support and participation.

Till next time 😊
Khosrow

Critical role of laboratory medicine in the global response to the COVID-19 pandemic

by **Khosrow Adeli**
President, IFCC

The global coronavirus disease 2019 (COVID-19) has presented major challenges for clinical laboratories, from initial diagnosis to patient monitoring and treatment. As I write this editorial, many laboratory specialists, technologists and trainees are selflessly and tirelessly standing on the front lines of the battle against COVID-19. This is happening at hospital laboratories and at private clinical laboratories around the globe. What is becoming very clear during this crisis is that clinical laboratory operations are critical in the global fight against this unprecedented pandemic through rapid diagnosis of viral infection, serological monitoring of the affected populations, and biochemical monitoring of hospitalized patients with more severe COVID-19 induced complications. Laboratory medicine is a key driver of healthcare delivery through provision of objective data to clinicians and other healthcare workers to guide appropriate clinical decision making. Indeed, laboratory medicine is integral to prevention, diagnosis, treatment, and management of clinical disease including such infectious disease outbreaks. It supplies health care professionals with evidence-based data necessary to provide safe, effective and high quality care to patients.

Unfortunately, this essential role of laboratory medicine has not been widely recognized within healthcare organizations or the public, leading to poor visibility both within the field of clinical medicine and externally with the public at large. The current worldwide pandemic has clearly started to change the public and governmental view of the critical role that clinical laboratories play in public health and safety. It is now abundantly clear that without laboratory medicine appropriate public health measures and evidence-based care of hospitalized patients are simply not conceivable. In response to the current pandemic, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has established a global taskforce on COVID-19 (<https://www.ifcc.org/executive-board-and-council/eb-task-forces/ifcc-task-force-on-covid-19/>) as well as an online resource called the IFCC information Guide on COVID-19 (<https://www.ifcc.org/ifcc-news/2020-03-26-ifcc-information-guide-on-covid-19/>). The taskforce and the online resource are helping to provide the latest evidence and up-to-date information on population screening, diagnosis, biosafety guidelines for clinical laboratories, and biochemical monitoring of hospitalized patients with COVID-19.

In addition to the online information guide, the taskforce has reviewed the latest evidence and has started publishing comprehensive reviews including an expert opinion article on *Biosafety Measures for Preventing Infection from COVID-19 in Clinical Laboratories: IFCC Taskforce Recommendations* (Lippi et al. 2020), and a critical review on *Molecular, Serological, and Biochemical Diagnosis and Monitoring of COVID-19* (Bohn et al. 2020). These articles not only review the current evidence but also provide practical recommendations on both laboratory biosafety as well as diagnostic/serological/biochemical markers used in infection control and monitoring. The taskforce will continue to review the latest evidence and publish new guidelines, and high-quality reviews to ensure a wide-ranging coverage of the role that clinical laboratories play in the fight against this unparalleled and unfortunate pandemic.

I recognize this is a time of immense turmoil and disruption in our lives. No one knows how long this crisis will last but one thing is certain: clinical laboratories have visibly demonstrated their vital role and value in the public health surveillance and patient care and management, and are in the front line of the global response to COVID-19. On behalf of the IFCC organization, I would like to thank members of the Taskforce on COVID-19 for their prompt and urgent action within a very short period time to gather the available evidence and assemble a number of key resources for laboratory medicine specialists and other healthcare

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workers around the world. The IFCC organization and the taskforce will continue this important work until the COVID-19 crisis is behind us.

Lippi G, Adeli K, Ferrari M, Horvath A, Koch D, Sethi S, Wang C-B. Biosafety measures for preventing infection from COVID-19 in clinical laboratories: IFCC Taskforce Recommendations [published online ahead of print,

2020 May 12]. Clin Chem Lab Med. 2020; doi:10.1515/cclm-2020-0633.

Bohn MK, Lippi G, Horvath A, Sethi S, Koch D, Ferrari M, Wang C-B, Mancini N, Adeli K. Molecular, serological, and biochemical monitoring of COVID-19: IFCC taskforce evaluation of the latest evidence; 2020 May; Clin Chem Lab Med. 2020 (in press).

News from the IFCC Website

IFCC eAcademy: Three new webinars now available!



Patient Based Real Time Quality Control webinar

Thanks to Dr. Tony Badrick, Chief Executive, RCPA Quality Assurance Programs Pty Ltd, Australia, the IFCC eAcademy is happy to offer a new eAcademy webinar. It takes only 25 minutes to understand the concept of Patient Based Real Time Quality Control, and the advantages and disadvantages of Patient Based Real Time Quality Control.

Do you want to know which variables are used in Patient Based Real Time Quality Control and to understand how to use Patient Based Real Time Quality Control with conventional Quality Control? [Click here](#) to listen to the webinar.



IFCC eAcademy - Ethics & Professionalism for IFCC Volunteers - webinars Part 1 and 2

Thanks to Dr. Joe Wiencek, University of Virginia, School of Medicine - VA, US, the IFCC eAcademy is happy to offer a new eAcademy webinar. The webinar, dedicated to IFCC and all volunteers, focuses on Ethics, Professionalism, Misconduct, Equality, and Non-discrimination. All topics that are fundamentals for the correct professional conduct.

The second part of the eAcademy webinar on "Ethics & Professionalism for IFCC Volunteers" focuses on business ethics, conflict of interest, publication ethics, and code of ethics. This course was developed on behalf of the IFCC Task Force on Ethics (IFCC TF-E). Listen to the webinar, for your education and visit the IFCC eAcademy, the IFCC open educational resource freely available to

laboratory professionals and trainees around the world.

This two parts course was developed on behalf of the IFCC Task Force on Ethics ([IFCC TF-E](#)).

[Click here](#) to listen to the webinar, Part 1.

[Click here](#) to listen to the webinar, Part 2.



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The new IFCC Task Force on COVID-19

by Giuseppe Lippi

Chair, IFCC Task Force on COVID-19

Full Professor of Clinical Biochemistry, University of Verona

Director, Service of Laboratory Medicine, University Hospital of Verona

Secretary of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

Executive Editor-in-Chief, Annals of Translational Medicine

Editor in Chief, Journal of Laboratory and Precision Medicine

Associate Editor, Clinical Chemistry and Laboratory Medicine

Associate Editor, Seminars in Thrombosis and Hemostasis



Prof. Giuseppe Lippi

A new viral outbreak, sustained by a member of the coronaviridae family that has been finally called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has originally emerged as atypical cases of interstitial pneumonia in Wuhan (China) in November 2019. Since then, the epidemic has spread all around the world, so that this new disease, which is much worse than a simple pneumonia and has been named coronavirus disease 2019 (COVID-19), has been upgraded to global pandemic by the World Health Organization (WHO), affecting millions of people worldwide, and causing several hundred deaths.

Soon, after its emergence, it became rather clear that laboratory medicine would have played a central role in diagnosis, prognostication, therapeutic monitoring and epidemiologic surveillance of this new and severe coronavirus disease. The firm recognition that *in vitro* diagnostic testing is an active player rather than a simple bystander in COVID-19, along with the awareness that this completely new disease represents one of the toughest challenges that mankind has been facing throughout its history, has persuaded the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) to establish an ad hoc Task Force on this matter, which has been called “IFCC Task Force on COVID-19”, and whose website is available here: <https://www.ifcc.org/executive-board-and-council/eb-task-forces/ifcc-task-force-on-covid-19/>. The leading objectives of this Task Force encompass the provision of regular updates on epidemiology, pathogenesis and laboratory diagnostics of COVID-19, the development of practical recommendations for harmonizing the use of diagnostic tests and biosafety measures for managing the specimens, as well as the organization of international studies to

improve the knowledge on pathogenesis, diagnostics and therapeutic management of COVID-19. In summary, the terms of reference are as follows:

- Establish and maintain an IFCC e-learning platform on COVID-19 (“IFCC Information Guide on COVID-19”, available at: <https://www.ifcc.org/ifcc-news/2020-03-26-ifcc-information-guide-on-covid-19/>), which provides regular updates on epidemiology, pathogenesis and laboratory testing of COVID-19;
- Provide tentative guidance and consensus documents for harmonizing the use of diagnostic and serological tests for COVID-19;
- Provide tentative guidance for harmonizing biosafety measures during management of COVID-19 specimens by clinical laboratories;
- Address clinical, technical and organizational perspectives of laboratory-based and POC testing in COVID-19 patients and provide guidelines/recommendation when feasible;

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- Integrate data on COVID-19 laboratory abnormalities from all over the world, and promote or coordinate new studies;
- Evaluate opportunities, risks and safety of using non-conventional biological materials for diagnosing COVID-19;
- Establish and maintain efficient distance learning channels, with organization of webinars and providence of other informative material;
- Maintain a repository of scientific articles on laboratory testing for diagnosing, prognosticating and monitoring COVID-19.

Importantly, the evidence of the large number of healthcare operators who have been infected by the virus, as high as 12% in certain counties like Italy, has prompted the Task Force to draft - as its very first activity - a guidance document aimed to disseminate a set of practical recommendations on biosafety measures that shall be used in routine clinical laboratories

operating at biosafety levels 1 and 2. These recommendations, which have been adapted from other official documents of international and national health agencies and organizations, are divided in four main sections, each of which targets a specific issue of laboratory biosafety. The full document (Lippi G, Adeli K, Ferrari M, Horvath AR, Koch D, Sethi S, Wang CB. Biosafety measures for preventing infection from COVID-19 in clinical laboratories: IFCC Taskforce Recommendations. Clin Chem Lab Med. 2020 doi: 10.1515/cclm-2020-0633) has now been published in *Clinical Chemistry and Laboratory Medicine* and is available for free to all the readers of this journal. The next steps that the Task Force has already planned include the publication of a two-part global survey on practices established by clinical laboratories for mitigating biohazard risks during the COVID-19 outbreak, and another document containing general indications on molecular, serological, and biochemical diagnosis and monitoring of COVID-19.

Highlights from recent events in Bioethics

Notes for better visualizing Task Force of Ethics collaborations

The screenshot shows the eAcademy website interface. At the top left is the IFCC logo (International Federation of Clinical Chemistry and Laboratory Medicine). At the top right is the eAcademy logo. Below the logos is a navigation bar with icons and labels for Home, Search, Topics (highlighted in blue), Authors, Events, and Content types. Below the navigation bar is a breadcrumb trail: eAcademy / Topics / Other Areas of Laboratory Medicine / Ethics in Laboratory Medicine. The main content area displays the title "Ethics in Laboratory Medicine" and indicates it consists of "6 modules".

by Dr. Nilda E. Fink
Chair, IFCC Task Force on Ethics

IFCC Task Force on Ethics (TF-E) Members have written several notes with the aim to highlight relevant events in Bioethics that might be of interest for colleagues. In the present note, the field of interest is extended because it is referred to a course produced by TF-E as a 2019 goal. The course, titled “Ethics and

Professionalism for IFCC volunteers” was prepared by Dr. Joesph Wiencek Professor of University of Virginia School of Medicine. It is a two parts course (Part I and Part II) and it will be commented in next paragraphs.

Part I is divided in four sections, being the first one on basic aspects of ethics in which terms such as Ethics,

Bioethics and Medical Ethics are defined. Evolution of Medical Ethics and fundamental documents on Ethics such as Nuremberg declaration, Belmont report and other relevant ones are also presented. The second and third sections of Part I relate to professionalism as basis of medicine contract with society and its relation to scientific misconduct acts are considered. As final item of Part I, principles of equality and non-discrimination are included. United Nations Declaration and the Rule of Law are relevant topics treated.

In Part II Dr. Wiencek focuses on Conflicts of Interest (COI), Business ethics and relation to industry, Publication ethics, Code of ethics and Compliance with relevant national laws. The author presents some examples of COI, comments on business ethics topics and relationship with the industry, along with its definition and twelve related principles. He also considers the IFCC code of practice related to industry and Med Tech Europe Code of Ethical business practice. Finally, tips for dealing with COI are listed. Another point in Part II, referred to Ethical publication, includes a definition

by Dr. Anthony Newman, and a list of guardian groups on Publication ethics. Terms such as plagiarism and self-plagiarism and examples of both are part of his presentation. Code of Ethics and its structure (introduction, statement of propose and implementation) are discussed. As a last item, regulatory compliance is considered for IFCC members as they must comply with all relevant laws in their own countries. A list of references is also attached.

At present, this course is part of the e-Academy together with other materials such as three AACC Pearls of Laboratory prepared by Drs Ann Gronowski, Jon J. Jonsson and Anthony Newman referred to Ethics in laboratory medicine, Ethics education and Publication ethics respectively. Another resource prepared by TF-E is a Toolkit that contains an ordered list of references on Ethics. It is permanently revised and updated and can be found at: <https://www.ifcc.org/taskforceethics/toolkit/>. The present course, AACC Pearls and a module on Ethics for laboratory staff by Dr. Lynn Allen will be part of Toolkit resources.

IFCC: Educational webinars on COVID-19

WEBINAR ON COVID-19 – APPROACH TO LABORATORY TESTING AND BIOSAFETY

Cosponsored by



Canadian Society of Clinical Chemists (CSCC)



Roche Canada

Moderator:

Dr. David Kinniburgh (Canada)

Alberta Centre for Toxicology
University of Calgary

Speakers:

Professor Giuseppe Lippi (Italy)

Stanford University
California

Professor Khosrow Adeli (Canada)

The University of Hong Kong
Hong Kong SAR (China)

Listen to the Webinar Recording clicking on the below link:

<https://www.youtube.com/watch?v=Z1GC7e3D3V8&feature=youtu.be>

The 90-minute recording, prepared by CSCC, includes presentations by above Speakers and following panel discussion session.

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WEBINAR ON COVID-19 – CHALLENGES IN LABORATORY INVESTIGATIONS AND CLINICAL MANAGEMENT

Cosponsored by



IFCC EMD



Transasia Erba Mannheim

Speakers:

Professor Nader Rifai (US)

Boston Children's Hospital
Dpt of Laboratory Medicine

Professor Mark Berg (US)

Stanford University
California

Professor Leo Poon (HK)

The University of Hong Kong
Hong Kong SAR (China)

Listen to the Webinar Recording clicking on the below link:

<https://erbamannheim.com/article/scientific-updates/212>

This recording of a live educational program about Covid19 attended by approximately 1200 physicians and laboratory medicine professionals in South East Asia is co-sponsored by Transasia Biomedical and the EMD of the IFCC. Professors Marc Berg of Stanford University and Leo Poon of Hong Kong University presented and addressed questions regarding the clinical and analytical aspects of Covid19, respectively. Professor Nader Rifai of Harvard University moderated the session."

Igniting the AI and e-Health creative sparks at APFCB in Jaipur (IN)



The XV Congress of the Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB) was held in Jaipur, India (IN), between November 17 and 20, 2019. With great pleasure, the IFCC community attended this extraordinary event and met our Asian Pacific colleagues during an event that was, as always, very inspiring. The multiple possibilities offered by the Jaipur Exhibition and Convention Centre

in the Sitapura Industrial Area, with multiple words of warm welcome from Prof. Sanjeev Misra, APFCB President, Prof. Praveen Sharma, chair APFCB Congress organizing committee (COC), Prof. LM Srivastava, co-chair COC, Dr. P Purohit, Dr. S. Sharma, Treasurers, Prof. Rajiv R. Sinha Executive Secretary, Prof. D.M. Vasudevan and Dr. S. Vasikaran, Scientific committee chairs were astonishing.

by Bernard Gouget

*IFCC-Chair Committee on Mobile Health
and Bioengineering in Lab Medicine*

Alexander Haliassos

*IFCC-Treasurer elect
GSCC-CB IFCC-Representative*

Pradeep K. Dabla

*former Chair IFCC TF-YS
IFCC C-MHBLM corresponding member*

Sergio Bernardini

chair-IFCC Emerging Technologies Division

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Jaipur, is well known as the famous pink city of Rajasthan. The royal terra cotta pink color represents welcome and hospitality. The historical reason for the uniform color of old city lies with the absolute power of the Maharaja Sawai Ram Singh to impress Prince Albert during his 1876 tour of India. When discovering the city, you must be prepared for both emotional highs and lows. Jaipur is a city of extremes and a fascinating Indian city that boasts the finest examples of Rajasthan architecture and history with magnificent forts, sumptuous palaces and inspiring religious temples but is blighted by the modern problems as pollution and poverty that afflict the present days of India. The Indian healthcare consists of contrasting landscapes. The structures delivering high tech Medicare to the well-heeled, mostly urban Indian, and the outposts in the remote reaches of the “other India” trying desperately to live up to their identity as health centers. Rajasthan is the largest State in India with many unapproachable areas making it difficult health facilities to be accessible to all. One of the major challenges and issues is the availability of a sufficient number of physicians and specialists. E-health is representing a hot topic in India, country with vast medical needs and it offers the potential to improve the quality of health care and reach the unreachable.

The C-MHBLM session highlighted the most imperative ideas focused on innovation in AI, IoT, digitalization and emerging technologies in laboratory medicine. Indian experiences with a special emphasis on the Rajasthan area were illustrated and the best possible utilization of mobile and e-technologies to further enhance clinical decision and patients’ healthcare journey were discussed. Prof. S. Dandekar, chairing the session, welcomed speakers, APFCB representatives amongst them, H Martin, E Hoyaranda, IFCC-ACBI members and a large Indian and international delegation of IFCC young scientists coordinated by Pradeep Kumar Dabla (photo). S. Bernardini, IFCC-ETD Chair, presented clear-eyed insight on the world of emerging technologies, their real-world applications, and their impact on the health and wellness through a scientific and trustworthy lens. He presented everything we need to be well informed and get access to the innovations about the digital world and tech breakthroughs shaping the way we

live and work in the different regions of the world. The hype about Artificial Intelligence (AI) is unavoidable and the thing about AI is that, when you work to push forward the research, the downstream applications are incredible. AI is used as a wide term to describe machines that can mimic human functions such as learning and problem solving throughout a sub field of AI, the Deep Learning Neural Networks (DLNN). In Healthcare, Machine Learning technologies (ML) will help medical professionals with a more accurate, personalized diagnosis based on wider data sets. Today, ML is routinely used for evaluating and interpreting data in genomics, transcriptomics and proteomics. ML methods are becoming more extensively used in the analysis of laboratory parameters, and especially for data that can be easily grouped and compared across different groups. Technological advances enabled the integration of expert system capabilities and software applications, including auto-analyzers and modules of Laboratory Information Systems. Patients can now directly access their laboratory test results by downloading them from the Web portal and increasingly so through smartphone apps. A. Haliassos explained that in lab medicine research, new distributed computing and communications technologies allow researchers to analyze big volumes of information, to access data, instruments, and expertise independent of their location. Health data and advanced data analytics can help accelerate scientific research, personalized medicine, early diagnosis of diseases and more effective treatments. Collaborative web tools from emails to online meeting discussion forum, and open science resources help scientists to work in harmony, learning together from a distance and creating active international scientific communities. Moreover, web-based applications have unique attributes providing novel teaching materials in an interactive form. e-Learning can be defined as any use of the Internet and web technologies to help create teaching and learning experiences.

India is working to provide its citizens access to safe and top-quality digital services in health and care. The Government of Rajasthan has been working extremely hard for the last years to improve the health of common people. Different health programs were launched as improving maternal health and child

health, encouraging vaccination of children. Moreover, initiatives like telemedicine, mobile dental van and many other e-health initiatives have been introduced by the State Government. The population must be well aware about their health needs, like cleanliness to prevent diseases such as dengue, swine flu and vector-borne diseases as zoonotic tick-borne diseases, scrub typhus and viral hemorrhagic fever. Preventing measures are essential and with awareness programs changes can be seen happening and, if authorities keep on promoting and maintaining health literacy in rural areas the challenge of health illiteracy can be met.

Mobile technologies hold great promising expectations, especially due to its ubiquitous nature. B. Gouget discussed their potential, particularly in India allowing access to better social care, health monitoring and recording. They have a great potential in bringing efficiency in service delivery and enhancing the reach of the health services. India is the world's second largest mobile phone manufacturer after China. With the current speed for growth, India is not far from becoming the leading handset market in the world. With more than one billion mobile users in the country, the mobile phones offer tremendous opportunities in efficient health service delivery which include: connecting remote areas with national centers of excellence or patients in villages with doctors in hospitals in urban areas through audio or video conferencing, ensuring treatment adherence by sending text messages to patients with chronic diseases reminding them to take their treatment, quick reporting of cases during outbreaks or epidemics, or informing populations and creating awareness about emerging health issues or health programs. The internet connectivity is presently being used to enhance, e-governance, network of telemedicine services and making patient consultations with experts such a tele-ophthalmology, tele-radiology, mother and child tracking system, data collection and disease surveillance as the web-based tuberculosis registration scheme and distant medical education, and more...

In addition, a range of programs are being run, the use of point-of-care diagnostic methods, such as a lab in a suitcase for diagnosis in rural and urban areas where such facilities do not exist, can be of great help. These examples show that technology already available can

enhance the quality and efficiency of the services, and this should be expanded and scaled up rapidly, in order to make health services available and accessible for the people living in geographically remote areas. Technology is not a limiting factor, but the unavailability of suitable health personnel is a major challenge, especially in rural areas. India is presently in a state of transition economically, demographically, and epidemiologically in terms of health. India is also a country with vast unmet medical needs. In health sector, India has made enormous strides over the past decades. eHealth and the adoption of artificial intelligence (AI) is reshaping the Indian healthcare systems significantly. Artificial intelligence is used in six healthcare segments: hospitals, pharmaceuticals, diagnostics, medical equipment and supplies, medical insurance, and tele-medicine. AI-enabled healthcare services like automated analysis of medical tests, predictive healthcare diagnosis, automation of healthcare diagnosis with the help of monitoring equipment, and wearable sensor-based medical devices, which are expected to revolutionize medical treatment processes in the country.

Transformation of health care in the digital market will benefit people, the health care systems and the economy. eHealth in India is primarily targeted at those who are not reachable by modern medicine. The capability of AI applications to improve the efficiency of health professionals will help in tackling challenges, like the uneven and low Indian doctor-patient ratio, by providing rural populations high-quality health-care, and by training doctors, laboratory specialists and nurses to handle complex medical procedures and medical diagnostics. AI and e-health are directly impacting on healthcare and patient outcomes. Decreasing the time of discovery in AI requires unwavering commitment from the health community and stakeholders to a more direct impact healthcare and patient outcomes. Laboratory medicine is at the forefront of the current technological shift in medicine. In this regard, the priority should be given to understanding the barriers to equitable access, integrating equity goals in policy and programs, and targeting resources and efforts to reach the poor and vulnerable sections of the society with the needed services.

Generally, politicians are better-off to respond to a disease or an outbreak than to prevent it. The Indian nation battles coronavirus as any other country and it is challenging. But it is also an amazing opportunity to unlearn, relearn, and test our capabilities and value systems. Resilience, hope and compassion are the needs of the hour.



B. Gouget and S. Bernardini, receiving an appreciation «For the dedication as IFCC visiting Lecturer to AFCB 2017-2019»
L to R: Santiago Fares Taie, Damien Gruson, Bernard Gouget, Endang Hoyaranda, Helen Martin, Sergio Bernardini, Khosrow Adeli, Alexander Haliassos, Tahir Pillay, Layachi Chabraoui, Felix Hernán Fares Taie

News from the IFCC Website



eJIFCC Vol 31 n°2 - May 2020

eJIFCC Vol 31 n° 2 is now available. The first two articles cast a light on different aspects of the dramatic topic of these months: “COVID-19: Armageddon before light?” and “Artificial Intelligence – powered search tools and resources in the fight against COVID-19”.

Six other articles focused on different laboratory topics follow. Among them: “Reference value for serum zinc level of adult population in Bangladesh”, “Blood lead levels in rag-pickers of Kathmandu and its association with hematological and biochemical parameters”, “Survey on stat tests in Catalan clinical laboratories” and “Critical results reporting in Portuguese hospital laboratories”. A Case report on paediatric nephrotic syndrome and a Letter to the editor complete the issue.

[Read more](#)

IFCC: THE PEOPLE

Election of the IFCC Executive Board: reflections on the procedure

*by Graham Beastall
on behalf of the IFCC Nominations Committee*

INTRODUCTION

The procedure for the election of the IFCC Executive Board to serve for the period January 2021 until December 2023 has now been completed. The composition of the Executive Board has been announced. This short article reflects on the work of the IFCC Nominations Committee, which oversaw the election procedure.

THE EXECUTIVE BOARD (2021-2023)

(Click links below for EB member biographies)

President*

[Prof. Khosrow ADELI](#) (Canada)

Past-President

[Prof. Maurizio FERRARI](#) (Italy)

Secretary

[Dr. David KINNIBURGH](#) (Canada)

Treasurer

[Dr. Alexander HALIASSOS](#) (Greece)

African Regional Representative (AFCC)

[Prof. Adekunle Bashiru OKESINA](#) (Nigeria)

Asian Pacific Regional Representative (APFCB)

[Dr. Sunil SETHI](#) (Singapore)

Arab Federation Regional Representative (AFCB)

[Prof. Abderrazek HEDHILI](#) (Tunisia)

European Regional Representative (EFLM)

[Prof. Ana Maria ŠIMUNDIĆ](#) (Croatia)

Latin American Regional Representative (COLABIOCLI)

[Dr. Ana María LENA RODRÍGUEZ](#) (Uruguay)

North American Regional Representative (NAFCC)

[Dr. Stephen HILL](#) (Canada)

Corporate Representative

[Mr. Joseph PASSARELLI](#) (Roche Diagnostics)

* Prof. Adeli became President in May 2020



Khosrow
ADELI
President



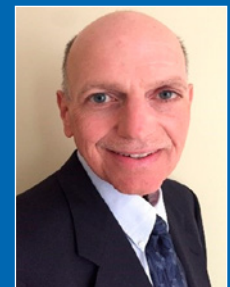
Maurizio
FERRARI
Past-President



David
KINNIBURGH
Secretary



Alexander
HALIASSOS
Treasurer



Joseph
PASSARELLI
Corporate
Representative

Article continued on next page



Adekunle Bashiru
OKESINA
AFCC



Sunil
SETHI
APFCB



Abderrazek
HEDHILI
AFCB



Ana Maria
ŠIMUNDIĆ
EFML



Ana María LENA
RODRÍGUEZ
COLABIOCLI



Stephen
HILL
NAFCC

The actual EB composition (until December 2020) is listed at: <https://www.ifcc.org/executive-board-and-council/executive-board/>.

THE NOMINATIONS COMMITTEE

Chair	Graham Beastall (UK)
Previous Chair	Bernard Gouget (France)
African Regional Representative	Angela Amayo (Kenya)
Asian Pacific Regional Representative	Endang Hoyaranda (Indonesia)
Arab Federation Regional Representative	Osama Najjar (Palestine)
European Regional Representative	Huib Storm (Netherlands)
Latin American Regional Representative	Montserrat Blanes (Paraguay)
North American Regional Representative	Nathalie Lepage (Canada)

THE ELECTION SCHEDULE

The election procedure commenced in February 2019 and occurred in four stages according to the illustration.

	2019											
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
President elect		CALL FOR NOM.			NC	LOBBYING			BALLOT	RESULTS		
Treasurer							CALL FOR NOM			NC	LOBBYING c/o NR	
Secretary							CALL FOR NOM			NC	LOBBYING c/o NR	
Corp. Memb.									CALL FOR NOMINATIONS			NC
6 Regional Reps									CALL FOR NOMINATIONS			NC

2020				
JAN	FEB	MAR	APR	24 MAY: COUNCIL
President elect term begins				
BALLOT	RESULTS			
BALLOT	RESULTS			
LOBBYING	BALLOT	RESULTS		
LOBBYING	BALLOT	BALLOT	RESULTS	

LEGEND

CALL	Call for nominations
NC	Nomination Committee evaluates
LOBBYING	Distribution to NR/CR-lobbying
BALLOT	Electronic ballot
RESULTS	Results announced

Article continued on next page

The four stages were:

1. President Elect, who becomes President
2. Secretary and Treasurer
3. Corporate Member Representative
4. Regional Federation Representatives

The sequential approach allowed for informed nominations at each stage of the procedure. The election concluded in early May 2020.

THE ELECTORATE:

The electorate for each position was as follows:

- President Elect, Secretary, Treasurer: All IFCC Full Members in good standing
- Corporate Member Representative: All IFCC Corporate Members in good standing
- Regional Representatives: IFCC Full Members in each Regional Federation

THE BALLOT:

All ballots were conducted using electronic voting. An independent company (Election Buddy) was used to conduct each of the ballots to assure fairness and transparency. Deadlines for each ballot were strictly observed. Results could be accessed directly from Election Buddy.

REFLECTIONS ON THE PROCEDURE

1. The Nominations Committee worked effectively using electronic communication. The schedule was followed closely. The work of the Committee was conducted in a confidential manner.
2. The main function of the Nominations Committee was to assess the validity of the nominations received. All valid nominations went forward to a ballot.
3. One Regional Federation nomination was adjudged to be invalid and so a second round of nominations was sought. This delayed the ballot by one month.
4. There were three nominations for each of the positions of President Elect, Secretary and Treasurer.
5. There were two nominations for the Corporate Member Representative
6. Most Regional Federations had internal communication before a single nomination was submitted
7. The number of votes cast for each position was satisfactory, except for the election of the Corporate Member representative

REFLECTIONS ON THE OUTCOME

1. The tragic death in post of former President Howard Morris caused major disruption to the functioning of the Executive Board. It also denied Khosrow Adeli the opportunity to serve one year as President Elect along side the President. IFCC is grateful that Khosrow agreed to become President midway through 2020 rather than in January 2021.
2. Six of the eleven members of the Executive Board are new appointments, while five are serving a second term. This mix gives a good blend of fresh thinking and established experience.
3. The revised composition of the Executive Board allows for excellent geographical representation from IFCC Members and facilitates effective communication between the Board and the Regional Federations.

THANKS

The Nominations Committee is grateful for the excellent support that it received from the IFCC Office, where Paola Bramati served as the key liaison.

Welcome and thanks to the Chairs

FAREWELL TO EVI LIANIDOU, Ph.D. (Greece)



Dr. Evi Lianidou

Dr. Evi Lianidou was the Chair of the IFCC Committee on Clinical Molecular Biology Curriculum (C-CMBC).

She is Professor of Analytical Chemistry and Clinical Chemistry at the Department of Chemistry, University of Athens, Greece.

Dr. Lianidou has established a Molecular Diagnostics Laboratory focused on Liquid Biopsy at the Department of Chemistry since 1998 (<http://en.actc-lab.chem.uoa.gr/>). Her lab is specializing in the Analysis of Circulating Tumor Cells (ACTC), and has access to many patient samples through extensive clinical collaborations. Her main research interests are on the development and clinical evaluation of:

- a) single-plex and multiplex quantitative RT-qPCR assays for the detection and molecular characterization of CTCs
- b) multiplex assays for gene expression in CTCs based on the liquid bead array (LUMINEX platform)
- c) DNA methylation assays in CTCs and ctDNA
- d) highly sensitive assays for mutation analysis in CTCs and in ctDNA
- e) evaluation of circulating miRNAs as tumor biomarkers in plasma.

Dr. Lianidou has 132 publications (<https://www.ncbi.nlm.nih.gov/pubmed/?term=lianidou>) and has organized together with Prof. K. Pantel four international meetings on liquid biopsy:

- a) the 7th International Symposium on Minimal Residual Disease in Athens (<http://ismrc2009.chem.uoa.gr/>);
- b) the 1st “Advances in Circulating Tumor Cells: From Basic Research to Clinical Practice” (www.actc2012.org);
- c) the 2nd ACTC meeting, (October 8th-11th, 2014), in Crete, Greece (www.actc2014.org);
- d) the 3rd ACTC meeting, (October 4th-7th, 2017), in Rhodes, Greece (www.actc2017.org) and the 4th ACTC meeting in Corfu, Greece (<https://actc2019.org>).

Prof. Lianidou is PI in the European TRANSCAN group “CTC-SCAN” and in the EU IMI Network Project “CANCER-ID” (www.cancer-id.eu) and serves on the Editorial Boards of many international journals including Clin Chemistry, Clin. Cancer Res, Breast Cancer Res, Cancer Res, Oncotarget, and many others.

Dr. Lianidou served the International Federation of Clinical Chemistry (IFCC) as an elected member and Chair of the Committee for Clinical Molecular Biology Curriculum (2014-2019, (<http://www.ifcc.org/ifcc-education-division/emd-committees/c-cmbc/>)) and is since 2020 an elected member of the IFCC Committee on Proficiency Testing (C-PT).

Thank you, Evi, for your hard work and commitment to developing curriculum and holding training courses in Molecular Biology techniques!

WELCOME TO VERENA HASELMANN, MD (Germany)



Dr. Verena Haselmann

Verena Haselmann, is the new Chair of the IFCC Committee Clinical Molecular Biology Curriculum (C-CMBC).

Verena has been member of the C-CMBC course since 2014. Since then, she got fascinated by the combination of the international team, her passion for teaching as well as the intercultural professional and personal exchange not only during the courses, but also during their preparation conducted at the University Medical Center Mannheim. Helping scientists and laboratory professionals from all over the world to broaden their knowledge and practical skills, and to implement molecular diagnostics on a high quality level in their countries, is more than a big motivation to proceed and further develop this course.

Verena is Deputy Director of the Institute of Clinical Chemistry at the University Medical Center Mannheim, Germany. Within the Institute she focuses on hematology, flow cytometry and hemostaseology.

She has further established and is now Head of the Department of molecular genetics being Reference Institute for molecular diagnostics of the Reference Institute of Bioanalytics (RfB). As part of the scientific advisory board of the RfB, she is responsible for the external quality assessment schemes for molecular genetics.

Within the last years she has substantially developed those schemes and established the first EQA for analysis of circulating tumor DNA (ctDNA).

Additionally, she became Head of the 2019 founded Next-Generation Sequencing core facility of the Medical Faculty Mannheim of the University of Heidelberg. The Core Facility has a focus on Single-Cell Sequencing and Oncology including the analysis of ctDNA. Verena is founding member of the University's Molecular Tumor Board. This is reflected also by her research interest in oncology, especially ctDNA, method development and validation including different aspects of quality assurance and integrated diagnostics.

Best wishes to Verena for many successful results to the new Chair of the [Committee Clinical Molecular Biology Curriculum \(C-CMBC\)](#)!

Breaking News! Abstract system re-opening – IFCC WorldLab Congress in Seoul



The IFCC WorldLab Congress in Seoul is re-opening the Online Abstract System. Another chance to submit your Abstracts!

New deadline: August 31, 2020.

Congress delegates are cordially invited to submit abstracts of their scientific work for presentation as a free communication at WorldLab Seoul 2021. An unlimited number of abstracts may be submitted provided the presenting author applies for “full registration”. Abstracts are welcome in all fields of clinical chemistry, hematology, clinical molecular biology and laboratory medicine, in the broader sense. Free communications are primarily presented via poster.

[Read more](#)

IFCC: THE YOUNG SCIENTISTS

Mentorship Interview

Presented by the IFCC Task Force for Young Scientists

AN INTERVIEW WITH DR. PRAVEEN SHARMA (THE MENTOR) AND DR. PRASENJIT MITRA (THE MENTEE)



Dr. Praveen Sharma is currently Professor and Head of Department of Biochemistry, and Controller of Examinations and Dean (Research) at The All India Institute of Medical Sciences, in Jodhpur, India.

WORKING AS A MENTOR

When considering the most valuable aspect of this mentor-mentee relationship, Dr. Sharma remarked:

I think trust and honesty is the basic foundation for any relationship. A mentor-mentee relationship is no different. The mentee should have full faith in the expertise of the mentor, while the mentor must be eager to help nurture the potential of the mentee in the best possible way. Once established, this relationship adds a lot of value to the career of both mentor and mentee.



Dr. Sharma, who has such an outstanding experience as a mentor, noted: "I have more than 40 years' experience of teaching Clinical Biochemistry and Laboratory Management in various Institutes. During this time, I have mentored many postgraduate, doctoral and post-doctoral trainees." Moreover, on the question of how to be a good mentor and maintain a good mentoring relationship, Dr. Sharma remarked: "I think the zeal to help others and the satisfaction in seeing your mentees grow and shape up their career is a must. I don't think there is a pre-requirement for being a good mentee or a mentor. Once a relationship of mentor-mentee starts, it is on the mentor to shape the relationship and help the mentee in every possible way in their career path." Continuing his evaluation, Dr. Sharma remarked:

It's not just a career, mentors can also teach their mentees life skills that could help the transformation of young laboratorians to be future leaders of the field. A mentor-mentee relationship should be bi-directional and open for any type of discussion. Therefore, being able to listen to any problems that the mentee

Article continued on next page

Mentor: Dr. Praveen Sharma
Professor and Dept. Head,
Department of Biochemistry
Controller of Examinations
and Dean (Research)
*The All India Institute of
Medical Sciences*

Mentee: Dr. Prasenjit Mitra
Assistant Professor
Department of Biochemistry
*The All India Institute of
Medical Sciences*

Interview conducted by:

Dr. Joe El-Khoury, DABCC, FAAC
Core Member IFCC-TFYS
Assistant Professor,
Laboratory Medicine
Director,
Clinical Chemistry
Laboratory Medicine
Co-Director, Clinical Chemistry
Fellowship Program
Yale New Haven Health

has and trying to resolve them in the best possible way, would definitely help boost the relationship.

Mentorship is clearly extremely important, and when asked how the mentorship program can help young scientists and laboratorians in their career, Dr. Sharma retorted: "I think the mentorship program is a great initiative for helping young scientists and early career laboratorians. Knowing about the mentor-mentee relationship will help budding young scientists get a clear perspective regarding searching, selecting and approaching a mentor."

And when it comes to young scientists seeking out a mentor, Dr. Sharma believes that:

In today's era of modern information technology, it is easier to search and know about eminent scientists and their expertise, field of work etc. Further, attending conferences, congresses, workshops or similar training programs, gives them an opportunity to meet new people who can be potential mentors. In addition, social media is another opportunity to identify, network, and choose potential mentors.

When examining the common challenges that young scientists currently face, Dr. Sharma notes: "The major challenges are lack of clarity in shaping a career pathway; lack of guidance in pursuing quality research; and lack of infrastructure for proper training in modern cutting-edge technology"

Advice for Young Laboratorians

Dr. Sharma advices:

Always look for opportunities from various sources which would allow exposure to recent trends in clinical chemistry and laboratory medicine. Young laboratorians should try pursuing research, and keep on publishing regularly, in order to maintain a proper track record. I think that attending Conferences and Congresses is a must, particularly for laboratorians from developing countries. There are a lot of opportunities for availing travel grants and obtaining fellowships to participate in conferences. One should always keep trying. Conferences are places where young scientists can gain exposure to many eminent scientists.

THE MENTEE

Background

When reflecting on his background, Dr. Prasenjit Mitra, who specialises in Clinical Biochemistry, and works as an Assistant Professor, in the Department of Biochemistry at the All Institute of Medical Sciences, Jodhpur, India, spoke about his successful pathway up from Senior Residency.

The Mentor's Perspective

As his mentorship has had such a positive impact on his career in clinical biochemistry, Dr. Prasenjit Mitra, remarked:

My first meeting with Prof. Sharma was at a job interview when I applied for Senior Residency in the All Institute of Medical Sciences Jodhpur. Ever since I was accepted for the role, and Prof. Sharma agreed to become my mentor, he served as a truly invaluable guide for me, helping me fully understand the department's routine academic work. Moreover, Prof. Sharma empowered me gain to an excellent understanding of good laboratory services. Further, in terms of research, he gave me opportunities to liase with other faculties of clinical departments to pursue research in my area of interest.

Adding to the plethora of benefits that can be gained through having a mentor, Dr. Mitra noted:

Prof. Sharma guided me so that I had a better understanding of laboratory management. I have successfully completed my internal auditor and International Laboratory Assessor course during this time. And now, after four and a half years as a mentee, even as a faculty member, I am still being guided by him so that I can improve myself and shape my professional career in a better way.

When asked about the general advantages of working with a mentor, Dr. Mitra remarked:

As a young scientist, it is difficult to have clarity on how to progress in your academic and research career. A mentor with his vast experience in the field may guide the young scientist in understanding and shaping up his career. Moreover, a mentor can help in introducing the mentee to other eminent scientists of the field, which may eventually lead to student exchange for betterment of the mentee

Advice to Fellow Students About Mentorship

Dr. Mitra considered the advice he could give to his peers who are also interested in seeking out mentors such as Dr. Sharma. The former noted:

Peers should be pro-active. If they don't try, they will never even achieve anything. But if they keep on trying, they will definitely find opportunities that could completely change their career. In today's world of social media and modern information technology, I think that reaching out for mentors is quite easy. Moreover, attending conferences is a must for the young scientists.

Dr. Mitra continued:

There are a lot of opportunities for availing scholarships, travel grants and fellowships, and one must try to access them. There

"The major challenges [facing young scientists] are lack of clarity in shaping a career pathway; lack of guidance in pursuing quality research; and lack of infrastructure for proper training in modern cutting-edge technology."

— Dr Sharma

"A mentor may guide the young scientist in understanding and shaping up their career. Moreover, a mentor can help in introducing the mentee to other eminent scientists of the field, which may eventually lead to student exchange for betterment of the mentee."

~ Dr Mitra

are several programmes that may help in identifying a mentor and working with him or her. For example, IFCC has a student exchange program that has already helped many students go and work in laboratories in different countries, thereby allowing them to meet new mentors and develop their professional careers.

My Relationship with My Mentor

Discussing his relationship with his mentor, Dr. Mitra remarked:

My relationship with Prof. Sharma has grown over the last four and a half years. He has always given me time, understanding, space, guidance, advice; and possibly everything that a young fellow would need at this vital point in his/her career. He has not only showed me opportunities which have allowed me to boost my academics; he has also shown me how to improve my laboratory works and research activities. Moreover, he has taught me several life skills which have not just helped my career, they have totally transformed me. There are no restrictions for me if I need to approach him for any kind of problems that I face in my day to day life. He has always been there to guide me, and that s the best part of our relationship.

Describing how his mentor helped him accomplish his project, Dr. Mitra noted:

Prof Sharma is the Director of The National Referral Centre of Lead Project, in India, Jodhpur The centre focusses on spreading awareness about lead and conducting research on lead toxicity. When I was a senior resident, he involved me in some of the work undertaken by the centre. I have gradually taken part in various research projects in the molecular pathogenesis of Lead Toxicity under his supervision. I wrote a project on Th17 and the Kynurenine pathway in depression and suicidality. Moreover, Prof. Sharma gave me thorough inputs and suggestion on making the project better.

Dr Mitra continued:

Eventually, I was awarded the Indian Council of Medical Research – Nurturing Clinical Scientist (ICMR-NCS) fellowship for the same. Further, there are a number of research projects from various departments in our Institute for which Prof. Sharma has always given his suggestions for proper conduct. We wrote a review article "Clinical and Molecular Aspects of Lead Toxicity: An update," that has been published in Critical Reviews in Clinical Laboratory Sciences. Prof. Sharma did all he could to help me write the review and improve the quality of the manuscript. Another area in which he has mentored me, is in regard to organizing conferences and educational activities. I was part of the organizing committee of 15th Asia Pacific Federation of Clinical Chemistry and Laboratory Medicine Congress 2019, at Jaipur, India. He mentored me throughout the preparatory phases, from which I have understood the processes of organizing such a big event.

CONTRIBUTE TO THE IFCC eNEWS

Ethical digital technologies to flatten the curve



Bernard Gouget

by Bernard Gouget

*Chair-IFCC Committee on Mobile Health
and Bioengineering in Laboratory Medicine (C-MHBLM)
co-Chair IFCC -TF on History
SFBC-International Committee
President-Human Health Care Committee-Cofrac
President-Committee for selection of the French reference
Medical Laboratories, Ministry of Health*

Managing the next phase of the pandemic is all about risk. During the lockdown, the pandemic is shaking up our vision and our representation of the world and offering new ones, such as those maps produced to follow the progression of the virus 24 hours a day or even the curiously fascinating videos, taken by drone, of deserted urban spaces, of almost dead cities, as if abandoned. By capturing all our attention and dictating our actions, this virus compromises our ability to think and interpret, like the Alien monster created by Ridley Scott. SARS-CoV-2 thinks and acts for us and makes it impossible to focus on anything else.

Its effects can be observed in the social, political, intellectual, media and scientific spheres. COVID-19 creates a real global drama, continuously broadcasted, to which the audiovisual and print media and digital networks and platforms contribute, as do the information channels of global players such as the WHO, international scientific journals, etc. The phenomenon is amplified by the exacerbation of emotions, positive or negative, starting with the fear that accentuates withdrawal, where we hope to find some security. The process affects the entire world; even those of us best equipped not to indulge in murky theories, as if we are only obeying stimuli with no context. We have seen and heard many coronavirus experts who explained what should have been done yesterday, what should not have been done, what to do today, and what to do tomorrow, sometimes indulging in murky theories or contradictory analyses. In the context of an unparalleled proliferation of communication, everyone is asked to follow an exclusive spectacle in real time and to give their opinion on the inevitable

progression of the disease, which tells us about the existence of an imminent danger for the world. Everyone claims that the world must change, but no new or unprecedented ideas arise, on the contrary everyone remains firmly settled in their role. During this time, anesthesiologist-critical care specialists, clinicians, infectologists, epidemiologists, imaging specialists and laboratory medicine specialists, etc., moving beyond scientific quarrels and ego competitions, with an educational will driven by the intelligence of the moment, continue collectively to make progress in solidarity and to confront uncertainty in order to fight the pandemic. It is time to pull ourselves together, stop all the noise and get our bearings, to find the creativity and imagination essential for life after.

Given its novelty, and the lack of specific scientific knowledge concerning this SARS CoV-2 virus, a certain degree of paralysis and gravity set in, given the contagiousness of the virus, everything indicated the need to use the precautionary principle. Everyone needed to be confined, constrained to a limited perimeter.

Article continued on next page

Confinement upsets our relationship to space and the convergence between the health and security fields is crystallized in the consent to this confinement. The mystique of borders reappears. Symbolic or actual borders have always had a prophylactic function, the primary function being to protect. They do define limits, but they are not an answer to everything. Conversely, they are often directed against migratory flows while we live in a world where any notion of limits is banished and rejected. This “anarchist” virus is effective because it takes advantage of the characteristics of power and efficiency of a connected and urbanized world, and transforms them into factors of vulnerability. Viral geography follows that of global urbanization and especially uses the networks of connections that urbanization has installed, which allow everyone to move around, all the time, everywhere, and by every means. The virus quickly became a planetary stowaway, taking advantage of all possible methods of travel by accompanying its hosts who transport it. It flourishes primarily where population concentrations and social ties are strong.

Now that the future becomes inseparable from the need to invent a way to live with the virus, the reflex to continue to confine populations, and especially to prevent economic and social life from continuing normally, conversely becomes unreasonable and perilous for the active and the most vulnerable, which is to say, the majority of the population. To end confinement or not to end confinement is the question. Screening policy and test availability are key factors for success. To continue confinement or end confinement too timidly would claim many more victims today. First of all, there are many more victims of other diseases than we are aware of, who have not been treated for several weeks. Confinement experienced collectively has had the merit of making us very concretely aware of the vital need for the freedom to come and go. However, we will have to learn to avoid two pitfalls: an inability to be civil and docile in the face of freedom-destroying measures that are being maintained or even strengthened.

Confinement has given rise to an increase in the use of the internet and digital technologies and, in particular, to the use of new surveillance technologies, especially drones, cameras, smart phones and robots that are responsible for keeping individuals in the public space

in order. Five hundred million cameras operate around the world and claim to detect our emotions, spot our suspicious behavior, and even predict potential crimes, reminiscent of the plot of Steven Spielberg’s *Minority Report*. By adopting the most sophisticated prevention/detection/suppression system in the world, will the digital revolution turn every citizen in the world into a suspect? Are we going to move towards digital totalitarianism? Will one have to choose between being safe or avoiding being scanned by an ethical AI.

The use of digital tools for monitoring social interactions is an important element of the system for ending confinement. There is a need for a strict framework for the various forms of emergency and an obligation to end them as soon as they are no longer strictly necessary. With the deployment of surveillance technologies, the ethics of privacy protection are now rightly on the agenda. As the end of confinement looms, many countries, in Asia and Europe, for example, are implementing an application for monitoring the social interactions of people: digital tracking of individuals. Several technologies are used to achieve this: telephone tracking, GPS applications, Bluetooth applications, bank card and transport card systems or even video surveillance and facial recognition; there are many technical means for different purposes. The use of digital tools for tracking individuals raises the risk of harming individual and collective freedoms, in particular respect for privacy and protection of personal data, as well as the risk of discrimination. Digital tools make it possible to quantify, geolocate, map, control and sometimes inform. In a time of health crisis, tracking may be used for three purposes. Firstly, observing collective mobility and confinement practices. Obviously, this can make it possible to reconstruct population movements and thereby check whether the confinement rules are being followed. This was done in Lombardy. Secondly, tracking could permit identifying contacts. In this scenario, it is a question of detecting people who were potentially exposed to the virus following a meeting with patients (known or asymptomatic). Finally, tracking can create control of individual confinements. In this context, it is a matter of observing in an individualized way if patients are respecting the quarantine and confinement measures. This was done by China, Israel and Russia. One

of the purposes is then to institute a travel authorization in a strategy for ending confinement.

The collection of data without the user's consent, but for the purposes of public interest humanitarian purposes, i.e. saving lives, is an authorized exception, in particular, and very explicitly, for epidemics (see GDPR in Europe). Once again, we must avoid taking any ideological position: neither pro-surveillance nor anti-surveillance. The idea is to protect data against the possible infractions of an authoritarian state or a private company. The Korean example of obtaining data without consent did not lead to a dystopian plunge into dictatorship. Even better, the Korean government was able to hold legislative elections in April. Participation was the strongest in twenty-eight years. Thanks to its system for controlling the epidemic, not only have there been no attacks on public freedoms, but rather democratic life has been able to fully prosper there.

Whether in China, Europe or the United States, countries use the legal and technical means at their disposal to legitimize these systems. Countries turn to practices usually reserved for combatting terrorism and therefore justified by protecting national security. This is where there is debate: in principle, national security does not include health issues. But the current situation--closing public places and educational facilities and prohibiting freedom of movement--is unprecedented. To justify these exceptional surveillance measures, questions of the legitimacy and proportionality of the systems arise. Despite the very intrusive nature of surveillance systems, it is difficult not to admit their usefulness in view of the health emergency. In return, the appropriate proportionality of the measures may be more complicated to prove when several surveillance technologies are combined. This was especially the case in China. In public transportation, in businesses or on the street, the country has deployed facial recognition devices, among other things, coupled with thermal imaging to detect sick people. The real value of tracking applications comes from their interoperability and their ability to share data with central and local health IT systems. It is only by receiving this information that statistical analysis, outbreak mapping, capacity management and early clinical intervention for high-risk groups can be conducted. There has been a huge increase in cyberattacks since the start of the

pandemic and especially in healthcare, with ransomware attacks targeting hospitals, government agencies and research centers, among others. This means that these e-platforms and telehealth resources are attractive targets for attackers who wish to spread malware through a health system, causing damage that really disrupts clinical care on a large scale. It is an immediate patient safety problem.

The deployment of such devices must be supervised, as it is in Europe, for example, by the GDPR and the e-privacy directive. They authorize the processing of geolocation data via electronic communication means, provided that they have previously obtained either the express consent of the individuals or have anonymized the data collected. A number of considerations must be taken into account to guarantee that personal data is legally processed and, in any case, it should be remembered that any measure taken in this context must respect general legal principles and must not be irreversible, a condition that can legitimize restrictions on freedoms provided that these restrictions are proportionate and limited to the period of emergency.

These digital tracking tools are becoming essential for mass surveillance. Of course, many people are worried about the power of the big four tech companies, but here we are not talking about commercial powers. It is a public interest mission for humanitarian purposes, which must be carried out by health authorities. We must also think about the consequences of our choices. Especially during a severe crisis when the alternatives are potentially devastating and deadly. The people of each country have adopted the protective measures they deem most appropriate or accessible, in the face of the unexpected risk. The weekly public applause for health services and key workers will be one to the enduring memories of this pandemic. It is hard not to find the common outpouring of support a little heartwarming. But are we all clapping for the same reasons? Each of us sees coronavirus in terms of culture and experience. But we are all rooted in the same humanity and faced with the same threat. *As Cardinal Richelieu, Minister of France (1624-1642) said, "there is no need to be afraid of everything but do be prepared for everything."* This is the task before us all and this global crisis will certainly make us aware of this lesson. This is, above all, an ethical consideration.



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Standardization and Personalization for Improved Healthcare



Standardized healthcare uses evidence-based data to ensure patients receive high-quality care, while personalized healthcare recognizes the uniqueness and individuality of the patient. Although they are often thought of as mutually exclusive, standardization and personalization can augment one another for measurably better healthcare.

Clinical laboratory testing provides valuable insights in diagnostic decision making. Results provided by the laboratory are used to identify individuals with diseases or those at risk for a disease, guide treatment decisions, determine prognosis, and monitor the success of treatment. Many clinical care plans use fixed laboratory values for decisions, particularly in comparison to established reference ranges or clinical decision limits. However, often care activities are based on unique clinical experiences and not unique patient factors. Standardization can supplement clinician experiences and reduce uncertainty through outcome specific resolutions powered by evidence-based medicine. Standardization ensures consistent, high-quality test results are equivalent across health systems or commercial assays, decreasing variability in patient care and outcomes.

Capitalizing upon the foundation of standardization can enable best-practice care initiatives. Classifying patients into subpopulations that differ in their susceptibility to a disease or their response to a specific treatment is maximized through personalization. Multidisciplinary integrated care teams can utilize their unique skills and contributions, collaboratively define the goals of standardization, and set the criteria for defining specific desired outcomes. Through partnerships, patient care is improved and enhanced with well-founded clinical judgment and consideration and appreciation for specific care needs across patients. Recognizing that every patient encounter is unique, can involve different presentations, and have distinctive characteristics, healthcare providers can provide insights for personalization while balancing standardization.

Recently recognized by the UNIVANTS of Healthcare Excellence Program, an integrated care team from Marienhospital in Stuttgart, Germany achieved an excellent balance of standardization and personalization. This team recognized that the “one size fits all” assessment for renal function testing using creatinine-based estimated glomerular filtration rates (eGFR) by Modification of Diet in Renal Disease (MDRD), or Chronic Kidney Disease

Epidemiology Collaboration (CKD-EPI) equations were misleading in selected populations, leading to the high potential of misclassification and/or incorrect targeting of treatment. A downside of standardization using the pre-established methods for GFR is that patients do not always resemble the population used to establish the estimation, leading to under or overestimations of GFRs. There are known disparities between creatinine and cystatin c-based eGFRs based on patient age, muscle mass, and other known conditions. Thus, eGFRs will differ as well. Dual reporting estimations of GFR using multiple equations can enable both personalization and standardization of care, particularly when the values do not agree. The use of equations that leverage the strengths of both creatinine and cystatin c methods improves the accuracy of staging associated with chronic kidney disease (CKD) while maximizing the ability of clinical care providers to generate treatment plans tailored to individual patients. According to Manfred Hoffmann MD, Ph.D, Head of Department of Gynecology and Obstetrics, “eGFR with Cystatin C enables me to optimally direct treatment for all my patients with confidence. I only start effective but highly toxic antineoplastic drugs if we also have the information on renal function based on Cystatin C-based GFR.” Through co-reporting, eGFRs pharmacological treatment could be adjusted to fit the needs of each patient and led to an annual cost avoidance of approximately 105,000 euros through the reduction of chemotherapy drugs alone. Highly specific individual markers, paired with custom-tailored care plans for patients, ensure sustainable value.

Opportunities to further bridge standardization-personalization gaps can be vast across disciplines and diseases. Novel insights powered by clinical laboratory data can transform clinical procedures and drive measurable benefits across stakeholders. If you have an example of a similar or valued best practice, visit www.UnivantsHCE.com to apply for team recognition or to learn more about other best practices of healthcare excellence.

NEWS FROM REGIONAL FEDERATIONS AND MEMBER SOCIETIES



News from the Kingdom of Saudi Arabia

Saudi Society for Clinical Chemistry (SSCC)

ةيريررسلا ءاي ميكلل ةي دوعسلا ةي عمجلا



by Anwar Borai

*IFCC National Representative for Saudi Arabia
King Abdulaziz Medical City, King Saud Bin Abdulaziz University
for Health Sciences, Jeddah, Kingdom of Saudi Arabia*

The SSCC has held two successful webinars in collaboration with Saudi Commissions for Health Specialties (SCHS). Both webinars were presented live and recorded at the same time for those guests, who could not attend.

The first webinar was held on April 19th and titled “**How Does the Laboratory Services Function in the COVID-19 Outbreak?**”. It was presented by three distinguished speakers and covered different aspects in clinical laboratories including Protective Measures and Safety (presented by Dr. Hosam Zowawi), How COVID-19 is Diagnosed (presented by Dr. Sana Alshaikh) and The Role of Blood Bank and Blood Transfusion in COVID-19 (presented by Dr. Abdullah Meshi). The webinar was moderated by Dr. Ali Alothaim. The number of guests who attended this webinar exceeded 1,000.

How does the Laboratory Services Function in the COVID-19 Outbreak?

Speakers :



Dr. Abdullah Ahmed Meshi
Consultant, Laboratories and Blood
Banks Administration
King Fahad Central Hospital, Jazan.



Dr. Hosam Mamoon Zowawi
Assistant Professor at the College of
Medicine, King Saud Bin Abdulaziz for
Health Sciences in Riyadh



Dr. Sana Alshaikh
Consultant Molecular Virologist
Head of Virology and Serology
Laboratory at Maternity and Children
Hospital, Dammam.

Objectives:

- Explain protective measures
- Describe how COVID-19 is diagnosed
- Demonstrate Understanding of other clinical laboratory work



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مجتمع صحي بكفاءة

الهيئة السعودية للتخصصات الصحية
Saudi Commission for Health Specialties

The second webinar was held on May 12th, 2020. As we currently are in the month of Ramadan and millions of Muslims are fasting this month, it was necessary for the webinar topic to be about fasting and health education. So the SSCC dedicated a webinar to “Health Benefits of Fasting and How Our Immune System can Be Improved”.

The webinar was presented by Dr. Abdulhadi Bima and moderated by Dr. Anwar Borai. The number of guests, who attended this webinar was around 140.

Both webinars were successful and many positive feedback messages were received. More webinars will be organized by the SSCC and will be announced soon.

صوموا صحوا .. وقاية و مناعة



الهيئة السعودية للتخصصات الصحية
Saudi Commission for Health Specialties



الهدف العام

التوعية بفوائد الصوم في
تقوية المناعة وأهمية تجنب
الإفراط في السكريات والنشويات
وأثرها على الصحة والمناعة

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في تقوية المناعة
- عاداتنا الغذائية في رمضان
وأثرها على الصحة و المناعة
- ضرورة تقليل السكريات
والنشويات لصحة افضل

المتحدث



د. عبدالهادي إبراهيم حسين بيم
- استاذ مساعد في قسم الكيمياء الحيوية السريرية
- استشاري الكيمياء الطبية وعلم الأمراض الكيميائية
- حامل لزمالة الكلية الملكية الأسترالية لعلم الأمراض



مدير الحوار

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News from the Spanish Society of Laboratory Medicine (SEQC^{ML})

The Spanish Society of Laboratory Medicine collaborates in the Ditunga Project

SEQC^{ML}

Spanish Laboratory Medicine collaborates in setting up a Clinical Laboratory in the Democratic Republic of the Congo.

- **The Spanish Society for Laboratory Medicine (SEQC^{ML}) is participating in this solidarity initiative by providing a grant for a visit by a Clinical Analysis specialist**
- **With the collaboration of a Spanish professional and member of the Society, a clinical laboratory has been launched in the new Hospital Nuestra Señora de Guadalupe**
- **The initiative is part of the CSR objectives of the SEQC^{ML} that seek to improve the quality of life in disadvantaged communities**

MADRID, MAY 11, 2020

The Spanish Society for Laboratory Medicine (SEQC^{ML}), through the José Luis Castaño Foundation-SEQC, has collaborated in an ambitious solidarity project in the Democratic Republic of the Congo that seeks to improve health conditions in the area through the launch of a new hospital. This initiative is part of the Ditunga Project, which has launched a new medical center, the Nuestra Señora de Guadalupe Hospital, and which is the most modern in the region in many ways, especially regarding equipment.

The Ditunga project is taking place in the Ngandanjika territory, in the province of Kasay Oriental, one of the most isolated in this African country, plagued by various armed conflicts in recent decades and with many development needs. As explained by Dr. Antonio

Moreno, member of the SEQC^{ML} Board of Directors, this initiative had the necessary characteristics to justify the Society's involvement. This participation takes the form of the financial grant so that one of the SEQC^{ML} members, Belén Fernández Puntero, a doctor in pharmacy and specialist in Clinical Analysis, could travel to and work in the area for two weeks. The objective was for this professional to participate in the start-up of a Clinical Laboratory in the new hospital.

“In this first mission we proceeded to establish the bases of the laboratory, adaptation of spaces, and start-up of equipment, but various actions are still pending”, explains Dr. Moreno, who details that, among other aspects, it is still necessary to reinforce the training of personnel in various areas, increase the portfolio of services, and improve the management of both documentation and the clinical laboratory itself.

Belén Fernández Puntero explains that the experience of launching the hospital has been “very intense”. “We found the building and little else. It was thus necessary



Snapshot of the Ditunga Project in Ngandanjika (Democratic Republic of the Congo)

Article continued on next page

to set up stretchers, operating room tables, an ultrasound machine, the blood bank refrigerator, the hospital pharmacy, the water distiller, sterilizers and, of course, the entire laboratory, which had walls, a laboratory worktable and little more. In fact, it was necessary to extend the worktable, electrical outlets, and finish the water connection”.

The Clinical Analysis specialist explains that shortly after arriving in Ngandanjika, the operating room started operations and was able to collaborate with the rest of the health professionals. At the same time, and while the laboratory was being completed, Dr. Fernández Puntero provided analytical guidance for some of the patients undergoing surgery or those who came for consultation.

“At a clinical level, you learn a lot, because there you can see live and in person the pathologies that we have studied in books; but also at a technical level it is a very enriching experience, because with the means available you have to be able to offer support to the clinicians with whatever laboratory medicine, you have available in the circumstances,” explains Dr. Fernández Puntero.

“Participating in these initiatives is a personal option, it is a way of contributing and giving back something that we have received. I have had the immense good luck of being born in a developed country, with advanced healthcare and sanitary conditions ... that is why I feel obliged to give back some of all this, and my way of doing so is to teach what little I know. In addition, I must thank the great effort made by the José Luis Castaño-SEQC Foundation and SEQC^{ML} itself to improve the training of its members and enhance the specialty of Laboratory Medicine”, concluded the specialist.

In the same direction, Dr. Moreno points out that in Spanish laboratories professionals are used to having technical and personnel resources that cannot be extrapolated to situations such as those seen in the Democratic Republic of the Congo. However, he indicates, “the needs of the population, we must attend to, are the same from the healthcare point of view, so our Clinical Laboratory specialists must also learn to cope in such situations”.

CORPORATE SOCIAL RESPONSIBILITY

As indicated by Dr. Moreno, the purpose of the SEQC^{ML} is to actively contribute, through its corporate social responsibility (CSR), in social, economic, and environmental areas, focusing particularly on communities in underdeveloped or developing countries. “Our objective in this project is to contribute in improving the quality of life in disadvantaged communities. We do not seek external recognition, but obviously, we project the importance and the high level of Spanish Laboratory Medicine”, said the doctor.

Along these lines, Dr. Moreno highlighted that the SEQC^{ML} participates in other initiatives, with special mention of the collaboration with the Latin American Confederation of Clinical Biochemistry (COLABIOCLI) through the José Luis Castaño-SEQC Foundation for the development of Laboratory Medicine, issuing financial grants so that members of Latin American countries associated with COLABIOCLI can carry out training in Spanish Clinical Laboratories.

You can find out more about **the Hospital Nuestra Señora de Guadalupe, in Ngandanjika**, in this video: <https://youtu.be/qgHoaSvB4wg>.

About the Spanish Society of Laboratory Medicine (SEQC^{ML})

The Spanish Society of Laboratory Medicine (SEQC^{ML}) -founded in 1976- is an active member of IFCC and EFLM. The SEQC^{ML} currently encompasses more than 2,500 professionals, and its main objectives are to bring together all scientists interested in the field of Laboratory Medicine, promote the dissemination of scientific and technical publications, organize meetings, courses and congresses of national and international character, cooperate with other Scientific Societies, and defend and promote the specialties of the field of Laboratory Medicine as well as those of its members. Likewise, the Society wishes to contribute to studying and recommending methods and guides, and to establishing guidelines and recommendations for training in the field of Laboratory Medicine.

More information at: www.seqc.es.

Postponement of the EU Medical Device Regulation to 26 May 2021

*by Christa Cobbaert**EFLM observer in the IVD Working Group
under the MDCG of the EC*

Amid all the COVID-19 headline news, the European Parliament recently voted decisively in favour of a proposal to delay by one year the implementation of the European Union's Medical Device Regulation 2017/745 (MDR). The proposal was crafted by the [European Commission](#) (EC) and was moved forward by the Council of the European Union (EU) in order to permit the medical device industry to prioritize its coronavirus response efforts. The approval (with 693 votes in favour, 1 against, and 2 abstentions) clears a key barrier to the enactment of the delay, but the proposal now has to be approved by the European member states and published in the Official Journal before taking effect. [According to Parliament](#), those actions are expected at the latest by 26 May 2020, MDR's original enforcement date. In a press release following the vote it was stated that a delay would ***“allow authorities and manufacturers alike to prioritise the fight against the coronavirus pandemic by continuing under current procedures.”*** Hence, this MDR postponement serves primarily to ensure the supply of critical medical devices and is intended in particular to relieve the EU and its member states during the current Corona pandemic.

Recall that the MDR describes the legal framework and governance for bringing medical devices (among them are high risk implantable devices) to the European market originally per May 2020. In the new MDR more stringent requirements are laid down as compared to the current Medical Device Directive (MDD), such as classification of medical devices, conformity assessment procedures, technical documentation, clinical evaluation/investigation, responsible persons, market surveillance, reporting obligations, quality

management and transparency. Key for improved transparency on the safety and clinical effectiveness of medical devices is the database EUDAMED database which should be open to competitors, notified bodies and the public. Appendix VI of the MDR explains in detail what information economic operators need to enter in this database. EUDAMED also includes the UDI database (unique device identification). Hence, every medical device is clearly labelled, and it is possible to trace back the supply chain (traceability).

POSITION STATEMENTS

Both **Medtech Europe** – the European trade association for the medical technology industry including diagnostics, medical devices as well as digital health – and **BioMed Alliance in Europe** – the latter being a non-profit organization representing 33 research and medical societies – welcomed in its press releases the postponement by the European Commission of the date of application of the Medical Devices Regulation (MDR) by one year to 26 May 2021. Both organizations considered it is as essential to ensure a smooth transition from the Medical Device Directive to the new regulatory framework, to guarantee that patients will continue to benefit from a timely access to safe and high-quality devices.

Both organizations urgently call upon all stakeholders, authorities and policy makers to continue preparations for the MDR and IVDR to the maximum extent that the current crisis situation allows. Insufficient progress had been made already in the pre-Corona period, whereas for proper implementation of the MDR, the following elements are essential:

1. The new regulatory system can only operate properly with a functioning EUDAMED portal. Therefore, the European Commission should operationalise the system by May 2021, and not postpone its implementation until the date of application of the IVDR in 2022 (as was previously announced).

2. For healthcare professionals and patients, transparency throughout the new system should be a top priority. Public access to clinical information (e.g. Summaries of Safety and Clinical Performance shared through EUDAMED) will help clinicians to select optimal treatments. The implementation of the clinical aspects of the EUDAMED portal should be implemented ahead of the new application date.

3. The delayed application date allows more time to ensure that the Expert Panels have the necessary support to carry out their important new role for high risk medical devices within the regulatory system. The members of the Expert Panels should receive sufficient education and training. In addition, the system should be tested to ensure that all aspects can run smoothly.

4. The number of notified bodies available to take MDR work and to do conformity assessments, as listed in the database of the European Commission, only stands at twelve.

MDR postponement: are all problems ironed out?

Anyone who has so far assumed, based on the headlines, that MDR in its entirety will now be postponed by one year is mistaken. Strictly speaking, **the period of entry into force with all its details will only be shortened by one year** - and that at the beginning. As a result, all those who would have to undergo a conformity assessment according to MDR in the period from 26 May 2020 to 26 May 2021, but who are not ready for it yet, can take a deep breath. However, not all transition periods and expiry dates will be postponed by one year but will remain with the known dates. Individual aspects, such as the introduction of the UDI, are only postponed by one year for the most part. In the worst case, this means that even more manufacturers will have to obtain certification in even less time. Manufacturers must nevertheless have shifted to an MDR certificate by May 2024 when their MDD/AIMD certificates expire.

Implications for the IVDR 2017/746 and IVD-stakeholders?

Notwithstanding the MDR postponement, it is important to realize that the In Vitro Diagnostic Regulation 2017/746 (IVDR), slated to take effect in May 2022, remains unaffected. Note that in essence the framework and governance of the IVDR is mimicking that of the MDR. However, for the IVD-sector the IVDR implementation is completely new and much more impactful than the MDR implementation. I.e., 85% of the medical tests must undergo certification in order to get European market access and CE-labelling under the IVDR, as compared to only 15% under the current IVD Directive (IVDD) regimen. Being far in the second half of the transition period from IVDD to IVDR, the time is there that medical and laboratory societies should consider the lack of progress on the preparations for IVDR implementation caused by the COVID 19 crisis, which even brought all MDR preparations to a standstill and led to postponement of the MDR application.

Other challenges are the limited number of notified bodies qualified for medical test conformity assessments (yet sufficient capacity for assessing 85% of some 40 000 IVD-products is needed), the nearly non-availability of guidance documents on this process (https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en; <https://ec.europa.eu/docs-room/documents/41182>), the fact that so far none of the experts for evaluating high risk medical tests has been appointed, the postponement of the EUDAMED database until May 2022, etc...



These challenges should make us realize that the timelines for careful implementation of the impactful IVDR regulation are no longer realistic.

The fact that the European Commission is still fully occupied with handling the huge effects of the COVID-19 crisis and is thus willing to slide forward the MDR implementation to May 2021, should alarm us about the non-feasibility of thoughtful IVDR implementation per May 2022. The IVDR implementation is the last domino in this domino game and it seems unrealistic to

chase that application date if neither the governance nor the infrastructure and guidance documents are in place.

Therefore, laboratory specialists and (inter)national laboratory medicine societies, task forces, commissions and working groups: be aware of this force field, let us take position and start the dialogue with the EC in order to make a mutually agreed plan with EU-wide realistic goals and deadlines, for the sake of better and safer patient care.



Updates on EFLM publications

by Aleksei Tikhonov

Full Member, YS of EFLM WG-Promotion & Publications

European Biological Variation Study (EuBIVAS)

- EDTA plasma samples from 91 healthy volunteers
- Collected weekly for ten consecutive weeks on a set day at the same hour from the same phlebotomist
 - 6 European laboratories
 - Stored for 3 years at - 80 °C before analysis



- Estimates of **biological variation (BV)** for five different bone metabolism and vascular calcification biomarkers
- 1738 results totally
- Samples from the same individual were measured in duplicate within the same instrument run for a single day
 - All the analyses were performed by the same technician within 2 months

Biomarkers	Mean value (95% CI)	Within-subject BV CV _i % (95% CI)	Reference change values RCV (%) decrease; increase
β-isomerized C-terminal telopeptide of type I collagen (β-CTX), ng/L	514.3 (499.5–529.1)	15.1 (14.4–16.0)	- 30.8; 44.5
N-terminal propeptide of type I collagen (PINP), µg/L	63.7 (62.3–65.0)	8.8 (8.4–9.3)	- 19.9; 24.8
osteocalcin (OC), µg/L	22.5 (22.1–23.0)	8.9 (8.5–9.4)	- 19.2; 23.8
intact fibroblast growth factor 23 (iFGF-23), ng/L	35.3 (34.7–35.9)	13.9 (13.2–14.7)	- 28.7; 40.2
uncarboxylated-unphosphorylated Matrix-Gla Protein (uCuP-MGP), pmol/L	397 (393–401)	6.9 (6.1–7.3)	- 20.3; 25.4

Cavalier E, et al. *Osteoporos Int*, 2020
<https://doi.org/10.1007/s00198-020-05362-8>

European Biological Variation Study (EuBIVAS): within- and between-subject biological variation estimates of β -isomerized C-terminal telopeptide of type I collagen (β -CTX), N-terminal propeptide of type I collagen (PINP), osteocalcin, intact fibroblast growth factor 23 and uncarboxylated-unphosphorylated matrix-Gla protein—a cooperation between the EFLM Working Group on Biological Variation and the International Osteoporosis Foundation-International Federation of Clinical Chemistry Committee on Bone Metabolism.

Cavaliere E, Lukas P, Bottani M, Aarsand A.K., Ceriotti F., Coşkun A, Díaz-Garzón J, Fernández-Calle P, Guerra E, Locatelli M, Sandberg S, Carobene A on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation and IOF-IFCC Committee on Bone Metabolism.

Osteoporos Int 2020; Available from: <https://doi.org/10.1007/s00198-020-05362-8>.

Biomarkers of bone formation and bone resorption are frequently used for monitoring patients' responses

to therapies and compliance. The reference change values (RCV) serves as an important tool used to correctly interpret the biological significance of a change observed between two consecutive biomarker measurements.

In the present study, a cooperation between the European Federation of Clinical Chemistry and the Laboratory Medicine (EFLM) Working Group on Biological Variation (WG-BV), the International Osteoporosis Foundation and the International Federation of Clinical Chemistry (IFCC) Committee on Bone Metabolism (C-BM) established updated biological variations (BV) estimates for five different biomarkers implicated in bone metabolism and vascular calcification, namely OC, PINP, β -CTX, iFGF23, and uCuP-MGP within the European Biological Variation Study (EuBIVAS).

The BV estimates of these analytes will be included in the EFLM Biological Variation Database, available at: <https://biologicalvariation.eu/>.

On Demand webinar:

Lipid Testing in 2020

Sponsored by

MERCK

Michel R. Langlois of Ghent University will give an overview on the strengths and weaknesses of emerging and traditional lipid tests and will provide guidance on which marker to preferably test in the contemporary and future settings of risk assessment and therapeutic targeting for the prevention of atherosclerotic cardiovascular disease (ASCVD).



Watch now at bit.ly/zzlryW1

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IFCC WELCOMES TWO NEW MEMBERS

New full member: Iraqi Society of Molecular Biology and Genetics (ISMBG)



٢٣ارول او ي ئ يزجلا ي جولوي ابلل ةي قار علا ةي عم جلا

by **Mohammad I. Mezaal Atheab**
ISMBG President
Baghdad, Iraq

The Society's mission is to advance the science of molecular biology and genetics and to promote the understanding of the molecular nature of life processes through:

- ▶ Publication of scientific and educational journals;
- ▶ Organization of scientific meetings;
- ▶ Advocacy for funding of basic and advance research and education;
- ▶ Support of science education and research at all levels; And promotion of the diversity of individuals entering the scientific workforce.
- ▶ The Department of Medical Laboratories was established in specialties (Molecular Biology and Genetics):
 - Interested in contributing to the development of medical examinations
 - Trying to develop staff working in medical laboratories
 - Covering the activities and events that serve the development of medical laboratories in private and government sectors
 - Benefiting from the international experience by cooperating with the specialized international federations, officially joining it and representing Iraq.



Iraqi Society of Molecular Biology and Genetics

The Iraqi Society of molecular biology and genetics (ISMBG) is a nonprofit scientific, clinical and educational organization (*newly established*).

We seek to achieve international cooperation with other institutions in research areas in order to find solutions for the most important health challenges and problems facing the international community, through joint research and through our relations with health institutions inside Iraq.

ISMBG was founded in 2019, the Society is based in Baghdad and will publish a magazine in the near future, the Iraqi Journal for Molecular Biology and Genetics (*coming soon*).

OBJECTIVES OF THE IRAQI SOCIETY OF MOLECULAR BIOLOGY AND GENETICS (ISMBG):

1. Supporting students and researchers in the field of molecular biology and genetics

2. Supporting state institutions academically and scientifically in this field through joint activities, exchanging insights and ideas in this field.
3. Keeping pace with the scientific development in the field of molecular biology and genetics.
4. Contributing in the provision of advice and the formation of joint committees with the competent authorities to take appropriate decisions in this specialization (molecular biology and genetics) in the government and private sector.
5. Also, we aim to:
 - Society Governance
 - ISMBG Meetings (inside and outside of Iraq)
 - Advocacy and Public Affairs
 - Patents
 - Researchs
 - Our Publications
 - Supporting medical laboratory activity and coordination with Iraqi Ministry of Health



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10	Dr. Mohammed Tariq Al-Mayhi	Member

New affiliate member: The Order of Biochemists, Biologists and Chemists in the Healthcare System from Romania (OBBCHSR)



by **Constanța Popa**
OBBCHSR President
IFCC National Representative for OBBCHSR

The Order of Biochemists, Biologists and Chemists in the Healthcare System from Romania (OBBCHSR) became an IFCC Affiliate Member since April 2020.

Since its founding by the passing of Law 460/2003 and until now, the OBBCHSR's activity resulted in drafting national legislation on the recognition of the professional status of biologists, chemists, biochemists in the Romanian health system and monitoring its implementation.

Since 2004, the OBBCHSR publishes the *Romanian Journal of Medical Laboratory*, where scientific papers are published covering the entire EC4 curriculum, with monthly appearances for many years after its establishment, then quarterly and more recently semiannually.

The annual conferences of OBBCHSR had both scientific programs in continuing medical training and agendas dedicated to the exercise of our medical professions. For example, in 2018, the theme was “**Laboratory medicine - techniques and/or laboratory diagnosis**”.

In 2017 National Conference topics was “**Harmonization of vocational training in laboratory medicine**”. This event had international participation of speakers, including IFCC and EFLM Executive Board Members, such as Dr. Gilbert Wieringa and Dr. Bernard Gouget.

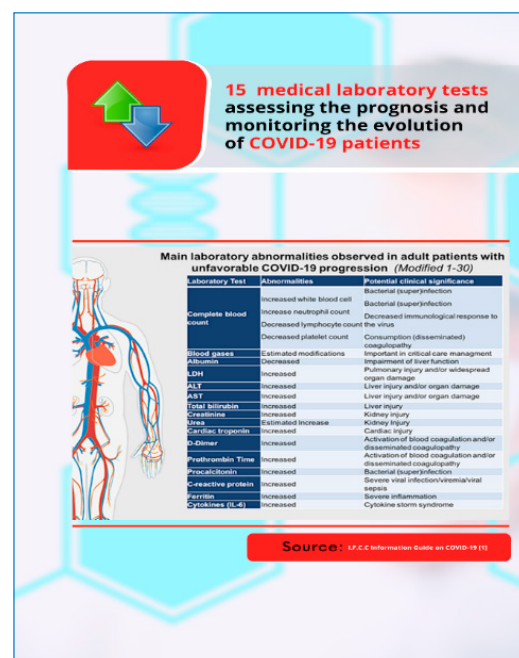
This year Romania was also affected by the pandemic of COVID-19. Starting in April 2020, we have published three practical Guides developed with the initiative of the OBBCHSR President, Dr. Constanța Popa, who coordinated the team of specialists who were the main contributors to the documentation.

The first two Guides, concerning mainly data on molecular diagnosis and associated error factors, were dedicated especially to the laboratory specialists.

The latest one, named “Fifteen medical laboratory test panels important in COVID-19”, based on the on the IFCC “*Information Guide on COVID-19*” presents the scientific information and it is publicly



Guide: front cover



Laboratory tests relevant in COVID-19 (acc. to IFCC “*Information Guide on COVID-19*”)

available on the official website obbcssr.ro, in order to be accessed by the 3,500 members of our professional body and all the specialists involved in the clinical chemistry field.

The OBBCSSR has proposed to the Romanian Ministry of Health to implement this orientation Guide for the laboratory test panel with the clinical utility to identify, monitor and prognose the COVID-19 patient outcome.

In the spirit of transparent scientific communication we have sent an English version of the 3rd OBBCSSR Guide to the IFCC Office, considering that any documented information can be useful to the healthcare medical and non-medical specialists, especially in terms of the clinical utility in the current context of the COVID-19 pandemic.

***"What you do for yourself disappears with you,
what you do for others remains for eternity."***

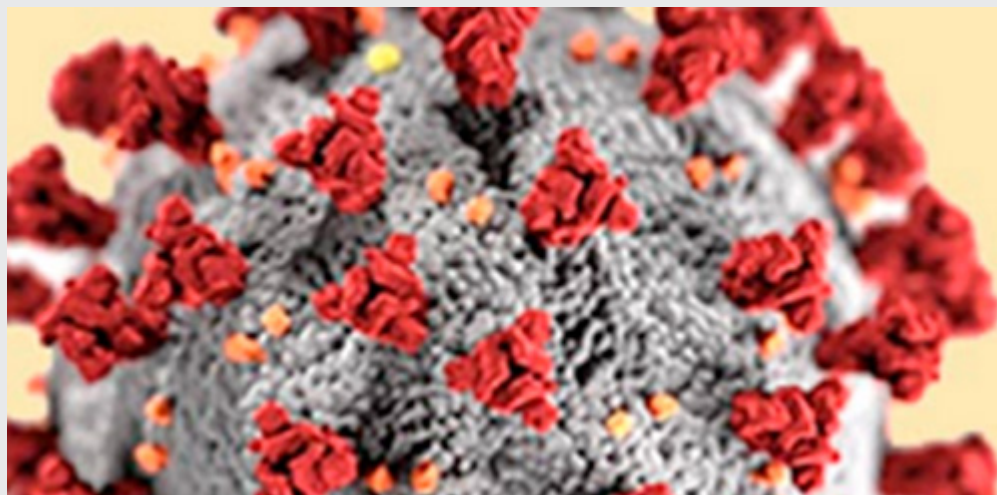
~ Albert Einstein



13th OBBCSSR National Conference, Bucharest, Romania

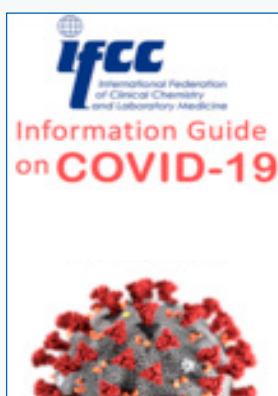
L-R: Dr. Tatiana Ciurea, OBBCSSR Professional, Scientific, Educational and Legislative Committee;
Daniela Beldean, Vice-president OBBCSSR National Executive Bureau;
Dr. Bernard Gouget, President Human Health Care Committee Cofrac, IFCC NC;
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Nicoleta Mihaela Stan, EuSpLM, Vice-president of OBBCSSR National Executive Bureau;
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Dr. Dalius Vitkus, IFCC and EFLM National Representative Lithuanian Laboratory Medical Society;
Prof. Dr. Bogdan Solnica, National Representative EC-4 Registration Commission
for the Polish Society of Laboratory Diagnostics.

News from the IFCC Website



The IFCC is pleased to publish an online resource that provided key information on laboratory guidelines, biosafety, and other important resources to assist member societies around the world and their clinical laboratories as they face the challenges posed by the COVID-19 outbreak.

The page is constantly updated with the most recent information.



IFCC Information Guide on COVID-19 (with **weekly updates**)

Summaries of the Guide in Spanish and Czech are also available:

Click [aquí](#) para descargar el Resumen traducido de la Guía de Información de la IFCC sobre COVID-19.

Kliknutím [zde](#) stáhnete českou verzi IFCC informačního souhrnu o COVID 19 z 16. dubna 2020.

Visit the IFCC website to get the most updated information on COVID-19.

Coronavirus disease 2019, abbreviated to COVID-19, is an emerging global pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As the number of individuals infected with COVID-19 continues to rise globally and healthcare systems become increasingly stressed, it is clear that the clinical laboratory will play an essential role in this crisis, contributing to patient screening, diagnosis, monitoring/treatment, as well as epidemiologic recovery/surveillance.

This guide aims to organize relevant available information on laboratory screening, testing protocols, diagnosis, and other general information on COVID-19 for laboratory professionals, including links to helpful resources and interim guidelines. It will be continuously updated as new guidelines and literature become available.

[Read more](#)

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www.ifcc.org



IFCC'S CALENDAR OF CONGRESSES, CONFERENCES & EVENTS

We advise readers to keep up-to-date about the evolving situation and possible rescheduled dates.
Contact organizing secretariats for updates on upcoming events.

Calendar of IFCC Congresses/Conferences and Regional Federations' Congresses

Jan 5 - 6, 2021		<i>IFCC Young Scientists Forum</i>	Seoul, KR
Jan 6 - 10, 2021		<i>XXIV IFCC WorldLab Seoul 2020</i>	Seoul, KR
May 16 - 20, 2021		<i>XXIV IFCC - EFLM EuroMedLab Munich 2021</i>	Munich, DE
Mar 28 - Apr 2, 2022		<i>XXV COLABIOCLI Congress</i>	Leon, MX
Oct 15 - 18, 2022		<i>16th APFCB Congress 2022</i>	Sydney, AU

Calendar continued on next page

May 21 - 25, 2023	 <p>21-25 May EUROMEDLAB ROMA 2023</p>	XXV IFCC - EFLM WorldLab EuroMedLab - Rome 2023	Rome, IT
New date TBA	 <p>XV ICPLM Emerging Technologies in Pediatric Laboratory Medicine</p>	International Congress of Pediatric Laboratory Medicine - WorldLab Seoul 2020	venue TBA
New date TBA	 <p>International Consortium for Harmonization of Clinical Laboratory Results</p>	IFCC - ICHCLR Workshop	venue TBA
New date TBA	 <p>IFCC International Federation of Clinical Chemistry and Laboratory Medicine</p>	IFCC C-POCT Satellite Meeting	venue TBA

Calendar of events with IFCC auspices

We advise readers to keep up-to-date about the evolving situation and possible rescheduled dates. Contact organizing secretariats for updates on upcoming events.

Feb 20 - Nov 15, 2020	<i>Virtual Diploma in Control of Analytical Quality in the Clinical Laboratory</i>	Internet series of lectures, MX
Jun 3, 2020 - Jan 3, 2021	<i>Virtual Postgraduate Course of Clinical Biochemistry</i>	Tultepec, MX - virtual page
Sep 6 - 8, 2020	<i>16th National and 7th International Congress of Biochemistry and Molecular Biology</i>	Tehran, IR
Sep 9 - 11, 2020	<i>4th Conference of the Romanian Association of Laboratory Medicine</i>	Târgu Mureș, RO
Sep 23 - 25, 2020	<i>XXII Serbian Congress of Medical Biochemistry and Laboratory Medicine and 16th Symposium for Balkan Region</i>	Belgrade, SRB

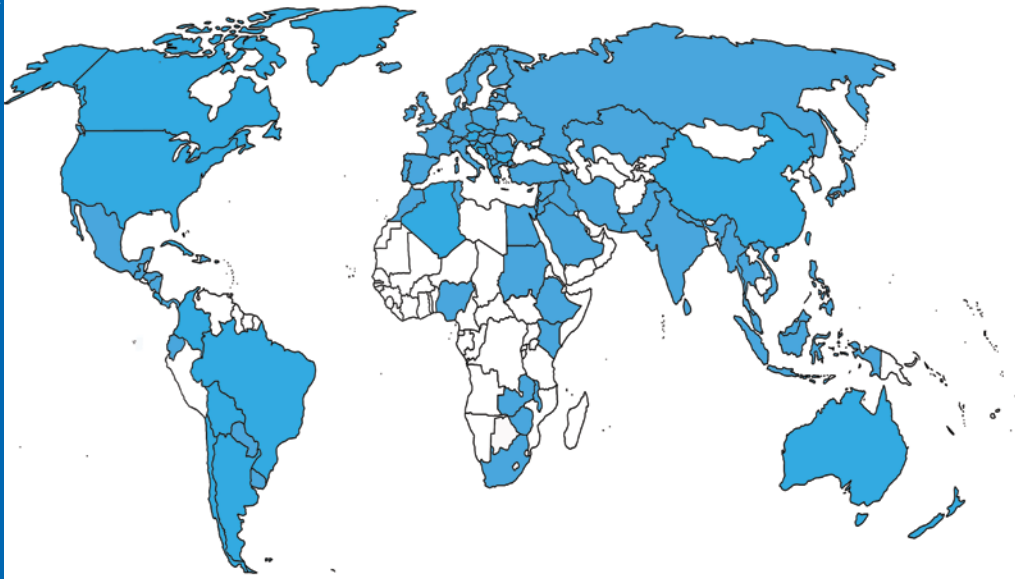
Calendar continued on next page

Sep 23 - 25, 2020	<i>LMCE 2020 (Laboratory Medicine Congress and Exhibition) KSLM 61st Annual Meeting</i>	Incheon, KR
Sep 28 - Oct 1, 2020	<i>10th Santorini Conference "Systems medicine and personalized health and therapy" – "The odyssey from hope to practice: Patient first – Keeps Ithaca always in your mind"</i>	Santorini, GR
Sep 30 - Oct 2, 2020	<i>28th International Critical and Point-of-Care Testing (CPOCT) Symposium</i>	Montreal, CA
Oct 7 - 10, 2020	<i>1st EFLM-AFCB Conference – Laboratory Medicine for Mobile Societies (LM4MS) – 34th National Days of Clinical Biology</i>	Hammamet, TN
Oct 8 - 11, 2020	<i>46th ISOBM Congress</i>	Bled, SI
Oct 23, 2020	<i>Pathology and Laboratory Medicine: The Promise, The Hope, The Peril</i>	Padova, IT
Nov 30, 2020	<i>14th CIRME International Scientific Meeting "Implementation of metrological traceability in laboratory medicine: where we are and what is missing"</i>	Milan, IT
Dec 4 - 5, 2020	<i>54 èmes Journées de Biologie Praticienne - JBP</i>	Paris, FR
Dec 7 - 8, 2020	<i>6th Serbian Biomarker Symposium (SERBIS): Lipid Metabolism in Health and Disease</i>	Belgrade, SRB
Dec 9 - 10, 2020	<i>7th Serbian Biomarker Symposium (SERBIS): Biomarkers of gastrointestinal diseases</i>	Belgrade, SRB
Mar 4 -5, 2021	<i>XVIII Meeting of the SEQCML Scientific Committee</i>	Madrid, ES
Mar 15 - 16, 2021	<i>POCT: Making the Point</i>	Rome, IT
Mar 27 - 29, 2021	<i>II National Meeting Conquilab and Technological</i>	Mazatlan, MX
Jun 10 - 11, 2021	<i>8th International Symposium on Critical Care Testing and Blood Gases</i>	Biarritz, FR
<i>New date TBA</i>	<i>The 13th International & 18th National Congress on Quality Improvement in Clinical Laboratories</i>	Tehran, IR
<i>New date TBA</i>	<i>VI Jornadas Bioquímicas de Cuyo 2020</i>	San Luis, AR
<i>New date TBA</i>	<i>LabMed Next</i>	Rome, IT
<i>New date TBA</i>	<i>XXXVII Nordic Congress in Medical Biochemistry</i>	Trondheim, NO
<i>New date TBA</i>	<i>24th International Conference on Laboratory Medicine and Pathobiology: An Expert Forum on Innovation in Clinical and Laboratory Medical Sciences</i>	Samos, GR

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Egypt: Egyptian Association of Healthcare Quality and Patient Safety
France: French National Network of Accredited Laboratories of Medical Biology (LABAC)
India: Association of Medical Biochemists of India (AMBI)
Iran: Iranian Association of Clinical Laboratory Doctors (IACLD)
Jordan: Society for Medical Technology & Laboratories (SMTL)
Kazakhstan: Public Association - Federation of Laboratory Medicine (FLM)
Mexico: Federación Nacional de Químicos Clínicos (CONAQUIC A.C.)
Nepal: Nepalese Association for Clinical Chemistry (NACC)
Philippines: Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL)
Romania: Order of the Biochemists, Biologists, Chemists in Romanian Health System (OBBCSSR)
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Turkey: Society of Clinical Biochemistry Specialists (KBUD)
Ukraine: Association for Quality Assurance of Laboratory Medicine (AQALM)

Regional Federations

Arab Federation of Clinical Biology (AFCB)
African Federation of Clinical Chemistry (AFCC)
Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB)
European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)
Latin America Confederation of Clinical Biochemistry (COLABIOCLI)
North American Federation of Clinical Chemistry and Laboratory Medicine (NAFCC)

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